ENHANCING THE QUALITY AND SAFETY OF SWISS HEALTHCARE
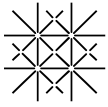## Swiss National Report on Quality and Safety in Healthcare – Short Reports
Oktober 2019

175	Healthcare from the point of view of patients	Umbrella association of Swiss patients' organisations (DVSP)	Erika Ziltener
184	Support for victims (patients, families, and staff)	Institute for Biomedical Ethics, University of Basel	Dr. Stuart Mc Lennan
196	Regulation system and quality/safety	University of Neuchâtel, Institute of Health Law	Prof. Olivier Guillod Dr. Rachel Christinat
203	Harm to patients in Switzerland – an overview	Patient Safety Switzerland	Dr. Stephanie Züllig
214	Safe communication between staff and with patients	Università della Svizzera Italiana, CAHQS	Prof. Annegret F. Hannawa
227	Safety culture in the context of Swiss Healthcare	Fachhochschule Nordwestschweiz, Hochschule für Angewandte Psychologie	Prof. Tanja Manser
Literature reviews			
241	The safety and quality of healthcare in Switzerland: Indicators and evaluation of quality and safety	Lausanne, Institut de médecine sociale et préventive	Prof. Bernard Burnand Dr. Muaamar Al-Gobari
287	Evidence of implementation of safety and quality interventions	Fachhochschule Nordwestschweiz, Hochschule für Angewandte Psychologie	Prof. Tanja Manser Jan Schmutz Jasmina Bogdanovic
Invited contributions			
324	The state of quality and safety in Swiss Healthcare	sQmh	Dr. Philipp Schneider
329	The current status of quality and (patient) safety in the Swiss healthcare system from the perspective of the Swiss Academy for Quality in Medicine (SAQM/FMH)	SAQM/ASQM	Dr Christoph Bosshard Esther Kraft Roxane Kübler
339	The understanding of quality management	SanaCERT	Maja Mylaeus-Renggli Christoph Cottier Markus Betschart Peter Ueberschlag
348	Development instead of a standstill: accreditation for medical practices	Equam	Dr. Martin Hošek Paula Bezzola
355	The state of quality and safety in Swiss Healthcare	Swiss Nurses Association SBK-ASI	Roswitha Koch
371	The contribution of clinical pharmacologists to improve medication safety	The Swiss Society of Clinical Pharmacology and Toxicology	Dr. Alessandro Ceschi

University
of Basel

Faculty of Medicine
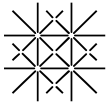Department of Public Health

Resident safety and quality of care in nursing homes

Contribution to the Swiss National Report on Quality and Safety in Healthcare

Franziska Zúñiga, PhD, RN

Nursing Science, Department Public Health, University of Basel

Basel, April 14, 2019

Introduction

Switzerland has roughly 1560 nursing homes, with a mean size of 62 beds, housing 149'000 people. Nursing homes are home to approximately 16% of people aged over 80 [1], most of whom are affected with multiple chronic conditions, cognitive and/or physical impairment and dependency regarding activities of daily living. Although the number of nursing homes has remained relatively stable in recent years, there is a tendency to reduce use of them, as increasing numbers of people have been opting for in-home care.

About 26% of Swiss nursing homes are non-profit, 44% for-profit and 30% for-profit with public subsidies [2]. And while nursing homes are regulated by the cantons, cantonal officials can delegate the associated tasks to individual communities.

Within nursing homes, the grade-mix is approximately 30% registered nurses (tertiary level education) and nurse aides (short training), and 40% practical nurses (secondary level, with either 2, 3 or 4 years' education). Some cantons regulate either the number of personnel or the expected grade-mix per shift or both, by asking, e.g., that at least 15% of nursing personnel have a tertiary-level education. While the sheer increase in older persons in Switzerland will require 40 to 48% more care workers by 2030 [3], the high number of older care workers in nursing homes [4] and early exits will both aggravate existing difficulties in recruiting qualified personnel and strain resident safety efforts.

Setting-specific characteristics of nursing homes

Nursing homes have specific characteristics that influence the handling of safety issues and quality of care and distinguish them from acute-care hospital settings. A roundtable organized by Patient Safety Switzerland in 2016 defined a set of core characteristics [5] that are also discussed in the international literature [6].

The nursing home is not only a place of care but also **a home to its residents**, where both safety and quality of life need to be in balance. In geriatric settings, the main goal is for the residents to have the best possible quality of life within the given circumstances. Person-centred care that promotes residents' dignity and respects their values, preferences and autonomy in decision-making is the goal of a culture change taking place in nursing homes over the last decades. While some safety measures might not be acceptable to residents, since they restrict their autonomy and quality of life, then, others might be willingly considered.

Residents' situations are often complex due to multimorbidity, dementia, polypharmacy, reduced mobility and behavioural and psychological symptoms of dementia (BPSD). Frail older persons are particularly vulnerable. As their health condition can change quickly, early symptom recognition and provision of appropriate interventions are extremely important. This is especially true for residents with dementia, who depend on staff to observe changes and speak up for them.

Nursing homes have **high organizational heterogeneity,** e.g., they use a wide range of staffing grade-mixes, physician models, pharmacy services and interfaces with other health care providers. This means no one-size-fits-all solutions exist for resident safety and quality issues. In addition, the field of long-term care is changing, with nursing homes diversifying their offerings to include not only long-term care but also assisted living, day care and specialised rehabilitation, post-acute care, dementia and palliative care services. And the rising numbers of residents living

University
of Basel

Faculty of Medicine
Department of Public Health

Pflegewissenschaft
Nursing Science
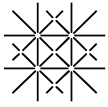
with chronic illness calls for more – and increasingly advanced – long-term care technology, e.g., for ventilated residents, or for special skills, e.g. for ageing psychiatric patients or those with disabilities who require constant care. Factors such as these multiply the complexity of resident safety- and quality-related issues.

In terms of nursing home regulation, each Swiss canton is a **distinct financial and/or regulatory context.** As a result, a multitude of financial constraints influence not only the allocation of personnel resources, e.g., to monitor risk and quality management activities, but also any other attempts to develop practice and introduce innovations. One solution is to seek external funding for nursing home quality improvement projects. However, finding contributors – whether governmental or private – to fund projects requires high levels of time, motivation and skill.
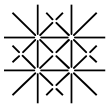
Safety and quality of care in nursing homes

In the context of nursing homes, typical resident safety and quality of care issues include falls, drug-related adverse events, healthcare-associated infections, avoidable hospitalizations, delirium, pain, weight loss, and pressure ulcers, as well as the use of physical restraints or the experience of physical, verbal or sexual aggression from either residents or staff. Additionally, promoting residents' quality of life and the experience of person-centred care are key markers of high-quality nursing homes. While most of these issues have been examined in the Swiss context, national data remain scarce.

One data source was the Swiss Nursing Homes Human Resources Project (SHURP), a national study in 163 nursing homes. SHURP reported prevalence rates of 1.7% pressure ulcers acquired in the nursing home at the time of data collection, with 2.0% of residents having sustained fall-related injuries and 5.1% having contracted urinary tract infections over the previous 30 days [4]. Additionally, 31.8% of care workers reported observing verbal resident-to-resident aggression several times per week, with 7.2% reporting physical aggression, 1.6% noting incidents of sexual aggression by residents. Roughly 10% had witnessed elder abuse more than monthly in the form of verbal or emotional abuse and neglect by staff [4].

In addition, a recent nation-wide pilot study of quality indicators in 152 Swiss nursing homes reported prevalence rates of 3.6% for use of physical restraints, 13.5% for use of bedrails, 7.3% for weight loss, 43.3% for polypharmacy, 18.4% for self-assessed severe pain and 12.0% for observed severe pain [7]. Several regional or local studies reported further prevalence rates regarding, e.g., physical restraints, pressure ulcers, aggression, delirium and administration of antipsychotic medication [8-12]. Overall, Swiss nursing homes show clinical outcome rates comparable to those reported internationally; however, the data indicate high inter-home variances in quality of care, with considerable room for improvement among low performers [4, 12].

However, as nursing homes provide both medical and social care, with the ultimate goal of maintaining their residents' quality of life, their safety and quality need to be viewed in a context that includes more than clinical quality. Accordingly, user reports regarding person-centred care, care coordination, and general quality of life are key aspects of quality in long-term care [13].

While little is known regarding these variables in Swiss nursing homes, when one national study interviewed residents in 51 nursing homes, 71% rated their overall quality of life as good. Still, while giving privacy and dignity high ratings, residents did not perceive their care to be person-centred [14]: Instead, only 33% noted that care workers' showed interest in the their lives, leading to a general lack of trustful relationships or even meaningful conversations between staff and

residents. Such a common result cannot be attributed solely to caregiver-level failures; it must be viewed systemically, from an organization- and policy-level perspective.

Quality improvement in nursing homes

Currently, most interventions to reduce harm and improve nursing homes' quality of care are conducted at the level of individual institutions [5]. As a result, many homes develop care guidelines and standards (e.g., for hygiene, pain, falls), introduce preventive measures, initiate interprofessional projects (e.g., with pharmacies for medication safety), implement critical incident reporting systems on an institution-specific basis [5] or start culture change projects. Occasionally they collaborate with external research partners like universities of applied sciences or private firms that conduct staff or resident/family surveys to provide data for internal safety and quality improvement.
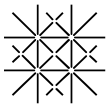
Several country-wide programs also cover nursing home safety and quality issues. For example, the National Dementia Strategy promotes the development and implementation of needs-oriented health care services, care coordination and interprofessional collaboration. In addition to increasing dementia-relevant knowledge and skills, it supports informal caregivers and promotes new models of care and data monitoring [15]. Similarly, the National Strategy for Palliative Care fosters quality of care in end-of-life situations, including the implementation of advance care planning, taking into account residents' values and preferences [16]. The strategy against healthcare-associated infections (NOSO) is aimed at reducing nosocomial infections in hospitals and nursing homes [17]. Similarly, the Federal Office of Health has produced an action plan to support informal caregivers and initiated two projects: one to coordinate care (focusing currently on very old, polymorbid persons); and another to implement eHealth with an electronic health record for patients. And the Swiss Academy of Medical Sciences (SAMS) offers broad support to improve both the quantity and the quality of interprofessional care. All of these examples address important aspects of safety and quality of care among frail, older persons – key themes of an integrated extended care service.

From 2019 onwards, based on Article 59*a* of the Swiss Health Insurance Act, nursing homes will be obliged to provide the relevant federal agencies with data about the quality of their medical care. Six national quality indicators will be publicly reported. For the first time, this will include national-level data on quality of care indicators concerning four measurement themes in Swiss nursing homes: use of physical restraints, weight loss, polypharmacy and pain. These indicators address important safety themes and should incentivize nursing home managers to address them if necessary; however, as shown above, these indicators do not represent the overall quality of nursing home quality.

As quality measurement is both administered and supported at the cantonal level, several ask nursing homes to report regularly on safety and quality themes, including structures and processes related to safety and quality of care. Some cantonal health authorities ask nursing homes to carry out surveys of staff and residents/families and to perform audits; and a number of cantons are initiating projects to evaluate and develop nursing homes' safety and quality.

Key themes in nursing home safety and quality of care

Experts on a roundtable organized by the Swiss Patient Safety Foundation identified several areas where improvements would be possible and necessary to reduce physical as well as emotional

harm, while extending independence in activities of daily living [5]. A similar roundtable of Canadian experts indicated very similar themes [6]. These will be explored in the following paragraphs.

The various medical professionals who provide care to nursing home residents need to have a common understanding of each resident's situation, wishes and values, as well as a common goal upon which to base intervention planning. **Interprofessional collaboration**, which provides a comprehensive assessment of the resident's situation and its management options, and **coordination of care** are key themes for improving quality of care. Moreover, care should be planned in **collaboration with residents and families**. Advance care planning helps to clarify each resident's preferences and values in order to focus care on what is important to the resident.

One major hurdle is the coordination of **transitions between health care settings**. When residents move between settings, be it from home to nursing home or from nursing home to hospital and back, fragmentation of information and failures of information flow commonly lead to conflicting information and missing details, thereby increasing the risk of errors. Residents are not only exposed to higher risks of medication errors or rehospitalisation, but also often feel distressed. The obvious solution is to provide timely, transparent and complete communication. This would be supported via the adoption of electronic health records (EHRs). Although EHRs will be introduced in Switzerland by 2020, general practitioners, who are key providers for nursing home residents, will not be obliged to work with them [18], which might hinder a complete documentation of resident health data.

Medication safety in nursing homes focuses on reducing adverse drug reactions, improving prescribing practices regarding potentially inadequate medications (PIMs), antibiotics and polypharmacy and promoting safe medication prescribing, dispensing and monitoring processes. In 2017, the Swiss Patient Safety Foundation launched a program focusing on polypharmacy and the use of PIMs in nursing homes [19]. In a recent survey, they confirmed that the current high level of organizational heterogeneity, which includes the use of various physician and pharmacy models, impedes care providers' efforts to maintain medication safety. Problems identified included missing prescriptions at admission, lack of continuity, poorly-structured systems of medication review and adverse event monitoring, and lack of relevant pharmacological knowledge among nursing home staff [19].

Addressing polypharmacy and PIM use will demand interprofessional collaboration. Projects in the French part of Switzerland have showed that collaborative pharmacy practice models reduce polypharmacy and costs without affecting quality of care [20, 21]. Currently, researchers on the National Research Programme 74 (NRP74) "Smarter Health Care" project are developing and introducing an interprofessional deprescribing process in the Cantons of Vaud and Fribourg. Insights from these projects might help to identify and implement interventions fit for the Swiss context. Additionally, the Swiss Patient Safety Foundation is launching a project for safe medication in nursing homes, addressing both polypharmacy and PIMs.

One serious knowledge gap involves the lack of data on **infections** in Swiss nursing homes. While the national NOSO strategy is intended to reduce healthcare-associated infections (HAIs) in hospitals and nursing homes, the StAR strategy addresses treatment-resistant microbes. For nursing homes, although it is likely that key themes will echo international findings, with urinary tract and respiratory tract infections being the most common, fulfilling these strategies' goals will require compiling baseline surveillance data [22]. Although Swiss data on antimicrobial resistance in nursing homes is not available nation-wide, it is known that multi-drug resistant organisms
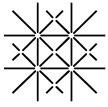
(MDROs) are increasingly prevalent [23]. However, since nursing homes are a residential environment and financing does not provide for acute care interventions, prolonged isolation precautions are unrealistic and inefficient [22]. Nursing home-specific evidence-based intervention guidelines such as those provided by four cantons in Switzerland's French-speaking region (https://www.hpci.ch) will be necessary. Key interventions are staff education, promotion of hand hygiene and influenza vaccination, as well as the designation of persons responsible for infection control – all of these support the goal of reducing HAIs [24].

Although international **guidelines** are available for a broad array of nursing home themes, with certain notable exceptions, such as those on the handling of BPSD [25], few have been developed in any of Switzerland's major languages. Producing a single set of nursing home guidelines directly relevant to each Swiss linguistic context and supported by empirical evidence on best practices will save individual institutions the time and expense of developing guidelines of their own. Moreover, nursing homes need support in implementing, monitoring and optimizing such guidelines, especially smaller ones without the corresponding resources.

Adequate staffing is essential for the tasks at hand. Recruiting problems particularly affect highly qualified staff and strains their ability to manage complex situations involving frail older persons, e.g., in relation to a comprehensive assessment, interprofessional collaboration, shared care planning, chronic disease management, end-of-life care, or medication and wound management. It is vital to distribute tasks between professions according to competencies: the grade-mix has to reflect the care needed by the residents. Additionally, high turnover rates pose a threat to safety: knowledge of processes, standards and guidelines can easily be lost, along with the long-term, trusting relationships that form the core of person-centred care and that allow care staff to recognize changes in residents' health. Care workers in Swiss nursing homes report rationing of care, especially in the area of social activities, emotional support and rehabilitation, when under time pressure [26]. This is not without effect on residents, who suffer from the emotional detachment and inattentiveness of care workers under stress [27]. A Swiss initiative addressing this problems is the Competence Network Health Workforce, a collaborative project shared by five universities of applied sciences, is to develop strategies to counter staff shortages among health professionals in Switzerland (https://www.cnhw.ch/). Further challenges include language barriers between staff and residents, particularly when less qualified personnel are not fluent in the residents' language. This hinders the affected staff members' understanding not only of residents' needs and symptoms, but of their supervisors' instructions and orders. A key factor for staff retention and the securing of safe care is a positive **work environment** [28, 29].

To be able to handle complex resident situations, nursing homes need **staff with expertise** in geriatric, gerontological, gerontopsychiatric or pharmaceutical fields. According to the international literature, advanced practice nurses (APNs) are effective at increasing quality across a variety of themes, e.g., pain management, alternatives to physical restraints, avoidance of unnecessary hospitalizations and resident satisfaction with care [30-32]. In the Swiss context, where APN education is a recent development, the current shortage of APNs requires adaptive solutions, such as providing registered nurses with in-depth training to fill out expert roles with competencies corresponding to their educational level. In the context of the NRP 74 "Smarter Health Care", INTERCARE is a research project to develop and evaluate a nurse-led nursing home care model, placing nurses with expanded geriatric expertise in clinical leadership roles, with the aim of reducing avoidable hospitalisations and improving the quality of care [33].

To perform their tasks fully, all staff must receive all necessary **education and training** regarding nursing home-specific safety issues, including risk assessment of the physical and social

University of Basel

Faculty of Medicine
Department of Public Health

environment, clinical signs, symptoms and first reactions, handling of aggression, handling of technical equipment and performance of infection control procedures. Moreover, it is important to support staff in offering person-centred care, maintaining residents' dignity and privacy and building meaningful relationships. As not all training can be offered by the nursing homes themselves, any outstanding themes will need to be taken up by educational institutions that specialize in nursing homes and elderly care. In all cases, training will need to match the learners' various educational levels and cultural backgrounds, while integrating an interprofessional approach wherever possible.

An important theme to tackle is **elder abuse**, which needs to be addressed as soon as observed to avoid a growing tolerance of abusive staff behaviour. One Swiss study reported that education and training was an important first step in addressing the issue, together with timely intervention, active management and providing a positive work environment with less work stress and the possibility of staff rotation in difficult resident situations [34]. Both the Unabhängige Beschwerdestelle für das Alter (Independent Complaint Centre for the Aged) in Zurich (http://www.uba.ch/) or Alter Ego in the (French-speaking) Romandy region (https://alter-ego.ch/) are important external contact points for staff, residents and families in challenging situations.

A positive **safety culture** treats errors as situations to learn from. The introduction of a critical incident reporting system (CIRS) can support learning from mistakes. However, many nursing homes in Switzerland are too small to profit from a system of their own and regional CIRSs are not yet available. Additionally, little is known about how nursing homes handle either internal errors or the disclosure of those errors to residents and their families.

Leaders are key to creating a culture of safety and improving safety and quality of care. Before they can do that, though, they need to understand both which structures and processes are relevant to safety and quality of care and how they can promote those processes. They need the training to link management practices and safety [35]. Moreover, they are key persons in promoting a culture of person-centeredness, where residents' dignity and autonomy are uphold.

Implementation science research, which evaluates interventions in the real world while exploring barriers, facilitators and effective implementation strategies, is still rare in the Swiss nursing home context. We miss projects that explore the improvement of resident safety and quality of care with independent measures of clinical and quality of life outcomes, in-depth assessment of staffing resources, system information about regulatory and payment contexts, as well as physician and pharmacy services [36]. One starting point is the NRP 74 "Smarter Health Care" with projects that focus on nursing homes. More research is needed to provide a firmer evidence base for improving resident safety and quality of care.

Recommendations

For all themes a common effort on all levels – from decision makers, professional organizations, provider organizations, nursing home management, to staff, residents and family – is necessary to improve and maintain patient safety and quality of care. The recommendations take up key themes discussed without being exhaustive.
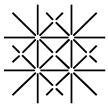
- Policy and decision makers:
  - **Transitions**:
    Incentivize high-quality transitions between settings regarding, e.g., quality indicators or changes in payment methods;
    Incentivize integrated care and the building of care networks with aligned care processes, documentation and transmission of information;
    Incentivize the use of electronic health records in nursing homes by residents or their authorized representatives and general practitioners.
  - **Adequate staffing**:
    Continue to address the lack of qualified staff by taking measures to increase numbers of trained nurses, improve staff retention, and support reintegration;
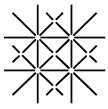   Provide the basis for resources that allow grade-mixes that cover the competencies needed for the complexity of resident cases.
  - **Staff with expertise**: Provide incentives and resources and develop payment methods for new care models and roles where expert nurses take the lead in increasing resident safety and quality of care.
  - **Research**: Provide incentives for implementation science research in nursing homes.

- Nursing home management:
  - **Collaboration and transition**:
    Put in place structures and processes that promote interprofessional collaboration and safe transitions;
    Strengthen the collaboration with residents and families, especially in the area of advance care planning.
  - **Adequate staffing and expertise**:
    Support a positive work environment, take possible measures to increase reintegration and staff retention;
    Strengthen grade-mix with optimal use of resources, including the strengthening of geriatric expert knowledge.
  - **Safety culture**: Strengthen a culture of safety where speaking up and learning from each other is possible, including the integration of CIRS.
  - **Elder abuse**: Sensitize staff for elder abuse and provide a work environment where cases can be addressed and timely intervention is possible.
  - **Medication safety**: Build up networks with general practitioners and pharmacists to reduce polypharmacy, put in place processes for medication reviews.
  - **Education and training**: Keep staff up to date in safety and quality of care themes relevant for their scope of practice.

- Professional and provider organizations:
  - **Leaders**:
    Train nursing home leadership in safety culture promotion, including a system-level view for safe structures and processes and the handling and disclosure of errors;
    Provide nursing home leaders with the knowledge and training to provide work environments, structures and processes designed to promote safety and quality of care.
  - **Education and training**: Incentivize continuous teaching and training of staff, matched to their educational level, in nursing home-specific safety and quality issues, covering the varying needs of nursing homes with different sizes and organizational contexts.

University
of Basel

Faculty of Medicine
Department of Public Health

Pflegewissenschaft
Nursing Science

- ➢ **Guidelines**:
  Define key issues in an interprofessional expert group regarding where specific Swiss guidelines for nursing home safety and quality of care are needed; Develop and implement national guidelines on key safety and quality issues.
- ➢ **Medication safety**: Incentivize interprofessional collaboration with general practitioners, pharmacists and nursing home staff to reduce polypharmacy.
- ➢ **Infection control**: Promote the national NOSO and StAR strategies, sensitizing nursing homes to the target themes and supporting them in implementing minimal requirements.
- ➢ **Elder abuse**: Raise awareness concerning elder abuse and train leadership in prevention and active management of cases.
- ➢ **Safety culture**: Establish regional CIRSs and network groups for nursing homes.

References

1. Bundesamt für Statistik, *Mehr Pflege zu Hause, stagnierende Anzahl Personen in Alters- und Pflegeheimen*. 2018, Neuchâtel: Bundesamt für Statistik.
2. Bundesamt für Statistik, *Statistik der sozialmedizinischen Institutionen 2017 – Definitive Standardtabellen*. 2017, Neuchâtel: Bundesamt für Statistik.
3. Merçay, C., L. Burla, and M. Widmer, *Gesundheitspersonal in der Schweiz. Bestandesaufnahme und Prognosen bis 2030 (Obsan Bericht 71)*. 2016, Neuchâtel: Schweizerisches Gesundheitsobservatorium.
4. Zúñiga, F., et al., *Schlussbericht zur Befragung des Pflege- und Betreuungspersonals in Alters- und Pflegeinstitutionen der Schweiz*, U. Basel, Editor. 2013.
5. Niederhauser, A. and M. Füglister, *Patientensicherheit in der Langzeitpflege*. 2016, Patientensicherheit Schweiz: Zürich.
6. Wagner, L.M. and T.B. Rust, *Safety in long-term care settings: Broadening the patient safety agenda to include long-term care services*. 2008, Canadian Patient Safety Institute: Edmonton.
7. Zúñiga, F., et al., *Schlussbericht zur Auswertung des Pilots zu den nationalen medizinischen Qualitätsindikatoren für Alters- und Pflegeinstitutionen. Version 1.2*. 2018, Basel: Institut für Pflegewissenschaft.
8. Hofmann, H., et al., *Use of physical restraints in nursing homes: A multicentre cross-sectional study*. BMC Geriatrics, 2015. **15**: p. 129.
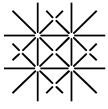9. Feng, Z., et al., *Use of physical restraints and antipsychotic medications in nursing homes: A cross-national study*. International Journal of Geriatric Psychiatry, 2009. **24**(10): p. 1110-1118.
10. Zeller, A., et al., *[Nurses' experiences with aggressive behaviour of nursing home residents: A cross sectional study in Swiss nursing homes]*. Pflege, 2013. **26**(5): p. 321-35.
11. von Gunten, A. and U.P. Mosimann, *Delirium upon admission to Swiss nursing homes: A cross-sectional study*. Swiss Medical Weekly, 2010. **140**(25-26): p. 376-81.
12. Courvoisier, D.S., et al., *Variation in pressure ulcer prevalence and prevention in nursing homes: A multicenter study*. Applied Nursing Research, 2018. **42**: p. 45-50.
13. OECD/European Commission, *A good life in old age? Monitoring and improving quality in long-term care*. 2013: OECD Health Policy Studies, OECD Publishing.
14. Sommerhalder, K., et al., *Lebens- und Pflegequalität im Pflegeheim – Beschreibende Ergebnisse der Befragung von Bewohnerinnen und Bewohnern in Pflegeheimen in der*

University
of Basel

Faculty of Medicine
Department of Public Health

Pflegewissenschaft
Nursing Science
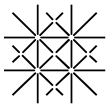
Schweiz. Residents' Perspectives of Living in Nursing Homes in Switzerland (RESPONS). 2015, Bern: Berner Fachhochschule, Fachbereich Gesundheit.

15. Bundesamt für Gesundheit, *Nationale Demenzstrategie 2014-2019.* 2016, Bundesamt für Gesundheit (BAG) und Schweizerische Konferenz der kantonalen Gesundheitsdirektorinnen und -direktoren (GDK): Bern.

16. Bundesamt für Gesundheit, *Nationale Strategie Palliative Care 2013-2015.* 2016, Bundesamt für Gesundheit (BAG) und Schweizerische Konferenz der kantonalen Gesundheitsdirektorinnen und -direktoren (GDK): Bern.

17. Bundesamt für Gesundheit, *Broschüre Strategie NOSO - Kurz und bündig.* 2016, Bundesamt für Gesundheit: Bern.

18. De Pietro, C. and I. Francetic, *E-health in Switzerland: The laborious adoption of the federal law on electronic health records (EHR) and health information exchange (HIE) networks.* Health Policy, 2018. **122**(2): p. 69-74.

19. Niederhauser, A., et al., *Nationales Programm progress! Sichere Medikation in Pflegeheimen.* 2018, Patientensicherheit Schweiz.

20. Zeukeng, M.J., et al., *Implementation of a collaborative pharmacy practice model in nursing homes of a Swiss canton: Drug cost monitoring between 2009 and 2012.* Value in Health, 2014. **17**(7): p. A519.

21. Locca, J.-F., et al., *Development of pharmaceutical care services in nursing homes: Practice and research in a Swiss canton.* Pharmacy World & Science, 2009. **31**(2): p. 165-173.

22. Uchida, M., et al., *Infection prevention in long-term care: A systematic review of randomized and nonrandomized trials.* Journal of the American Geriatrics Society, 2013. **61**(4): p. 602-14.

23. Kohler, P., et al., *Antibiotic resistance in Swiss nursing homes: analysis of National Surveillance Data over an 11-year period between 2007 and 2017.* Antimicrobial Resistance and Infection Control, 2018. **7**: p. 88.

24. Flanagan, E., T. Chopra, and L. Mody, *Infection prevention in alternative health care settings.* Infectious Disease Clinics of North America, 2011. **25**(1): p. 271-83.

25. Savaskan, E., et al., *Empfehlungen zur Diagnostik und Therapie der behavioralen und psychologischen Symptome der Demenz (BPSD).* Praxis, 2014. **103**(3): p. 135-148.

26. Zúñiga, F., et al., *The relationship of staffing and work environment with implicit rationing of nursing care in Swiss nursing homes – A cross-sectional study.* International Journal of Nursing Studies, 2015. **52**(9): p. 1463-74.

27. Braun, D., O. Mauthner, and F. Zúñiga, *Rationing of Nursing Care: Exploring the Views of Care Workers and Residents in a Swiss Nursing Home.* Journal of the American Medical Directors Association, 2018.

28. Gaudenz, C., et al., *Factors associated with care workers' intention to leave employment in nursing homes: A secondary data analysis of the Swiss Nursing Homes Human Resources Project.* Journal of Applied Gerontology, 2017. **0**(0).

29. André, B., et al., *The impact of work culture on quality of care in nursing homes - a review study.* Scandinavian Journal of Caring Sciences, 2014. **28**(3): p. 449-457.

30. Bakerjian, D., *Care of nursing home residents by advanced practice nurses: A review of the literature.* Research in Gerontological Nursing, 2008. **1**(3): p. 177-185.

31. Donald, F., et al., *A systematic review of the effectiveness of advanced practice nurses in long-term care.* Journal of Advanced Nursing, 2013. **69**(10): p. 2148-61.

32. Morilla-Herrera, J.C., et al., *A systematic review of the effectiveness and roles of advanced practice nursing in older people.* International Journal of Nursing Studies, 2016. **53**: p. 290-307.

University
of Basel

Faculty of Medicine
Department of Public Health

Pflegewissenschaft
Nursing Science

33.   Zúñiga, F., et al., *Das Projekt INTERCARE: pflegegeleitete Versorgungsmodelle in der Langzeitpflege.* Primary and Hospital Care, 2017. **17**(14): p. 270-271.
34.   Wangmo, T., K. Nordstrom, and R.W. Kressig, *Preventing elder abuse and neglect in geriatric institutions: Solutions from nursing care providers.* Geriatr Nurs, 2017. **38**(5): p. 385-392.
35.   IOM (Institute of Medicine), *Keeping patients safe: Transforming the work environment of nurses.* 2004, Washington DC: National Academies Press.
36.   Simmons, S.F., et al., *Defining Safety in the Nursing Home Setting: Implications for Future Research.* Journal of the American Medical Directors Association, 2016. **17**(6): p. 473-81.
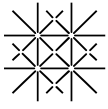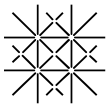
Frail older people in home care

Contribution to the Swiss National Report on Quality and Safety in Healthcare

Franziska Zúñiga, PhD, RN

Nursing Science, Department Public Health, University of Basel

Basel, April 14, 2019

Increasing home care needs

Extended life expectancy, increases in chronic conditions and shortened hospital stays have rapidly increased the demand for home care services in Switzerland in recent years. In 2017, Swiss home care firms logged 16 million hours, with 73% of their clients 65 years or older, and more than half of their patient care time provided to clients aged over 80 [1, 2].

Two main types of home care services are available: nursing and domestic. While the former is physician-prescribed and covered by health insurance, the latter is either paid for directly by the clients or via complementary insurance. In Switzerland, services are offered partly by non-profit home care organizations, which represent 30% of all organizations, but cover more than 80% of home care clients [1]. However, for-profit organisations and independent nurses are increasing in terms both of numbers and of services offered [1]. In addition, firms offering 24/7 care schedules often enlist care migrants, many of whom work in grey legal areas with long working hours and short rest periods [3].

As the demand for home care grows, it is increasingly difficult to recruit enough qualified care workers to cover staffing needs [4]. The home care workforce currently consists of 42% registered nurses, 29% licensed practical nurses or home care nurse aides (2-3-year education with certificate or attest), and 29% aides with either short training courses or no specific qualifications. By 2030, projections indicate that the home care workforce will have to grow by 57% to meet demand; and while this will equal almost 8'200 fulltime equivalent positions, a shortage of registered nurses is virtually certain [5]. The resultant shortfall of expertise poses a risk to both safety and quality of care.

Adverse events in home care

According to a review, between 3.5 and 15% of home care clients experience care-related adverse events [6]. Among these, the most frequent were falls, fall-related injuries and adverse drug events [7-10]. Other typical adverse events in the home care setting include wounds, infections (e.g., pneumonia, urinary tract infections), line-related (e.g., catheter-related blood stream infection or catheter site infections) or technology-related adverse events (e.g., home ventilator failure). According to a Canadian study, self- or informal caregiving is a contributing factor to in over half of adverse events in home care settings [7]. A recent Swedish record review study considered almost three quarters of the reviewed adverse events preventable [11]. To date, no corresponding surveys exist for Switzerland.

Setting-specific challenges to safety and quality of care

Maintaining safety and quality of care for frail older people at home has its specific challenges: unlike in institutional care, informal carers often carry the main burden of care in an environment not primarily built for healthcare provision [12]. In untrained or inexperienced hands, medical technology can also be problematic: increasingly, medical devices that find their way into clients' homes actually function as obstacles to safe care [13]. Formal care workers spend only a limited time in clients' homes, doing assessments, providing care and consulting the clients and their families, with no control over what happens between their visits. Clients decide autonomously about the services provided in their home [14]. Informal caregivers often work around the clock seven days a week; such heavy care burdens are linked with fatigue and might increase the risk of errors. On the other hand, informal caregivers have intimate knowledge of the client and perform
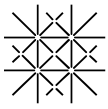
informal coordination work, increasing care safety [15]. Overall, though, top-level quality and safety can only be achieved via partnerships between formal care workers, clients and their families [14, 16, 17]. In addition to clients' care needs, these teams' decisions consider clients' and their families' physical and cognitive competencies, financial resources, reading skills, and social and environmental contexts [18].

Formal home care workers also face different challenges than their colleagues in institutional settings. They work mostly alone, with only on-call support from a central office [18], but no on-site collegial support. With contact with physicians limited mostly to phone calls, they often have to make on-the-spot decisions in critical situations [18]. Moreover, if needed medical supplies or equipment are not available, it may be necessary to improvise on-the-spot solutions [16]. For each client, based on a physician's prescription, health insurance companies assign a number of hours they will provide for nursing services; and while some flexibility is built into this system, the time is limited. Nurses are under pressure to work within the limits of the time covered and sometimes have to cut short the time needed for risk assessments, discussion of preventive measures, consultation and patient education, all of which would be especially important for frail older persons with multiple chronic conditions and complex care needs. Moreover, the less-trained care workers who are mainly present in the home might not recognize early signs of cognitive or functional impairment. Such shortfalls exacerbate the effects of chronic diseases or environmental hazards, further impacting the safety and quality of care provided.

In a recent review of safety guidelines for home health care [14], the authors suggested eight safety themes for home-care settings: communication and interaction, integration of client and family, risk assessment, medication management, qualification, medical assisting devices, hygiene/infection control, and establishing a safety culture. Similar themes arose from an expert roundtable organized by the Swiss Patient Safety Foundations [19]. These will be the topic of the following paragraphs, which will first highlight several hotspots in home care safety and quality, then discuss structural and procedural aspects important to safe care.

Issues in safety and quality of care

Home care clients are exposed to a wide variety of risks, all of which must be assessed before beginning a plan for service and integrated in-home care. Assessments address risks both within the physical and social environment and clinical risks (e.g. fall-related injuries, pressure ulcers). As for **physical risks**, older frail persons living at home are subject not only to increased risk from environmental hazards such as unsanitary conditions (e.g., insects, rodents), poor air quality (e.g., mold, peeling paint), unhealthy room temperatures, pet-related hazards, or unsafe neighbourhoods [20], but also from barriers to mobility such as uneven floors or tight spaces, poor lighting, and electrical, chemical, and fire hazards [13]. A safety hazard assessment supports clients and their families to recognize and tackle unnoticed risks [21].

Older frail persons are also subject to **risks in the social environment**. These include physical, emotional, or sexual abuse, financial exploitation and neglect. An estimated 10% of older persons experience one or more of these forms of abuse [22]. Internationally, the main victim-level risk factors are functional dependence, poor physical health, cognitive impairment, low mental health and low income. One protective factor is social support [23]. A survey in northern Switzerland showed psychological abuse to be most frequent, followed by financial and physical abuse [24]. Perpetrators were most at risk when overburdened, living with and dependent on the victims [24]. Overall, an interprofessional, community-based approach, including not only healthcare professionals but also community resources and policy makers, is key to addressing the problem

of abuse [22, 24]. Alongside support interventions to relieve caregiver burden, telephone helplines for victims or perpetrators, including the Unabhängige Beschwerdestelle für das Alter (Independent Complaint Centre for the Aged) in Zurich (http://www.uba.ch/) or Alter Ego in the (French-speaking) Romandy region (https://alter-ego.ch/) are both promising approaches.

As for **clinical risks**, this report takes as an example the most frequent adverse event in home care: falls, which often lead to hospitalizations and eventually to nursing home admission. Responding to a national survey in 2015, one-quarter of respondents over 65 and living at home reported falling at least once in the previous 12 months [25]. A main risk factor is frailty, which often includes reduced muscle strength and disturbances to the subject's gait and equilibrium [26]. As falls most commonly have multifactorial causes, a careful, interdisciplinary assessment is often necessary to prevent further incidents [26]. While evidence supports multi-component interventions including exercise to reduce fall rates among older persons [27], a Swiss research team concluded that frail persons need such programs to be adapted to their specific circumstances [28]. In Switzerland, the Beratungsstelle für Unfallverhütung (BFU: The Swiss Competence and Coordination Center for Accident Prevention) launched a fall prevention program in 2016 to motivate senior citizens toward strength and gait training, including specific exercises for those with functional impairment (http://www.sichergehen.ch/). Ideally, in addition to regular updates regarding clinical risks and their influencing factors, home care workers will be able to perform evidence-based risk assessments and interventions in an interdisciplinary context that includes clients and their families.

Drug-related problems (DRPs, encompassing adverse drug reactions and medication errors) are among the most frequent patient safety risks in home care–more so than in institutional settings [29]. Within this group, potentially inappropriate medications and medication errors are both common, with respective prevalences of 20–48% and 17–41%. Specific problems identified were medication discrepancies based on inconsistent information sources, problems with the medication management continuum, as well as medication preparation and dispensing errors, for example, inappropriate splitting of tablets. Adverse drug events were found in 8–45% of cases, with drug interactions in 10–57% [29].

Older polypharmacological persons bear a particularly high risk for DRPs. Based on the above-cited review, the Swiss research team identified five safety hotspots: transitions from hospital to home with insufficient discharge instructions and discrepancies in medication lists, lack of regular medication reviews, use of several healthcare providers with insufficient interprofessional collaboration and communication, informal caregivers and the clients themselves [29]. In line with Canadian guidelines for home care [21], that study's authors recommend introducing clinical pharmacy services to perform medication reviews in cooperation with clients and informal caregivers during critical periods such as transitions from hospital to home.

In fact, **transitions from hospital to home** represent a specific set of safety risks. In a study in the Canton of Lucerne [30], three specific problems were identified in relation to medication safety: prescriptions were often either unavailable or ambiguous at the first home care visit; communication was incomplete and medications unavailable when clients were at home, partly due to a regional system allowing physicians to dispense medications. The "doMESTIC Study of medication safety in home care"–a project currently shared between the City of Lucerne and the University of Basel (2016-2020), addresses three issues: communication, medication availability and the quality of physician prescriptions [31]. In addition, the implementation of clinical pharmacy services such as medication reconciliation at transition of care and an electronic health record accessible to all professional healthcare providers would support information exchange. Patient
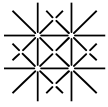
Safety Switzerland lead a National Program for Medication Safety approaching the problem from the hospital side via systematic medication reviews at hospital admission and discharge [32]. Moreover, international literature emphasizes the importance of nurses monitoring possible medication safety problems during their visits, providing clients with the information and, where necessary, tailoring the technology to support medication preparation and adherence [18].

Acquiring **infections** in home care is another common risk for older frail persons. A key intervention to reduce the risk of healthcare-associated infections is compliance with hand hygiene guidelines and the corresponding training of all care workers [21, 33]. Another is the tracking of healthcare-associated infections (HAIs) [21]. While a national strategy is in play to examine HAIs in hospital and nursing home settings, ambulatory and home care settings have yet to be integrated [34]. However, a preliminary study indicated an overall lack of data about HAIs in these settings and the lack not only of systematic controls but of guidelines and standards [34].

Contextual factors related to safety and quality of care

A major risk factor concerning safe formal care is the lack of **qualified care workers** and the concomitant lack of comprehensive assessment, timely detection of deterioration, or preventive measures. Additionally, to achieve safe care, staff need continuous training and education in safety issues such as medication safety, hand hygiene, risk assessment, prevention of harmful events and the building of partnerships with clients and their families. This includes the training of care migrants, who may be in danger of working beyond their competencies. Since some interventions are not frequently offered, an update in knowledge and skills training is needed to ensure their safe delivery [16], especially in view of the increasing use of assistive technology.

The establishment of a **safety culture** is essential to safe care. In addition to developing awareness regarding safety issues, this includes increasing knowledge about how to disclose, handle and learn from patient safety incidents. Since 2017, non-profit home care organizations in Switzerland have been invited to share knowledge via the Critical Incident Reporting System (CIRS) platform [35].

On the other hand, as each organization is accountable for the quality of care it delivers, it is also necessary to monitor its quality and guide its improvement. Both of these tasks require the tracking of quality indicators and feedback from clients and families [21]. Several organizations in Switzerland, including Concret AG, sanaCERT, QUALIS evaluation or NPO Plus, support healthcare providers in assessing their quality or surveying clients. And for this to work, the **leadership** of each home care organization must start with a coherent vision regarding safety issues and quality of care, then implement structures and processes that support quality issues and finally steer the organization accordingly.

The lack of **communication and care coordination** between different healthcare providers, including physicians, insurance companies, pharmacies, specialists, therapists and community-based programs, the variety of unlinked documentation systems and the fragmentation of information all disrupt the continuum of healthcare provision, threatening patient safety and quality [16]. A central repository of care plans, medications and patient information would facilitate both safe home health care and transition management.

Switzerland is in the process of introducing Electronic Health Records to all regions by 2020 [36]. However, as its use is voluntary for patients as well as for general practitioners and outpatient services, it has had a slow start. One specific hotspot is the transition home from a hospital stay

with missing information [37]. In Geneva, it could be shown that an integrated care model with a multidisciplinary geriatric home visit team that regularly exchanged information with the home care services could reduce unnecessary hospitalizations and emergency room visits [38].

As shown above, **clients and families** need not only to be included in the discourse about patient safety in home care, but also to be partners in identifying safety risk and making decisions about possible interventions. This includes the building up of a trustful relationship between client, family and nurses, the provision of supporting information to those who need it and the resources for patient safety and quality education.

Technology is increasingly important in home care [12], from monitoring systems, oxygen or infusion therapy to home dialysis apparatus and ventilators. Technology can greatly assist informal caregivers, e.g., with alarm systems, motion sensors or sound monitors, to keep clients safe. However, often both clients and their caregivers can have physical, cognitive or sensory impairments that hinder that technology's safe use [13]. Moreover, constant alarms day and night can lead to fatigue, increasing safety risks [39]. Thus, to use assistive devices efficiently, informal caregivers need not only knowledge, skills and abilities, but safety awareness. Above all, the introduction of home care technology requires consideration of human factors that could hinder safe care [13]. The Interdisciplinary Centre of Competence for Ageing (IKOA) at the University of Applied Sciences in St. Gallen tests, adapts and supports the safe introduction of new technology by setting up Living Labs for older persons in their own homes.

Quality measurement and improvement

Based on Article 59*a* of the Swiss Health Insurance Act, all health care providers are obliged to provide federal agencies with any data needed to monitor their quality of care. In 2008, based on data from the Resident Assessment Instrument – Home Care Version (RAI–HC), 19 quality indicators were developed for Swiss home care settings. These included pertinent safety themes such as falls, no medication review, skin ulcers and informal caregiver distress [40]. However, to date, no federal agencies have either collected such data or publicly reported quality of care indicators. Spitex Schweiz, the national organization of non-profit home care agencies, provides the HomeCareData IT platform, which allows their members to anonymously upload their data, monitor their performance and compare themselves with other agencies. It is currently used by roughly 74 organizations. In the context of the National Research Program 74, the national "Better data on the quality of home care" project is refining HomeCareData. This will both develop a measurement for client and family satisfaction and update existing quality indicators.

As cantonal governments can define quality standards for home care organizations in the context of operating approvals and continuous quality monitoring, they play a key role in quality assurance. Some cantons not only define minimal requirements but also regularly monitor or audit the fulfilment of structural and procedural requirements. Additionally, the national organizations of both non-profit and for-profit home care organizations offer instruments that support their members in assessing their quality. However, as no national standards for home care organizations exist, inter-cantonal variability is high concerning quality standards and the allocation of financial resources to work on projects. Moreover, few evidence-based guidelines exist regarding safety issues in home care [14, 41]. Many projects to improve safety and quality of care run on the level either of single home care agencies or of collaborations between home care agencies. The degree of investment depends on each involved agency's size, structure and offers, as well as on its leaders' commitment to quality management.
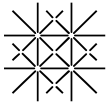
Recommendations

All stakeholders can contribute at different levels to better quality of care and patient safety. While the recommendations are here assigned to specific stakeholders, most of them can be taken up by several stakeholders.

- Policy and decision makers:
  - ➢ Promote respite care, support, information and training for both caregivers and clients to keep them safe
  - ➢ Assess the current situation in Switzerland concerning adverse events in home care, including healthcare-associated infections
  - ➢ Implement national quality indicators that monitor hotspots in patient safety and quality of care
  - ➢ Provide incentives for smooth transitions where medication prescriptions are readily available and systematic post-transition medication reviews are performed for at-risk older persons
  - ➢ To ensure the flow of relevant information, provide incentives to use electronic health records across all healthcare providers and sectors
  - ➢ Adjust current payment provisions to reflect the time necessary for safety risk assessments, for client and family education and for consultation adapted to the individual needs and situations of frail older persons

- Home care management:
  - ➢ Monitor quality indicators and hotspots in patient safety and quality of care including transitions between health care providers
  - ➢ Increase care worker awareness of safety and quality issues in home care according to their educational level, build a common understanding of quality of care and a positive safety culture
  - ➢ Update knowledge and skills of care workers of all educational levels regularly, including the use of assistive technology
  - ➢ Assess physical risks as well as risks from the social environment and clinical risks when initiating a service
  - ➢ Integrate caregivers as partners in managing safety issues

- Professional and provider organizations
  - ➢ Train leaders to promote safety and quality of care
    Build competencies to assess risks and implement safety measures in collaboration with clients and their families
  - ➢ Support the ongoing use of a standardized assessment tool such as the Resident Assessment Instrument (RAI) across all home care organisations that support standardized risk assessment
  - ➢ Support the systematic monitoring of hotspots in patient safety and quality of care
  - ➢ Provide national standards and guidelines for home care safety, supporting risk assessment and safety measures
  - ➢ Support the development and implementation of technology adapted for use by older persons
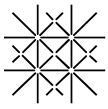
References

1. Bundesamt für Statistik, *Mehr Pflege zu Hause, stagnierende Anzahl Personen in Alters-und Pflegeheimen*. 2018, Neuchâtel: Bundesamt für Statistik.
2. Bundesamt für Statistik, *Statistik der Hilfe und Pflege zu Hause. Ergebnisse 2014: Zahlen und Trends*. 2015, Neuchâtel: Bundesamt für Statistik.
3. Schilliger, S., *Transnationale Care-Arbeit: Osteuropäische Pendelmigrantinnen in Privathaushalten von Pflegebedürftigen*, in *Who cares? Pflege und Solidarität in der alternden Gesellschaft*, Schweizerisches Rotes Kreuz, Editor. 2013, Schweizerisches Rotes Kreuz: Bern.
4. Merçay, C. and A. Grünig, *Gesundheitspersonal in der Schweiz − Zukünftiger Bedarf bis 2030 und die Folgen für den Nachwuchsbedarf (Obsan Bulletin 12/2016)*. 2016, Neuchâtel: Schweizerisches Gesundheitsobservatorium.
5. Merçay, C., L. Burla, and M. Widmer, *Gesundheitspersonal in der Schweiz. Bestandesaufnahme und Prognosen bis 2030 (Obsan Bericht 71)*. 2016, Neuchâtel: Schweizerisches Gesundheitsobservatorium.
6. Masotti, P., M.A. McColl, and M. Green, *Adverse events experienced by homecare patients: A scoping review of the literature.* International Journal for Quality in Health Care, 2010. **22**(2): p. 115-25.
7. Sears, N., et al., *The incidence of adverse events among home care patients.* International Journal for Quality in Health Care, 2013. **25**(1): p. 16-28.
8. Doran, D.M., et al., *Adverse events among Ontario home care clients associated with emergency room visit or hospitalization: a retrospective cohort study.* BMC Health Services Research, 2013. **13**: p. 227.
9. Sears, N.A., et al., *Associations between patient factors and adverse events in the home care setting: A secondary data analysis of two canadian adverse event studies.* BMC Health Services Research, 2017. **17**(1): p. 400.
10. Blais, R., et al., *Assessing adverse events among home care clients in three Canadian provinces using chart review.* BMJ Qual Saf, 2013. **22**(12): p. 989-97.
11. Schildmeijer, K.G.I., et al., *Adverse events in patients in home healthcare: A retrospective record review using trigger tool methodology.* BMJ Open, 2018. **8**(1): p. e019267.
12. Lang, A., et al., *Broadening the patient safety agenda to include home care services.* Healthcare Quarterly, 2006. **9 Spec No**: p. 124-6.
13. Henriksen, K., A. Joseph, and T. Zayas-Caban, *The human factors of home health care: A conceptual model for examining safety and quality concerns.* Journal of Patient Safety, 2009. **5**(4): p. 229-36.
14. Czakert, J., Y. Lehmann, and M. Ewers, *[Patient safety in home care : A review of international recommendations].* Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen, 2018. **135-136**: p. 18-26.
15. Schaepe, C. and M. Ewers, *"I see myself as part of the team" - family caregivers' contribution to safety in advanced home care.* BMC Nursing, 2018. **17**: p. 40.
16. Lang, A., N. Edwards, and A. Fleiszer, *Safety in home care: A broadened perspective of patient safety.* International Journal for Quality in Health Care, 2008. **20**(2): p. 130-135.
17. Doran, D. and R. Blais, *Safety at home. A Pan-Canadian home care safety study*. 2013, Canadian Patient Safety Institute: Edmonton.
18. Ellenbecker, C.H., et al., *Patient safety and quality in home health care*, in *Patient safety and quality: An evidence-based handbook for nurses*, R.G. Hughes, Editor. 2008, Agency for Healthcare Research and Quality (US): Rockville (MD).

University
of Basel

Faculty of Medicine
Department of Public Health

Pflegewissenschaft
Nursing Science

19.   Niederhauser, A. and M. Füglister, *Patientensicherheit in der Langzeitpflege*. 2016, Patientensicherheit Schweiz: Zürich.
20.   Gershon, R.R.M., et al., *Home health care patients and safety hazards in the home: Preliminary findings*, in *Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 1: Assessment)*, K. Henriksen, et al., Editors. 2008, Agency for Healthcare Research and Quality: Rockville (MD).
21.   Accreditation Canada, *Required Organizational Practices. Handbook 2017*. 2017, Accrediation Canada: Ottawa, ON.
22.   Lachs, M.S. and K.A. Pillemer, *Elder abuse.* New England Journal of Medicine, 2015. **373**(20): p. 1947-1956.
23.   Pillemer, K., et al., *Elder Abuse: Global Situation, Risk Factors, and Prevention Strategies.* Gerontologist, 2016. **56 Suppl 2**: p. S194-205.
24.   Simone, L., et al., *Types of abuse and risk factors associated with elder abuse.* Swiss Medical Weekly, 2016. **146**: p. w14273.
25.   Schweizerisches Gesundheitsobservatorium, ed. *Gesundheit in der Schweiz - Fokus chronische Erkrankungen - Nationaler Gesundheitsbericht 2015*. 2015, Hogrefe: Bern.
26.   Heinimann, N.B. and R.W. Kressig, *[Accidental falls in the elderly].* Praxis (Bern 1994), 2014. **103**(13): p. 767-73.
27.   Hopewell, S., et al., *Multifactorial and multiple component interventions for preventing falls in older people living in the community.* Cochrane Database of Systematic Reviews, 2018. **7**: p. Cd012221.
28.   Gschwind, Y.J., et al., *Basis for a Swiss perspective on fall prevention in vulnerable older people.* Swiss Medical Weekly, 2011(141:w13305).
29.   Meyer-Massetti, C., C.R. Meier, and B.J. Guglielmo, *The scope of drug-related problems in the home care setting.* International Journal of Clinical Pharmacy, 2018. **40**(2): p. 325-334.
30.   Meyer-Massetti, C., et al., *Medication-related problems during transfer from hospital to home care: Baseline data from Switzerland.* International Journal of Clinical Pharmacy, 2018. **40**(6): p. 1614-1620.
31.   Meyer-Massetti, C., *doMESTIC 2016-2019. Study of medication safety in home care*. 2018.
32.   Stiftung Patientensicherheit Schweiz, *Der systematische Medikationsabgleich im Akutspital. Empfehlungen im Rahmen des nationalen Pilotprogramms progress! Sichere Medikation an Schnittstellen*. 2015.
33.   The Joint Commission, *National patient safety goals effective January 2017. Home Care Accreditation Program*. 2017, The Joint Commission: Washington DC / Oakbrook Terrace IL.
34.   Vettori, A., V. Angst, and T. Von Stokar, *National Strategie zur Überwachung, Verhütung und Bekämpfung von healthcare-assoziierten Infektionen im nichtstationären Bereich. Vorstudie*. 2016, infras: Bern.
35.   Spitex Magazin, *Von den Fehlern der anderen lernen.* Spitex Magazin, 2017(2): p. 6-7.
36.   De Pietro, C. and I. Francetic, *E-health in Switzerland: The laborious adoption of the federal law on electronic health records (EHR) and health information exchange (HIE) networks.* Health Policy, 2018. **122**(2): p. 69-74.
37.   Romagnoli, K.M., et al., *Home-care nurses' perceptions of unmet information needs and communication difficulties of older patients in the immediate post-hospital discharge period.* BMJ Quality & Safety, 2013. **22**(4): p. 324-32.
38.   Di Pollina, L., et al., *Integrated care at home reduces unnecessary hospitalizations of community-dwelling frail older adults: A prospective controlled trial.* BMC Geriatrics, 2017. **17**(1): p. 53.
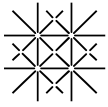
39.   Lang, A., et al., *Home care safety perspectives from clients, family members, caregivers and paid providers.* Healthcare Quarterly, 2009. **12**(Sp): p. 97-101.
40.   Burla, L., et al., *Entwicklung und Erprobung von Qualitätsindikatoren für die ambulante Pflege in der Schweiz.* Gesundheitswesen, 2010. **72**(02): p. 106-113.
41.   Harrison, M.B., et al., *Safety in home care: A mapping review of the international literature.* International Journal of Evidence-Based Healthcare, 2013. **11**(3): p. 148-160.

Swiss National Report on Safety and Quality of Care

Care for frail older people in the hospital

Mieke Deschodt, RN, PhD

Pflegewissenschaft – Nursing Sciene (INS), Department of Public Health, University of Basel, Switzerland

Gerontology and Geriatrics, Department of Chronic Diseases, Metabolism and Ageing, KU Leuven, Belgium

February 2019

ABSTRACT
Population is ageing, resulting in an increased number of hospitalisations of frail older people who are characterized by multimorbidity, functional and cognitive dependencies, and at risk for developing geriatric syndromes. To prevent, identify or treat these geriatric syndromes, comprehensive geriatric assessment (CGA), consisting of screening, in-depth assessment, integrated care planning and follow-up, has been put forward for delivering high quality care for these frail older patients. CGA as a multicomponent intervention has been included as core intervention in different care models. Although acute geriatric units have the strongest evidence-base and are therefore still the golden standard in geriatric hospital care, they are more expensive in terms of infrastructure and require more geriatric expertise. As a result, alternative CGA based care models have been implemented and evaluated. The geriatric co-management models based on proactive and collaborative care have stronger evidence than the purely consultation-based models and should therefore be favoured. It is unclear to what extent the different models have been implemented in Swiss hospitals. Research has shown that having a legislative framework and having sufficient capacity in terms of geriatric expertise are key in moving implementation of these care models forward. Yet, although the number of geriatric beds and geriatricians has been increasing in Switzerland, it seems that the growth is insufficient to keep up with the demographic ageing. Investments in the development of guiding frameworks and geriatric training for all medical and allied health professionals should be prioritized, while hospital administrators locally push the implementation forward.

Increasing number of older people in the hospital
Improvements in living conditions and progress in medical and surgical management have caused progressive ageing of the population in developed countries (1). The EU predicts that by 2060, between 22 and 36% of all citizens will be ≥ 65 years, with 12% of EU citizens being ≥ 80 years (2). In Switzerland the population aged ≥ 65 years is expected to increase from 18% in 2016 to 28% in 2060 (3). Although gains in life expectancy can be considered a positive outcome, not all the newly-won years will be spent in good health and free of physical limitations. Older adults are increasingly faced with disability and chronic illnesses, such as diabetes, hypertension and dementia (4). In Switzerland one quarter of the people between 65-79 year and 40% of the people aged ≥ 80 years suffer from two or more chronic diseases (5). Subsequently, as the annual likelihood of hospitalisation for people aged ≥65 years is more than three times that of someone aged 45 to 64 years, the hospital population will age as well (6). In 2017, 35.2% of all hospitalized patients in Switzerland were 65 years or older, with 36.7% of them being hospitalized at least twice (7). The goal of this report to give a brief

1

overview of the current evidence reviewing the international literature and practice with a view to identifying areas for further optimizing care for frail older people in the hospital.

Comprehensive geriatric care for frail older people
The hospital is a high-risk environment for older people, especially those who are frail, meaning that they have a reduction in physiologic reserve with higher rates of comorbidity and disability (8). Frail older patients are at higher risk for developing geriatric syndromes, such as delirium, functional decline, cognitive impairment, acute continence, malnutrition, falls, and pressure ulcers, both during and after hospitalization, compared to non-frail patients (9, 10). Consequently, ageing is also associated with prolonged hospital stay, discharge to an increased care level, rehabilitation, nursing home admission, and hospital readmission (11).

To ensure the early detection and accurate management of geriatric syndromes and determining the best treatment of older patients, **comprehensive geriatric assessment** (CGA) has been recommended by researchers and societies both nationally and internationally. CGA has been defined as *"a multidimensional interdisciplinary diagnostic process focused on determining a frail older person's medical, psychological and functional capability in order to develop a coordinated and integrated plan for treatment and long term follow up"* (12). It is considered to be one of the cornerstones of modern high-quality geriatric care. This geriatric care pathway originates from the observation that in frail older patients many conditions are unrecognised or misdiagnosed, either by lack of attention or by misinterpreting atypical disease presentations, leading to poorer outcomes after acute hospital admission (12). The key point is that conventional medical care focuses mainly on the disease of presentation and too often offers a 'one size fits all' approach. CGA on the other hand encompasses a holistic picture of the patient and offers individualised care by a multidisciplinary team with expertise in geriatric care (13, 14). CGA includes **four consecutive steps or core components**: screening, assessment, integrated care planning and follow-up.

Because in-depth evaluation with CGA is of most benefit in frail older patients, CGA should be preceded by a **risk or frailty screening** with a standardised screening test or questionnaire in order to target the population at risk for adverse outcomes in the hospital and post-discharge. Such an approach saves efforts and resources (15). Several validated screening instruments have been recommended for systematic screening of older adults in the hospital, such as the Identification for Seniors At Risk, the Triage Risk Screening Tool, the interRAI ED Screener or the Edmonton Frail Scale. Although the overall predictive accuracy of all these instruments is moderate, their sensitivity and negative predictive value is good. However, because of their poor specificity, screening tests alone are not sufficient to conclude that all patients who are rated as at risk are actually in need of further CGA. Although, this is one of the limitations of this type of screening, it is still recommended as a necessary first step because 1) it allows to efficiently exclude patients who are not at risk and 2) it increases the awareness about geriatric care aspects in those conducting the screening. Alternatively, one can define the at risk population by clearly describing the target population, e.g. all patients with a traumatic hip fracture aged 75 years or older, or all patients aged 75 years or older who had an unplanned readmission within 30 days after hospital discharge. This approach is often used for determining who can be admitted to a geriatric ward or an orthogeriatric ward.
Second, an **in-depth geriatric assessment of the at-risk patients** should be conducted. This comprehensive assessment is not limited to a medical evaluation or clinical assessment, but also includes the evaluation of the cognitive and functional abilities, the mental status, and the social and environmental context of the older person. Also informal caregiver burden, the

need to discuss advance care planning and the patient's preferences and care goals are to be assessed (16). As the assessment of all these domains requires expertise of different health and social care disciplines, this assessment can be conducted by several members of the multidisciplinary geriatric team. Validated geriatric scales and instruments are used to assess the patients' baseline status and detect unidentified problems and specific geriatric syndromes, such as the Confusion Assessment Method to assess delirium, the Geriatric Depression Scale to assess depression, the Katz or Barthel Index to assess activities of daily living and the Timed Get up and Go test to assess mobility and risk for falls, among many others.

Based on the in-depth and holistic geriatric assessment a coordinated and integrated care plan including **tailored interventions** to implement in clinical practice needs to be formulated (16, 17). In surgical patients, pre-operative CGA delivers important information for **preoperative optimisation** of health and social issues and to set rehabilitation goals. It also aids in prevention (e.g. delirium prevention), risk stratification, estimation of residual life expectancy, and preoperative shared decision making (15-18). **Post-operatively**, CGA aids to timely recognise acute complications or delayed recovery, to manage complications and comorbidities, to successfully rehabilitate, and to prepare for successful hospital discharge (18, 19).

Lastly, after implementation of the care plan with all health and social care providers, **a follow-up should be foreseen**, with the frequency and duration of the follow-up depending on the number, type and complexity of the identified problems.

Although the practical implementation of care models for frail older people is context-specific, these four steps are considered evidence-based core interventions in all settings to impact safety and quality of care for frail older people in the hospital.

CGA based care models for frail older people in the hospital
Different types of care models based on the CGA-approach have been described in the literature and have been implemented in daily clinical practice.

- The **acute geriatric unit** is a defined medical unit that has been designed specifically to prevent functional decline and related complications in frail older adults admitted to the hospital for an acute event (20). An interdisciplinary care approach based on CGA, patient-centered care, frequent medical review, early rehabilitation to maximizing functional status, proactive discharge planning and an adapted infrastructure are core components of acute geriatric wards (21, 22). Several meta-analyses have shown that admission on an acute geriatric unit prevents in-hospital functional decline, decreases mortality and institutionalization rates and results in shorter length of stays, a lower incidence of delirium, fewer falls, more discharges to home and lower costs (22-24). Because of the repeatedly shown impact on clinical and system outcomes, acute geriatric care units are still considered the gold standard for delivering high quality of care to hospitalized frail older people.

- **Inpatient geriatric consultation teams (IGCT)** are mobile multidisciplinary teams that evaluate older patients at risk for functional decline or acute complications hospitalized on non-geriatric wards (25, 26). The team members make their extensive geriatric expertise available for other professionals working in non-geriatric nursing units by formulating care commendations, developing an evidence-based care plan, and/or providing bed-side education (27). Because acute geriatric units have been and still are increasingly being tested to the limits of their capacity, these consultation teams are attractive because they can reach a large number of frail older patients and can be

implemented in a short period of time (28). They are also seen as an efficient way to bring in geriatric expertise, given the lack of geriatricians and geriatric expert nurses in many Western countries (29). Although a meta-analysis could only show a beneficial effect of IGCT interventions on mortality rate up to 8 months post-discharge, individual studies also demonstrated improved functional outcomes, decreased incidence of delirium, and decreased readmission rates in patients seen by the IGCT (25). Compared to acute geriatric wards, the effectiveness is limited, mainly because of the recommendation-based character of the care model, the rather reactive than proactive approach, and the low adherence to the proposed interventions (23, 25, 27). Research and clinical focus has therefore shifted towards co-management models (15, 30).

- **Geriatric co-management models** are characterized by direct proactive care and shared responsibility and decision-making between at least one primary treating physician and a geriatrician or interdisciplinary geriatric team in the prevention and management of geriatric-oriented problems (31, 32). In a recent meta-analysis including 12 prospective quasi-experimental studies a potential beneficial effect on complications, length of stay and in-hospital mortality was demonstrated (30). The majority of these studies had been conducted in surgical, mainly orthopedic, patients. One example of geriatric co-management is the Proactive care of Older People undergoing Surgery (POPS) program, a multidisciplinary preoperative CGA service with post-operative follow-through, which has proven successful in improving postoperative outcomes (33). In non-surgical patients, a recent effectiveness-implementation evaluation of the 'Geriatric CO-mAnagement Cardiology patients in the Hospital (G-COACH)' program has shown that the geriatric co-management intervention resulted in decrease of in-hospital functional decline (34% vs. 17%, $p<0.001$), infections (12% vs. 3%, $p<0.001$), and delirium (13% vs. 3%, $p<0.001$) (Preliminary analysis - results not yet published) (34, 35).

- Finally, several geriatric care models were designed to address the needs of older people in the **emergency department (ED)**, such as the use of discrete geriatric boxes, cubicles or rooms (36). These are places especially equipped for older patients and have a multidisciplinary team of specialists - including a geriatrician - available that can immediately assess patients and speed up the decision-making process regarding hospital admission or discharge. A recent meta-analysis suggested that discrete geriatric boxes at the ED have infrastructural benefits and seem to nourish consistent geriatric-oriented practice and the development of geriatric expertise and some care models resulted in a shorter hospital length of stay and fewer readmission (36)., Offering multidisciplinary CGA at ED observation units has also been found feasible and resulting in targeted interventions (37).

Implementation of CGA based models in clinical practice
The implementation of CGA based models has recently been studied in 8 European countries as part of the imAGE.eu study (38). Overall, CGA-based models of care are most widely implemented in Belgium, Denmark and Ireland, while the uptake has been lower in the other surveyed countries (i.e. Estonia, Greece, Iceland, Malta, Slovenia). Despite the current evidence supporting the implementation of several CGA-based models of care, there is still a long way to go in terms of further scaling up and working toward system sustainability in most European countries. Having a political framework and sufficient capacity in terms of geriatricians or geriatric specialists were found to be two important facilitators to speed up the large-scale implementation of care models for frail older people.

Switzerland did not participate in the imAGE.eu study and finding reliable numbers regarding the degree of implementation of each of the CGA-based models of care is challenging. In 2010 the Federal Statistical Office reported the total number of hospital beds and hospitalizations for rehabilitation and geriatrics as a total, but not separately. So although an increase is observed of both the number of geriatric/rehab beds (6'808 or 17.5% in 2010 versus 7'143 or 18.7% in 2014) and geriatric/rehab hospitalizations (85'123 or 0.06% in 2010 versus 96'734 or 0.07% in 2014), we cannot evaluate whether this is due to an increase in geriatric or in rehabilitation beds. Nevertheless, the total increase is limited and does not keep up with the health care needs of the aging populations. For the other models of care, no numbers could be found.

With regard to the capacity in terms of geriatricians, it is important to mention that in 2000 the Swiss Medical Association certified the geriatric discipline consisting of 2 years of additional postgraduate training in geriatrics and 1 year in geriatric psychiatry. This has resulted in an increasing number of certified geriatricians from 149 in 2008 up to 246 in 2017 (39). This corresponds to an increase from one geriatrician per 8'567 people to one per 6504 people aged ≥ 65 years, respectively. Although there are no clear guidelines regarding the ideal 'geriatrician : older people' ratio, earlier studies already described 1 : 4'736 as burdensome (40), so the current number can be considered insufficient. As attracting sufficient young physicians towards geriatrics is believed not to meet the demands, it has been advocated that all physicians should be equipped to give quality of care to older adults, while geriatricians should focus on treating the most complex and frail patients (41).

Call for action

To hospital administrators and management
- Acute geriatric care units are still considered the golden standard for delivering high quality of care to frail older people. Investments in these units result in better quality of care for the patient and improve system outcomes.
- When resources and/or geriatric expertise is limited, invest in the implementation of geriatric co-management teams or wards, guaranteeing proactive and direct care in an at-risk population.
- Although systematic frailty screening should not be implemented as a stand-alone intervention, it supports decision-making regarding the place of admission in the hospital, indicates the need for follow-up assessment, tailored interventions and follow-up, and increases awareness regarding geriatric care aspects.

To educators
- Baseline knowledge and skills regarding geriatric syndromes and care should be included in curricula of all physicians, social and health care professionals, as all will be faced with the frail older people regardless of the setting or ward they are working.
- Nurses play a crucial role in the CGA approach, but too often the focus in curricula is too strongly focused on the assessment. The complexity of CGA lays however in the development and coordination of an integrated care plan. Skills in the field of communication, leadership, change management, coaching and supporting self-management are therefore often overlooked and should be more central in the nursing curricula.

To policy and decision-makers

- Legislation or national frameworks have shown to be effective tools to speed up the implementation of CGA based models of care in other European countries. As the most successful approach is to combine a top-down and bottom-up approach, involvement of stakeholders in the development of any legislation and framework is crucial.
- Comprehensive assessment, interdisciplinary teamwork, and care coordination are not only relevant within one setting, but also across care settings. Indeed, due to illness or increased dependency, older people often receive health and social services by a large number of care providers in different care settings over time. Unfortunately, care across settings is often not well coordinated. Too often, health and social care workers apply a 'silo mentality' and operate without knowledge of the personal preferences expressed, problems addressed, services provided, or treatments prescribed in other settings. As a result, older people are at risk of receiving fragmented care and poorly executed care transitions to and from the hospital, resulting in duplication of services, gaps in information delivery, inappropriate or conflicting care recommendations, medication errors, increased confusion and distress, and higher costs (42, 43). Political structures and financial incentives that support integrated care need to be provided.

To researchers
- CGA-based models of care are per definition multilevel complex interventions (44-46). Taking into account the current evidence-base of these models, researchers should at this point decide clearly for hybrid effectiveness-implementation designs to study the impact as well as the implementation efforts. To go for full and sustainable implementation, context analysis, stakeholder involvement, and focus on implementation outcomes (e.g. reach, fidelity, acceptability, implementation cost) should be part of any study evaluating the implementation of complex models of care (47).

Reference list

1.   High KP. Infrastructure and resources for an aging population: embracing complexity in translational research. Translational research : the journal of laboratory and clinical medicine. 2014;163(5):446-55.
2.   Union E. Adequate social protection for long-term care needs in an ageing society. . Report jointly prepared by the Social Protection Committee and the European Commission Luxembourg: Publications Office of the European Union,. 2014
3.   Swiss Confederation - Federal Statistical Office. Alter, Zivilstand, Staatsangehörigkeit 2018.
4.   Rechel B, Grundy E, Robine JM, Cylus J, Mackenbach JP, Knai C, et al. Ageing in the European Union. Lancet. 2013;381(9874):1312-22.
5.   Swiss Confederation - Federal Statistical Office. Demos 1/2018. Active ageing. Neuchâtel; 2018.
6.   Etzioni DA, Beart RW, Jr., Madoff RD, Ault GT. Impact of the aging population on the demand for colorectal procedures. Diseases of the colon and rectum. 2009;52(4):583-90; discussion 90-1.
7.   Swiss Confederation - Federal Statistical Office. Medizinische Statistik der Krankenhäuser. 2018.
8.   Partridge JS, Harari D, Dhesi JK. Frailty in the older surgical patient: a review. Age and ageing. 2012;41(2):142-7.
9.   Buurman BM, Hoogerduijn JG, de Haan RJ, Abu-Hanna A, Lagaay AM, Verhaar HJ, et al. Geriatric conditions in acutely hospitalized older patients: prevalence and one-year survival and functional decline. PLoS One. 2011;6(11):e26951.
10.   Inouye SK, Studenski S, Tinetti ME, Kuchel GA. Geriatric syndromes: clinical, research, and policy implications of a core geriatric concept. J Am Geriatr Soc. 2007;55(5):780-91.

11.   Sandini M, Pinotti, E., Persico, I., Picone, D., Bellelli, G. and Gianotti, L. Systematic review and meta-analysis of frailty as a predictor of morbidity and mortality after major abdominal surgery. BJS Open. 2017;1(5):128-37.

12.   Rubenstein LZ, Stuck AE, Siu AL, Wieland D. Impacts of geriatric evaluation and management programs on defined outcomes: overview of the evidence. J Am Geriatr Soc. 1991;39(9 Pt 2):8S-16S; discussion 7S-8S.

13.   Gladman JR, Conroy SP, Ranhoff AH, Gordon AL. New horizons in the implementation and research of comprehensive geriatric assessment: knowing, doing and the 'know-do' gap. Age and ageing. 2016;45(2):194-200.

14.   Cesari M, Marzetti E, Thiem U, Perez-Zepeda MU, Abellan Van Kan G, Landi F, et al. The geriatric management of frailty as paradigm of "The end of the disease era". European journal of internal medicine. 2016;31:11-4.

15.   Alvarez-Nebreda ML, Bentov N, Urman RD, Setia S, Huang JC, Pfeifer K, et al. Recommendations for Preoperative Management of Frailty from the Society for Perioperative Assessment and Quality Improvement (SPAQI). Journal of clinical anesthesia. 2018;47:33-42.

16.   Pilotto A, Cella A, Pilotto A, Daragjati J, Veronese N, Musacchio C, et al. Three Decades of Comprehensive Geriatric Assessment: Evidence Coming From Different Healthcare Settings and Specific Clinical Conditions. Journal of the American Medical Directors Association. 2017;18(2):192.e1-.e11.

17.   Wildiers H, Heeren P, Puts M, Topinkova E, Janssen-Heijnen ML, Extermann M, et al. International Society of Geriatric Oncology consensus on geriatric assessment in older patients with cancer. Journal of clinical oncology : official journal of the American Society of Clinical Oncology. 2014;32(24):2595-603.

18.   Parks RM, Rostoft S, Ommundsen N, Cheung KL. Peri-Operative Management of Older Adults with Cancer-The Roles of the Surgeon and Geriatrician. Cancers. 2015;7(3):1605-21.

19.   Braude P, Partridge JS, Hardwick J, Shipway DJ, Dhesi JK. Geriatricians in perioperative medicine: developing subspecialty training. British journal of anaesthesia. 2016;116(1):4-6.

20.   Amador LF, Reed D, Lehman CA. The acute care for elders unit: taking the rehabilitation model into the hospital setting. Rehabil Nurs. 2007;32(3):126-32.

21.   Baztan JJ, Suarez-Garcia FM, Lopez-Arrieta J, Rodriguez-Manas L, Rodriguez-Artalejo F. Effectiveness of acute geriatric units on functional decline, living at home, and case fatality among older patients admitted to hospital for acute medical disorders: meta-analysis. BMJ. 2009;338:b50.

22.   Fox MT, Persaud M, Maimets I, O'Brien K, Brooks D, Tregunno D, et al. Effectiveness of acute geriatric unit care using acute care for elders components: a systematic review and meta-analysis. J Am Geriatr Soc. 2012;60(12):2237-45.

23.   Ellis G, Gardner M, Tsiachristas A, Langhorne P, Burke O, Harwood RH, et al. Comprehensive geriatric assessment for older adults admitted to hospital. Cochrane Database Syst Rev. 2017;9:CD006211.

24.   Van Craen K, Braes T, Wellens N, Denhaerynck K, Flamaing J, Moons P, et al. The effectiveness of inpatient geriatric evaluation and management units: a systematic review and meta-analysis. J Am Geriatr Soc. 2010;58(1):83-92.

25.   Deschodt M, Flamaing J, Haentjens P, Boonen S, Milisen K. Impact of geriatric consultation teams on clinical outcome in acute hospitals: a systematic review and meta-analysis. BMC Med. 2013;11:48.

26.   Ellis G, Whitehead MA, Robinson D, O'Neill D, Langhorne P. Comprehensive geriatric assessment for older adults admitted to hospital: meta-analysis of randomised controlled trials. BMJ. 2011;343:d6553.

27.   Deschodt M, Claes V, Van Grootven B, Milisen K, Boland B, Flamaing J, et al. Comprehensive geriatric care in hospitals: the role of inpatient geriatric consultation teams. Brussels: Health Services Research (HSR) - Belgian Health Care Knowledge Centre (KCE); 2015. Report No.: KCE Reports 245Cs. D/2015/10.273/47.

28.	Winograd CH, Stearns C. Inpatient geriatric consultation. Challenges and benefits. J Am Geriatr Soc. 1990;38(8):926-32.

29.	Reuben DB, Zwanziger J, Bradley TB, Fink A, Hirsch SH, Williams AP, et al. How many physicians will be needed to provide medical care for older persons? Physician manpower needs for the twenty-first century. J Am Geriatr Soc. 1993;41(4):444-53.

30.	Van Grootven B, Flamaing J, Dierckx de Casterle B, Dubois C, Fagard K, Herregods MC, et al. Effectiveness of in-hospital geriatric co-management: a systematic review and meta-analysis. Age Ageing. 2017;46(6):903-10.

31.	Grigoryan KV, Javedan H, Rudolph JL. Orthogeriatric care models and outcomes in hip fracture patients: a systematic review and meta-analysis. J Orthop Trauma. 2014;28(3):e49-55.

32.	Sennour Y, Counsell SR, Jones J, Weiner M. Development and implementation of a proactive geriatrics consultation model in collaboration with hospitalists. J Am Geriatr Soc. 2009;57(11):2139-45.

33.	Harari D, Hopper A, Dhesi J, Babic-Illman G, Lockwood L, Martin F. Proactive care of older people undergoing surgery ('POPS'): designing, embedding, evaluating and funding a comprehensive geriatric assessment service for older elective surgical patients. Age Ageing. 2007;36(2):190-6.

34.	Deschodt M, Van Grootven B, Jeuris A, Devriendt E, Dierckx de Casterle B, Dubois C, et al. Geriatric CO-mAnagement for Cardiology patients in the Hospital (G-COACH): study protocol of a prospective before-after effectiveness-implementation study. BMJ open. 2018;8(10):e023593.

35.	Van Grootven B, McNicoll L, Mendelson DA, Friedman SM, Fagard K, Milisen K, et al. Quality indicators for in-hospital geriatric co-management programmes: a systematic literature review and international Delphi study. BMJ open. 2018;8(3):e020617.

36.	Ellis G, Marshall T, Ritchie C. Comprehensive geriatric assessment in the emergency department. Clin Interv Aging. 2014;9:2033-43.

37.	Southerland LT, Vargas AJ, Nagaraj L, Gure TR, Caterino JM. An Emergency Department Observation Unit Is a Feasible Setting for Multidisciplinary Geriatric Assessments in Compliance With the Geriatric Emergency Department Guidelines. Acad Emerg Med. 2018;25(1):76-82.

38.	Deschodt M, Boland B, Lund CM, Saks K, Velonaki V-S, Samuelsson O, et al. Implementation of geriatric care models in Europe (imAGE.eu): a cross-sectional survey in eight countries. Eur Geriatr Med. 2018;9(6):771-82.

39.	FMH-Ärztestatistik. Berufstätige Ärzte nach Schwerpunkten und Ausweisen 2017.

40.	Lee WC, Sumaya CV. Geriatric workforce capacity: a pending crisis for nursing home residents. Front Public Health. 2013;1:24.

41.	Leipzig RM, Granville L, Simpson D, Anderson MB, Sauvigne K, Soriano RP. Keeping granny safe on July 1: a consensus on minimum geriatrics competencies for graduating medical students. Academic medicine : journal of the Association of American Medical Colleges. 2009;84(5):604-10.

42.	Helleso R, Lorensen M, Sorensen L. Challenging the information gap--the patients transfer from hospital to home health care. Int J Med Inform. 2004;73(7-8):569-80.

43.	Kripalani S, LeFevre F, Phillips CO, Williams MV, Basaviah P, Baker DW. Deficits in communication and information transfer between hospital-based and primary care physicians: implications for patient safety and continuity of care. Jama. 2007;297(8):831-41.

44.	Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ. 2008;337:a1655.

45.	Richards DA, Rahm Hallberg I. Complex interventions in health. An overview of research methods. 1st ed. London: Routledge; 2015.

46.	Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance. BMJ (Clinical research ed). 2015;350:h1258.

47.	Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health. 2011;38(2):65-76.

Swiss National Report on Quality and Safety in Healthcare

Invitations for short reports and confirmed contributions

From a surgical point of view

Professor Michele Genoni
Department of Cardiovascular Surgery
UniversityHospital Zurich
CH-8090 Zurich

Date of Submission: 16.01.2019

Zusammenfassung

Die Qualität in der Medizin liegt allen chirurgischen Fachgesellschaften in der Schweiz am Herzen. Entsprechend dem föderalistischen Gesundheitssystem der Schweiz, sind die Aktivitäten in den einzelnen Fachgesellschaften angesiedelt und nicht koordiniert. Der Dachverband der chirurgisch und invasiv tätigen Fachgesellschaften und Fachgruppierungen (FMCH) unterstützt und koordiniert die Qualitätssicherung.

Daneben gibt es viele Organisationen (Stiftung für Patientensicherheit, Swiss Medical Board, Schweizerische Akademie für Qualität in der Medizin, Arbeitsgemeinschaft für Qualitätssicherung in der Chirurgie AQC u.a.), welche Projekte und Richtlinien für die fachübergreifende Qualität entwickeln. Diese Projekte ergänzen die Aktivitäten der einzelnen Fachgesellschaften und bilden ein Fundament, auf welchem die Fachgesellschaften auch neue Projekte aufbauen können.

Das Schweizerische Gesundheitssystem, stellt grosse Herausforderungen an die Qualitätssicherung in der Medizin. Viele Stakeholder mischen mit und es birgt die Gefahr, dass die Verantwortungen ständig wechseln. Umso wichtiger ist es, dass die angesprochenen Berufsgruppen die Verantwortung in der Qualität tragen und die Träger des Gesundheitswesens die Leitplanken festgelegen. Diese Arbeits- bzw. Verantwortungsteilung ist zielführend. Noch ungelöst ist die Finanzierung der Qualitätsmassnahmen sowie die Sicherung der Datenqualität und des Datenschutzes. Diese offenen Punkte werden zurzeit im eidgenössischen Parlament diskutiert.

In Zukunft muss sich die Medizin von der leistungsbasierten Abrechnung und Beurteilung durch einen Paradigmenwechsel lösen hin zur Value Based Medicine. Dabei wechselt der Fokus zur Prozessqualität mit besonderer Gewichtung der Indikationenqualität und den Bedürfnissen des Patienten als Ganzes.

Abstract

Quality in surgery is close to the heart of all surgical societies in Switzerland. According to the federal health system in Switzerland, the activities are located in the individual medical professional societies and are not coordinated. The Umbrella Association of Surgical and Invasive Societies and Specialist Groups (FMCH) supports and coordinates quality assurance.

In addition, there are many organisations (Foundation for Patient Safety, Swiss Medical Board, Swiss Academy for Quality in Medicine, Working Group for Quality Assurance in Surgery AQC, etc.) which develop projects and guidelines for interdisciplinary quality. These projects complement the activities of the individual professional societies and form a foundation on which the professional societies themselves can also create new projects.

The Swiss healthcare system, which has a federal structure, poses major challenges in terms of quality assurance in medicine. Many stakeholders are involved and there is a danger that responsibilities could constantly change. It is therefore all the more important that those directly responsible (the professional groups addressed) bear responsibility for quality and that the healthcare providers define the guiding framework. This division of work and responsibility leads to success. The financing of quality measures and the safeguarding of data quality and data protection are still unresolved. These open points are currently being discussed in the Federal Parliament.

In the future, medicine will have to move away from performance-based billing and assessment by means of a paradigm shift towards value-based medicine. The focus will shift to process quality with a special emphasis on indication quality and the needs of the patient as a whole.

Introduction

Various specialist disciplines have emerged in surgery in parallel with the development and refinement of surgical treatment options. Members of the various disciplines are organised in independent medical professional societies at both the national and international level. What members of the specialist surgical societies have in common is their physical place of work, the operating theatre, and the invasive nature of their procedures. The patient is increasingly the focus of attention in modern medicine. As a result, new fields of medicine are emerging on the basis of commonalities in the treatment of organ disease, for example cardiac medicine (cardiology and cardiac surgery) and hepatobiliary medicine (gastroenterology, oncology, visceral surgery, etc.).

Quality is a deep concern for all the specialist surgical societies in Switzerland. We all want patients to attain the best possible state of health following treatment. This means that:

➢ Society has to realistically plan optimum public healthcare with the resources available
➢ Patients must be given the best possible opportunities to heal
➢ Doctors must conduct the right treatment flawlessly.

So what does a patient's final health or medical state depend on? A whole host of different factors feed into this:

➢ The patient's initial state of health
➢ The quality of the way the case history is recorded (anamnesis)
➢ The quality of the way the condition is identified (diagnosis)
➢ The quality of the way the treatment is determined (indication)
➢ The quality of the treatment
➢ The quality of patient involvement and collaboration

This points the way to the potential approaches for measures to promote and assure quality to attain the best possible state of health for our patients:

1. Basic and ongoing training of medical staff
2. Mentoring and coaching for junior staff
3. Interdisciplinary and interprofessional culture
4. Performance measurement (processes and functions)
5. Continuous, systematic improvement

Organisation of surgical societies in Switzerland

Swiss Medical Association (FMH)
The FMH (Foederatio Medicorum Helveticorum) is a professional body representing more than 40,000 members. At the same time, the FMH serves as the umbrella association for more than 70 medical organisations, with various bodies performing the functions necessary for successful association policy. Powers and responsibilities are set down in a legal framework including the articles of association. The general secretariat, employing more than 90 people, serves as the interface between doctors and the general public, and is in charge of coordinating the operational and strategic/policy levels.

The **medical professional societies** are professional and scientific associations as defined in Article 60ff of the Swiss Civil Code. They monitor the quality of medical work, safeguard the professional and economic interests of their members, and promote scientific activity in their specialist field. The societies also play an important role in developing young talent by providing continuing training and education. They are guided by the professional rules of the FMH.

The FMCH is an umbrella association bringing together 21 surgical and invasive societies and specialist groups and three medical professional organisations representing around 10,000 doctors. The FMCH supports its members and represents their health and professional policy interests as well as coordinating medical care, continuing education, quality assurance, tariffs and fees.

Quality in surgery

Doctors, hospitals and other healthcare providers are legally obliged to ascertain and account for the quality of their services. Various institutions and associations occupy themselves with quality in surgery, with the active involvement of surgeons.

These days the **Swiss Academy of Medical Sciences (SAMS)** acts as a bridge-builder between science and society. Its areas of focus include clarifying ethical questions in connection with developments in medicine. The SAMS influences quality in medicine at a strategic level through its work to formulate recommendations (registers, certification and quality data) and its involvement in the Swiss Medical Board.

The **Swiss Patient Safety Foundation** is a recognised think tank dedicated to excellence. It serves as a national centre of competence advocating a consistent, constructive culture of safety in Swiss healthcare. It works in constructive partnership with a wide range of actors in healthcare to develop joint solutions to promote patient safety, process quality and the necessary framework, and facilitate their propagation.
The foundation launches and manages national programmes, research projects and training offerings designed to reduce safety risks.

The **Swiss Medical Board (SMB)** is a leading Swiss centre of competence for health technology assessment, analysing and evaluating preventive and diagnostic procedures and therapeutic interventions from a medical, economic, ethical and legal point of view. On this basis the SMB formulates recommendations for political decision-makers, medical specialists and other care providers. In select cases it also publishes information sheets for patients.
The Swiss Medical Board (SMB) is sponsored by an association with the following institutions and bodies as members: the Swiss Conference of Cantonal Ministers of Education (EDK), the Swiss Academy of Medical Sciences (SAMS), the government of the Principality of Liechtenstein, Interpharma (the association of pharmaceutical companies in Switzerland doing research), health insurers' associations (santésuisse and curafutura), the SPO Swiss patient organisation, the DVSP (umbrella association of Swiss patients' organisations) and the FMCH (Umbrella Association of Surgical and Invasive Societies and Specialist Groups).

Cantonal departments of health (taking Canton Zurich as an example). A core task of the department of health is to work with the hospitals and other partners to assure high-quality medical treatment for people in the canton of Zurich. The department has an excellent basis for doing so in the form of its 2012 hospital lists and the canton's hospital planning and funding act. Its work on quality takes place, for example, by way of quality controls in selected specialist areas at listed Zurich hospitals and quality development with the relevant hospital representatives.

The **Swiss Academy for Quality in Medicine (SAQM)** is the physicians' own quality organisation, promoting all aspects of medical quality-related work to the benefit of patients, their families and doctors, and playing a pioneering role in quality in medicine. Its efforts to develop medical quality take the form, for example, of its own projects, competitions, and support and guidance for external projects.

The **Swiss National Association for Quality Development in Hospitals (ANQ)** is an association under the terms of Art. 60ff of the Swiss Civil Code with its office in Bern. Its goal is to coordinate and execute quality development measures at a national level, in particular the uniform implementation of outcome quality measurements in hospitals and clinics with the aim of documenting, developing and improving quality. The goal is to facilitate nationwide comparisons and define the framework necessary to do so. It also assures coordination with

the requirements of the Federal Health Insurance Act. The association is a non-profit organisation (NPO).

The **working committee on quality assurance in surgery (AQC)** is a group of heads of surgery and inpatient doctors aiming to create and compare joint statistics on cases and intervention as a way of assuring quality and recognising their own strengths. To this end, the AQC draws up comprehensive quality documentation for all medical cases with prospective data on cases, operations and interventions, paediatrics and outcomes.

Current projects related to safety, quality and efficiency in surgery

It is well known that the Swiss healthcare system is organised along federalist lines. As a result, and extraordinary number of different stakeholders have an influence on the quality of the individual components of care and thus on the healthcare system as a whole.

Surgery in general has always been concerned with quality, thanks to the fact that treatments can be evaluated directly. Increasing options for gathering, storing and comparing data electronically have also set the stage for cross-comparisons of the work of surgeons. Surgeons have embraced this challenge and are actively participating in endeavours to develop and plan quality in medicine.

The **Umbrella Association of Surgical and Invasive Societies and Specialist Groups (FMCH)** is involved with quality-related issues within various institutions:

The FMCH is represented on the steering committee of the SAQM and has actively worked on the following projects:

➢ *Quality charter*
   Every physician is dedicated to impeccable quality of medical treatment and serving the needs and wellbeing of patients and society as a whole. For this reason the SAQM and various medical organisations have drawn up a binding quality charter. It is a declaration of the will to network and cooperate on quality matters in Switzerland. The charter is built on three pillars:

   1. Transparency – making visible existing and new medical activities designed to promote the quality of medicine and medical care provision
   2. Commitment – the signatory medical organisations develop a quality strategy and evaluate work regularly in a quarterly report
   3. Sustainability – the quality strategy is geared to the long term and assures quality development. Quality-related work is an integral component of basic and continuing medical training and education, and is based on the foundation of the law and data protection legislation.

➢ *"Guidelines Schweiz" online platform*
   Medical guidelines are intended to facilitate the process of making evidence-based decisions in the interests of providing the best possible treatment to patients. Countless guidelines already exist, and new ones are being created all the time. This makes it hard to keep track of all the guidelines and leads to uncertainty when it comes to applying them.

   The "Guidelines Switzerland" online platform gives an overview of the guidelines and information about them which are endorsed by the professional Swiss associations.

   Since 2017 professional associations, hospitals, clinics and other healthcare organisations have been able to document guidelines recognised by them on the online platform. The platform is updated on a regular basis and serves as a foundation for ongoing work by the SAQM on the topic of guidelines.

Since 2018 the FMCH has been a sponsoring member of the Swiss Medical Board (SMB) and represented on its executive committee. This way the surgical and invasive societies can exert a direct influence on processes for systematically evaluating medical procedures and technologies in terms of public healthcare. The aim is to come up with evidence-based medical decisions. By way of example, here are the five most recent surgically-relevant topics that have already been completed:

➢ Bariatric surgery versus non-surgical treatment for obesity
➢ Acute and subacute radiculopathies due to intervertebral disc herniation: conservative versus surgical treatment
➢ Systemic screening mammography
➢ Surgical therapy of liver metastases from colorectal cancer
➢ Vertebroplasty and kyphoplasty for osteoporosis-related fractures of the vertebral body.

The FMCH sits on the foundation board of the Patient Safety Foundation alongside representatives of the Federal Office of Public Health, the Swiss Academy of Medical Sciences and numerous other professional associations in healthcare. In this capacity it has actively worked on or supported various projects:

➢ *Safe surgery:*
At the heart of this project is the WHO's 2009 safe surgery checklist, which was specifically adapted to Switzerland with the intention of working through it. The "Safe Surgery" pilot programme was primarily funded by the FOPH as an integral component of the national quality strategy, and was co-funded by the FMCH. Besides a nationwide campaign, a more in-depth project was conducted with ten pilot hospitals, and the checklist was implemented and applied in practice. The core elements were four cross-institutional workshops and in-house activities such as adapting the checklist and training staff. The programme was accompanied by a comprehensive evaluation concentrating on the way the implementation of the necessary activities was supported, guided and evaluated. The programme also involved publishing a series of papers, developing an e-learning course and putting together an implementation toolkit. Now it is applied by Swiss surgeons almost across the board!

➢ *Morbidity and mortality conferences (MoMo)*:
Together with the FOPH, the FMH and the H+ Die Spitäler der Schweiz umbrella association, the FMCH is actively supporting the Patient Safety Foundation's MoMo project. The intention is to adapt and refine this patient safety instrument for Switzerland, ultimately to be applied across the board at all surgical clinics.

In collaboration with the Dialog Ethik ethics institute, the FMCH has created and implemented the Swiss Oath pledge for medical doctors. The oath is designed to protect and strengthen the medical ethos, safeguard the dignity of the medical profession and its responsibility towards patients, and thus express the humane orientation of the profession. An important aspect of the pledge is thus safeguarding and improving patient indication and treatment.

The surgical societies initiate projects in their specialist field, either individually or as part of joint working parties. The annex contains a list of the quality-related projects run by the societies affiliated to the FMCH. In this context a number of projects should be highlighted:

- **The AQC working committee on quality assurance in surgery (AQC)** involves most of the surgical teaching hospitals and private clinics. The AQC provides more than ten medical professional societies with modular technologies for the simultaneous, integrated and largely automated completion of multiple questionnaires, and takes charge of capturing and analysing the data. This analysis enables cross-comparisons, covering the quality of both indication and outcome.

- **Swissorthopaedics (the Swiss Society of Orthopaedics and Traumatology)** operates the SIRIS register as a tool for measuring quality in medical implants. All types of implantation can be registered in SIRIS. Around 20,000 artificial hip joints and 16,000 artificial knee joints are currently implanted in Switzerland every year. Impressive are the annual growth rates: 1% for hips and 4-5% for knees. SIRIS serves as an early warning system for implant failure, an indicator of complications in surgical interventions, a benchmark for comparisons at industry and hospital level, and a database for long-term outcomes and survival analyses.

- **The Swiss Society for Cardiac and Vascular Thoracic Surgery (SGHC)** runs the national cardiac surgery register, in which all cardiac surgery centres in Switzerland participate. The register follows the European QUIP database. In the process of developing the register the interfaces to data protection in Switzerland were clarified, and comprehensive audits were conducted to assure data quality. The register is one of the requirements for inclusion on the Canton Zurich hospital list.

The medical professional societies, within the framework of their quality strategies, also define the interdisciplinary and interprofessional requirements for indication quality, for example, the interdisciplinary indication conferences (tumour boards, angioboards, heart team conferences, etc.) developed by doctors and adopted by the societies in their guidelines.
The Swiss Society of Cardiology and the Swiss Society for Cardiac and Vascular Thoracic Surgery have set down and published details of collaboration in interdisciplinary decision-making for the best treatment of patients (quality of indication) in Switzerland (Thorac Cardiovasc Surg. 2017 Oct;65(7):519-523).

Difficulties and hurdles in the implementation of quality-related projects

The Swiss healthcare system, set up along federalist lines, is acknowledged to be one of the best in the world, enabling people to lead long, active lives. In line with the times, however, the quality of healthcare must be transparent, sustainable and fundable. To assure this, the efforts of the various stakeholders in the Swiss healthcare system have to be structured and coordinated.

The way the system is set up is complex but amenable to progress, and innovation is encouraged and promoted. The federal government is responsible for nationwide healthcare strategy, stipulating what services must be provided and laying down the condition that care must be effective, expedient and economical. The federal government can plan systematic scientific controls to safeguard quality and delegate the performance of these controls to the professional associations. The federal government sets down the measures used to assure the quality or appropriate deployment of services.

The cantons are responsible for actual implementation by drawing up hospital lists, awarding contracts for services and monitoring compliance with the provisions of healthcare legislation. Ultimately, it is a matter of striking a balance between a patient-friendly healthcare system and the entrepreneurial freedom of providers with clear principles of conduct (a clear framework, the same rules for everyone, transparent procedures, involving care providers, etc.).

At the same time, there are other stakeholders with a say in the healthcare system: insurers, hospital associations, patient organisations, doctors, etc. There is a risk that competencies will be fragmented on the different levels and that those involved will focus on their own interests, even though everyone has a commitment to quality.

Medical authority and powers and responsibilities for developing rational structures for medical facilities, systems and treatments must lie in the hands of the relevant group of professionals: the doctors. The guiding framework within which these structures, processes and activities should run must be defined by the sponsors of the healthcare system. A good example is the successful demarcation of responsibilities in Canton Zurich between the canton's department of health and the hospitals listed for cardiac surgery. Every year the hospitals report on their quality indicators and activities (in 2018 this was done around the table) and discuss appropriate measures for improvement. As a matter of interest, these quality metrics were proposed by the medical specialists to the department of health, which also approved them. In other words, the specialists have defined the quality indicators, while the authorities monitor their development.

There is still plenty of preliminary work to be done in the healthcare system if Switzerland is to establish a cross-disciplinary healthcare quality strategy across the board.

> ➢ The question of who covers the **costs** of capturing and analysing data on treatment quality has to be settled. At the same time, unrestricted independence has to be guaranteed. In my opinion, funding proof of quality has to be part of the system of compensation. Only this way can the measurement of quality be demanded by the provider. The quality strategy should be drawn up by the medical professional society in question and then submitted to the sponsors.
> ➢ **Data quality**. Capturing quality-related key performance indicators (KPIs) is a major challenge and will remain so in future. How can one be sure that the data gathered corresponds to reality? Given the growing significance of value-based measurements, it is important to realise that data are often gathered on the basis of

an individual judgement on the part of those doing the gathering. At this point, audits designed to assure the quality and transparency of the data gathered reach their limits.

- ➢ **Data protection**. The data protection rules in Switzerland are currently in development. The country's federalist set-up certainly does not make this any easier. To paraphrase the troubadour of Bern, Mani Matter, democracy can never be more than a process of agreeing to disagree. I believe that arrangements should be in place to ensure that data are gathered on a pseudonymised basis. Once data have been audited, and before they are analysed, they should be completely anonymised to assure that our patients' personality rights are protected.
- ➢ The **publication** of data must be regulated in advance. Quality measurements should be done primarily to improve quality; their use for the regulation of the healthcare system should be only secondary. Care should always be taken not to upset patients or make them insecure by publishing data. It follows that publications of quality-related data should be produced jointly by all those involved.

At the federal political level, on 11 June 2018 the Swiss National Council passed draft health insurance legislation on improving quality and cost-efficiency (15.083) with a large majority. The debate in the Council of States is still pending. The surgical profession supports this project as a whole.

The draft legislation proposes a bottom-up approach, designed to boost the quality assurance role of the actors involved. The most important institutional pillars of quality assurance in Switzerland are the Patient Safety Foundation and the ANQ. The Patient Safety Foundation covers matters of process quality, while the ANQ works on outcome quality. The two organisations complement each other and fit well into the quality architecture set down in the Federal Health Insurance Act. Approval of this legislation should assure sustained funding for these organisations.

Under the draft, the tariff partners will also have to conclude contracts on quality development (so-called quality agreements). This provision should be welcomed, especially given that since it entered into force in 1996, the Health Insurance Act has required that tariffs and quality assurance be linked. The FMCH and santésuisse have already taken a step in this direction by concluding a tariff agreement for flat charges for outpatient services. Providers wanting to bill on a flat, per-case basis must undertake to take part in a recognised quality assurance scheme. This means that the tariff agreement on flat charges for outpatient care could be described as a quality agreement *avant la lettre*. In any case, modern tariff systems which do not involve an evaluation of quality and benefit are no longer conceivable. The draft is therefore a sensible step into the future.

The proposed legislation mentions quality of indications by name. Requirements governing the quality of indication place the debate on "unnecessary operations", which unfortunately often takes a populist and sensationalist form, on a firm scientific and objective basis. From the point of view of the medical profession these endeavours are worthy of support, as they will improve the quality of indications.

Quality in surgery going forward

What were the attributes of good surgeons at the beginnings of medical history? Above all they had to be fast so that patients would not have to suffer for long. With the advent of anaesthetics, surgery changed radically. Surgeons could start refining their actual craft. Quality was measured by different criteria, also taking account of a certain sustainability. Surgeons made their skills and craftsmanship available to patients.

In the era of DRGs (diagnosis related groups) quality is measured on the basis of the intervention itself: mortality and infection rates, reoperations, etc. The patient takes second place to the action. Performance-based billing does not focus on the actual benefit to the patient.

Now we are seeing a gradual change. Fewer and fewer interventions take the form of open surgery, and these days we often have a range of treatment options to choose from. Specialisation is leading to a situation where each physician is increasingly focused on narrower areas. This development in medicine gives additional weight to the choice of intervention. The quality of indication increases under the Donabedian model. What approach is best for this individual patient? What treatment can be expected to deliver the greatest benefit or utility for the patient? How will a therapy impact their quality of life in the longer term? This "value-based medicine" approach means that the result of therapy has to be rated somewhere between the two extremes of "perfect health" and "death". The value or quality of a medical treatment should be measured and financially "rewarded" by the attainment of a desired result for the patient rather than by the procedure used to treat the patient.

As medicine undergoes inexorable transformation, surgery must reorient itself within the framework of **value-based medicine**. Outcome measurement remains as a way of evaluating a small sub-section of medical quality using tried-and-tested means. But the actual focus has to be on process quality. In addition to being of major importance for patients, quality of indications also makes economic sense.

This paradigm shift can only take place if we devote our attentions to training our young colleagues. What kind of surgeons will be needed in the future? What skills will they have to master? With the quality of indications being given greater weight, surgeons will have to be more like doctors again. In addition to having the necessary manual skills and craftsmanship, they must focus on the needs of the person in their entirety. For this to happen, we have to discuss what skills will be required in the future.

Recommendations

In surgery, many quality programs are applied by various stakeholders. There is a lack of coordination of these activities and a miss of a common goal. Surgeons and invasive physicians are convinced that the quality activities in medicine must be managed by the service providers. The task of the Confederation, the cantons, insurers, hospitals and politicians in general is to define the tasks, to set the guiding framework and guarantee funding.

Surgeons and invasive physicians recommend an uniform strategy for their specialist area, which assesses the activity in the most objectifiable form possible. The milestone of a quality strategy comprises
- the indication quality with the interdisciplinary boards
- the outcome quality with which the subject-specific risk adjustment is mandatory and finally
- the introduction of Patient Reported Outcome Measures tools. Indicators for quality measurement must be defined by the specialized physicians or their professional associations, taking into account the international guidelines, which must also be adapted to Swiss conditions (e.g. minimum case numbers).

Appendix

1. PROMS (Patient-reported outcome measures)
The showcase project is the SIRIS Register of Swiss orthopedics. In this register, the patients are checked area-wide after the implantation of an orthopedic prosthesis. The register will be described and first results published in the Annual Report 2015.
www.swissorthopaedics.ch/images/content/SISRIS/170516_SIRISAnnualReport2015_Finalc opie.pdf

2. SSI (Surgical Site Infection)
In Switzerland, the defined SSI Swissnoso is recorded. Siwssnoso is the association of leading experts in the field of infectious diseases and hospital hygiene. The Swiss Society of Cardiac Surgery requires its members to join Swissnoso, which, for example, measures sternum infections (integrated in the national register of cardiac surgery). Siwssnoso publishes the infections in an annual bulletin:
https://www.swissnoso.ch/fileadmin/module/ssi_surveillance/Dokumente_D/9_Results/20170 904_SSI_Nationaler_Vergleichsbericht_2015_2016_Swissnoso.pdf

3. Outcome Data
As described in the report, the surgical societies have different outcome data. From my experience, I can tell you about the national registry for cardiac surgery. As you can see from the attached annual report of the register, the data quality is a big problem. We have discussed our register with the Federal Data Protection Commissioner and sent it to the Swiss Academy of Medical Sciences for review. All input has been included in the enclosed handbook.
Although the data quality is not satisfactory, the list hospitals in Zurich are discussing the results together with the cantonal health directorate. This open exchange leads to an enormous awareness of quality.
Many registers that we operate in Switzerland do not control data quality. From my experience with the national register for cardiac surgery, the evaluation of all these registers is questionable.

4. Federal Statistical Office
The Federal Statistical Office also publishes outcome data. In our opinion, however, these data are only risk-adjusted in terms of age and gender and cannot be used in everyday life. In addition, the classification is based on the coding, which does not reflect the medical point of view.

5. Surgical Checklist
The "Safe Surgery" checklist is used throughout Switzerland. However, the effects with regard to quality indicators are not recorded. Rather, the Foundation for Patient Safety is in the process of carrying out a so-called refresher to ensure that the checklist is applied correctly.

6. M&M Conference
The Foundation for Patient Safety has investigated and published the application of the M&M Conference in Switzerland (Schwappbach D. et al. Morbidity and mortality conferences in Lower Saxony: Implementation status and further development needs,
Z Evid Fortbild Qual Gesundhwes. 2018 Sep;135-136:34-40), attached to this writing. The survey underlined the need for a national guideline. This initiative has led various hospitals to implement the introduction of a structured M&M Conference, e.g. University Hospital Zurich.

Quality and Safety of Anaesthesiology in Switzerland

A contribution to the Swiss National Report on Quality and Safety in Healthcare

By Sven Staender

Regional Hospital Maennedorf
CH-8708 Maennedorf
Switzerland
s.staender@spitalmaennedorf.ch
www.spitalmaennedorf.ch

1. Abstract

Anaesthesiology today in Switzerland is still very safe and delivered with highest quality. But this safety is beginning to be eroded. Pressure on staffing, medication issues, dealing with post-operative complications, confidentiality of reporting systems etc. are only a few emerging problems. We still have the possibility to tackle this challenge. But action must be taken now.

2. General remarks

Anaesthesia in the elective, more or less healthy patient is considered to be very safe. The mortality risk from complications and adverse events of anaesthesia appears to be at approximately 1:100'000 cases today[1]. Anaesthesiologists have a long history of engaging with safety: as early as 1978, a group at Harvard University systematically analysed errors in anaesthesiology and highlighted the special importance of the 'human factor'[2]. Consequently, under the acronym '*Crew Resource Management*', teams were trained in simulators starting back in 1987. In the United States, from 1984 onwards, closed claims in anaesthesiology were analysed systematically, to draw lessons from them[3]. In 1993, the technique of 'Incident Reporting' was used as an instrument for recording critical incidents in anaesthesiology at the national level in Australia and to exploit their learning potential[4]. This systematic collection and provision of critical incidents was disseminated in 1995 by anaesthesiologists in Switzerland under the acronym CIRS (Critical Incident Reporting System) using Internet technology[5, 6]. Thus, anaesthesiology is justified in claiming to be in the vanguard of safety management in medicine. But despite these success factors, systematic and large-scale outcome data for morbidity in anaesthesiology is lacking (at least in Switzerland).

3. Methods

For that reason, this report can't base on strong facts on quality and safety in anaesthesiology in Switzerland (with the exception of published data from the committee for the analysis of closed liability claims in anaesthesiology). To address this problem the author has put together a set of questions around the published spectrum of safety-relevant aspects in the literature, using the taxonomy of a tool called '*Safety Management in Hospitals*' (SMAHO)[7]. These questions then were used for a structured interview with representatives from hospitals of various care levels in Switzerland. Interviews were performed with senior anaesthesiologists from University hospitals, cantonal hospitals, regional hospitals, and private hospitals as well as anaesthesiologists working in office-based service in the German as well as French speaking parts of Switzerland. In total, 12 interviews have been performed between November and December 2018.

4. Main findings and valuation

4.1. Established tools on Quality & Safety in Anaesthesiology in Switzerland

Various tools and projects on quality and safety in anaesthesiology do exist in Switzerland. The following list gives an overview. For more details please consult the corresponding information available on the internet:

a) Anaesthesia Patient Safety Foundation[8]

b) Various committees at the Swiss Society for Anaesthesiology and Resuscitation (SGAR/SSAR)[9]

- Committee for data and quality with a Minimal Data Set in Anaesthesiology (MDS) now followed by the project called A-QUA$_{CH}$[10]
- Committee for structure and processes supporting the global '*Helsinki Declaration on Safety in Anaesthesiology*'
- Committee for the analysis of closed liability claims in anaesthesiology

c) Various local simulation centres with regional training opportunities

4.2. Main topics under concern

4.2.1. Measures and warning systems

4.2.1.1. Closed Claims Analysis

Since 1987 more than 200 **closed claims** with liability aspects related to anaesthesiology have been filed in Switzerland. A committee of the SGAR/SSAR collects and analyses these data. The majority of claims (54%) were related to regional anaesthesia, with general anaesthesia accounting for 28% and other anaesthesia-related procedures for 18%. The quality of care was judged by the committee to be substandard in 55% of cases, and liability was accepted in 46% of all claims. The incidence as well as mortality of claims in Switzerland is of a similar magnitude to those in the UK and a bit lesser than in the USA[11]. Closed claims analysis has proven beneficial in monitoring and learning from this aspect of medical care and is thus recommended for other disciplines. In addition, this group has published quality-standards for legal reports like mandatory 4-eyes-principle for every report etc.

4.2.1.2. Lack of outcome-data

Although the SGAR/SSAR has quite a tradition with registries of **outcome data** (MDS and A-QUA$_{CH}$), most of the anaesthesiology departments contacted do not collect outcome data in anaesthesiology. One of the problems behind is the lack of proper definitions of anaesthesiology-outcomes. The rather old (and unfortunately no longer existing) project called '*OUTCOME*' in canton Zürich[12] was considered to be a very valuable system especially due to frequent benchmarking workshops with the possibility to interact with other anaesthesiologists peer-to-peer. Proper definitions, large registries as well as regular benchmarking should be considered.

4.2.1.3. Threat on reporting systems

The recent decision by the federal court on the edition duty of incident-reporting data-collections led to a severe uncertainty among hospital staff to continue reporting safety-relevant events. This uncertainty may completely destroy the confidence in these systems and by that destroy the reporting-culture at all. A legal protection of such incident reporting systems is an old request[13] (almost 20 years old) that must now be taken forward by the regulating bodies with utmost priority. A corresponding request is actually pending in the National Council[14].

4.2.2. Threats to Safety in Anaesthesiology

4.2.2.1. Problems with staffing

The '*Helsinki declaration on Patient Safety in Anaesthesiology*'[15] is a global adopted declaration. Among other requirements, this declaration states: "*The funders of healthcare have a right to expect that perioperative anaesthesia care will be delivered safely and therefore they must provide appropriate resources.*"

Economic considerations lead to more and more **pressure on staffing levels** in anaesthesiology in all professions like specialised anaesthesia nursing-care as well as physician anaesthesiologists. It has been reported that especially small hospitals are forced to cut back the staffing-levels of specialised anaesthesia nurses on duty, by that colliding with published minimal staffing levels of the SGAR/SSAR as well as the basic requirements of the '*Helsinki Declaration on Patient Safety in Anaesthesiology*'.

In parallel goes an increasing **shortage** of specialised anaesthesia nurses as well as a beginning shortage of physician anaesthesiologists in Switzerland. The SGAR/SSAR is currently running a demographic study and the results shall be available mid 2019. The shortage of specialists on the one hand and the cutback of staffing levels lead to a decrease in the availability of well-trained specialists. This poses a big threat on safety in anaesthesiology in Switzerland.

Another aspect are the rigid rules of the labour law (Arbeitsgesetz, ArG). These rules are often troublesome when applied to hospitals (especially small teams) and they lead to an increase in handovers of care-teams, which again are correlated with increased numbers of complications[16]. Here, a version of the ArG that is adapted to the special needs of hospitals must be considered.

4.2.2.2. Patient selection and indication, role of the Anaesthesiologist

The safety of anaesthesiology already starts in **patient selection** and proper optimization of sick patients. This selection requires a true partnership between surgeon and anaesthesiologist in order to properly select these cases that do NOT qualify for surgery or for an office-based procedure. Whenever this relationship is not a partnership of peers the opinion of the anaesthesiologist on the individual patient risk involved may not be heard. This poses avoidable risk to the patients. So, a true partnership of peers is required and the **standing and reputation of the anaesthesiologist** must be kept high in order to support that partnership between surgeons and anaesthesiologists. Decision making on the risk and risk mitigation should be mandatory and to be done interdisciplinary.

An aspect closely related is the topic of **widening the indication** for a procedure. This may happen due to problematic incentives that are established in Swiss health care (including personal case-load levels for certain procedures). As reported in the interviews, anaesthesiologists sometimes back-up these widened indications for various reasons. These kinds of incentives and goals should be re-evaluated.

4.2.2.3. Medication safety

The last decade was characterized by an increasing rate of **drug shortages** in medicine for various reasons. This shortage may in the best case be just troublesome

but in the worst case it is a threat to patient safety (e.g. antibiotic shortages etc.). Specifically, in anaesthesiology the shortage of Remifentanil posed a threat to anaesthesiology departments that have a high rate of so-called "Target-controlled general anaesthesia" cases. In these departments, the standard procedures had to be adjusted to this shortage. Although to the author's knowledge no patient harm has been reported, such a change in standard procedures may be considered a safety hazard. Larger stock of essential medication or a better network among hospitals should be considered.

Another topic with safety hazard potential is related to the so-called **off-label use of drugs**. Such an off-label use is not considered to be a '*no-go*' but is related to strict rules on informed consent[17]. According to the results of the interviews with peers of anaesthesiology in Switzerland, this detailed informed consent in off-label use of drugs is not a reality in the majority of cases. Here, a practical solution must be found not only for anaesthesiology but also for intensive care medicine or other disciplines.

4.2.2.4. Challenges in hygiene

Today, a growing number of equipment is meant to be **one-way equipment** mainly due to hygiene aspects. This requires quite a large stock of supply with its related cost. In office-based anaesthesia various single-used equipment like e.g. face masks for mask ventilation are sometimes used repeatedly, mainly due to limited stock capacity. The impact on infection rates due to this practice may be low but not zero.

4.2.2.5. Recovery after anaesthesia

Recovery after general anaesthesia is a crucial aspect of safety. Various standards and recommendations (like staffing and equipment as well as physiologic cut-off levels for transfer etc.) are published. After hours availability of recovery room facilities is an on-going challenge for hospitals with impact on safety. This is amplified in the office-based setting due to insufficient compensations for recovery care in the TarMed tariff.

4.2.2.6. '*Failure-to-rescue*'

Still, patients die after surgery, but not mainly in the operating room (mortality rate less than 0.001%) rather post-operatively and mainly on the normal ward (mortality rate as high as 4%)[18]. There is growing evidence that a large proportion of this post-operative death rate derives from complications. This phenomenon has more recently been called '*failure to rescue* (FTR)', which has been defined as death after complications[19]. Proper complication management therefore can help saving lives in a large proportion. This aspect is not only related to post-OP recovery facilities but also to the rapid availability of specialized personnel and appropriate monitoring technology to treat these patients. The concept of '*Medical Emergency Teams*' (METs) has proven beneficial in various publications but is not followed in Switzerland in a large scale. In addition, anaesthesiologists should play a role also on the ward, outside the operating room (OR): they are already involved in post-operative pain management and they know their patients from the time in the OR. Consequently, anaesthesiologists would very much qualify as perioperative physicians together with their surgical partners and by that could help reducing the problem of '*failure to rescue*'. Here, an interdisciplinary project could work on that question.

4.2.2.7. Uncertainty with the handling of complications

The interviews showed that even senior physicians of anaesthesiology departments felt challenged when facing a severe complication. This goes for legal advice as well as questions around proper communicating with the patient/relatives. A 24/7 helpline, a professional network of peers available for advice or a training course should be considered to deal with that problem.

4.2.3. Safety Practice in Anaesthesiology

4.2.3.1. Marking of the surgical site

The WHO safe-surgery checklist requires the surgical site to be marked by the surgeon. This mark is a true problem in an era of more and more patients coming to the hospital on the day of surgery. In such conditions the process of reliably marking the surgical site is not clear and easy because the surgeon involved often already is operating while his/her next patient comes to the hospital in the meantime. Now the question arises whom under which conditions should do the marking of the surgical site. This uncertainty is a true safety hazard and should be eliminated by a joint decision between all the involved process partners in hospitals.

4.2.3.2. 'Second victim' concepts

The term 'Second Victim' relates to all the aspects around dealing with the involved specialist or team after a severe complication. The interviews could demonstrate that only very few hospitals do have concepts/recommendations about how to proper handle this problem. Patient Safety Switzerland has published very useful recommendations and these documents should be promoted/made available in all medical facilities in Switzerland[20].

4.2.3.3. Interpersonal competence

Team communication, coordination, decision-making etc. are basic and highly safety-relevant concepts in modern health care. The interviews could demonstrate that only very few hospitals have training courses available for these aspects of safety-management. FMH as well as the SIWF should make these competencies mandatory in medical education. Courses and course concepts are available and should be promoted/be made mandatory[21].

5. Personal view and conclusion

Anaesthesiology today in Switzerland is still very safe and delivered with highest quality. But this quality is more and more endangered by increasing economic pressures which may lead to threats on staffing levels as well as shortcuts in processes. Certain aspects must be watched carefully (threats to reporting systems; medication problems; patient selection and proper preparation; complication management including 'second victim' problems as well as 'failure to rescue') while others must be developed (outcome parameters must be defined, and registries installed; mandatory team-training established; rules for 'closed-claims' analysis groups defined). Overall, the role of the Anaesthesiologist must be kept in focus, as they are among the most important (but often hidden) pillars of safety in hospitals.

6. Recommendations

(Immediate priorities in bold and marked with an *).

6.1. Anaesthesiology specific

6.1.1. Appropriate numbers of **staffing*** should be defined and must not be fallen short of. This goes for the routine clinical management as well as for the staffing needed for emergencies as well as on-duty schemes in hospitals.

6.1.2. Special care must be taken to guarantee the number of sufficient well-trained experts (nurses and doctors) in anaesthesiology in the future. This is a difficult task and not limited to Anaesthesiology at all. But concepts as well funding for the next generation must be appropriate.

6.1.3. The role of the anaesthesiologist as an equal partner to the surgical colleague must be kept in focus and critical decisions must be done interdisciplinary. The scope of the responsibilities of the Anaesthesiologist must not be limited to the operating room but expanded to whole peri-operative process where Anaesthesiologists might also be considered as 'perioperative physicians', like in other countries (e.g. the United Kingdom etc.). This could help addressing the imminent problem of 'failure to rescue' on the wards.

6.2. Medication related

6.2.1. Larger stock of **essential medication*** (to be defined) or a well-organized exchange-network between hospitals/drug-suppliers should be considered. A shortfall of essential medications like antibiotics, opioids or Propofol is a major threat to safety.

6.2.2. The problem of '*off-label-use*' of medications must be tackled in a way that fulfils the requirements of the regulator as well as of the practitioner.

6.3. General recommendations

6.3.1. Closed claims analysis committees should be established in all medical disciplines because these cases do have an immense potential for improvement. Today, most of these cases do not find their way to the specialists and stay on the desk on the people involved. All legal reports should fulfil certain quality-criteria (like 4-eyes-principle for every legal report etc.) and must be made available, anonymously.

6.3.2. Outcome parameters must be defined, and systematic registries should be implemented that would allow for benchmarking and learning.

6.3.3. The labour law should be adapted to the special needs of hospitals in order to reduce the number of shift-handovers between specialists (which is prone for

complications).

6.3.4. Established concepts of dealing with '*Second Victims*' should be made available and followed in every hospital.

6.3.5. Courses for the interpersonal competence and team-work should be mandatory during medical education and sub-specialty training (in analogy to mandatory courses for radiation-safety).

6.3.6. Reporting systems must have a proper **legal frame***. The current uncertainties to the confidentiality of these reporting systems may lead to a severe deterioration of the general safety-culture in healthcare.

7. Addendum

7.1. References

1. Li G, Warner M, Lang BH, Huang L, Sun LS. Epidemiology of anesthesia-related mortality in the United States, 1999-2005. *Anesthesiology* 2009; **110**:759-765.

2. Cooper JB, Newbower RS, Long CD, McPeek B. Preventable anesthesia mishaps: a study of human factors. *Anesthesiology* 1978; **49**:399-406.

3. Cheney FW. The American Society of Anesthesiologists Closed Claims Project: what have we learned, how has it affected practice, and how will it affect practice in the future? *Anesthesiology* 1999; **91**:552-556.

4. Runciman WB, Sellen A, Webb RK et al. The australian incident monitoring study. Errors, incidents and accidents in anaesthetic practice. *AnaesthIntensiveCare* 1993; **21**:506-519.

5. Staender S, Davies J, Helmreich B, Sexton B, Kaufmann M. The anaesthesia critical incident reporting system: an experience based database. *Int JMedInform* 1997; **47**:87-90.

6. Staender S. [Incident reporting as a tool for error analysis in medicine]. *ZArztlFortbildQualitatssich* 2001; **95**:479-484.

7. Manser T, van Vegten A, St Pierre M, Rhaiem T, Schleppers A, Staender S. Safety management in anaesthesiology: a screening instrument for self-assessment. *ANASTHESIOLOGIE & INTENSIVMEDIZIN* 2013; **54**:458-+.

8. SGAR/SSAR. Stiftung Patientensicherheit in der Anaesthesie. https://sgar-ssar.ch/services/stiftung-fuer-patientensicherheit-in-der-anaesthesie/.

9. SGAR/SSAR. Schweizerische Gesellschaft für Anaesthesiologie und Reanimation. https://sgar-ssar.ch/

10. SGAR/SSAR. A-QUA - Monitoring der Anästhesiequalität in der Schweiz. https://sgar-ssar.ch/a-qua/

11. Staender S, Schaer H, Clergue F et al. A Swiss anaesthesiology closed claims analysis: report of events in the years 1987-2008. *EurJAnaesthesiol* 2011; **28**:85-91.

12. Schwappach DL, Hochreutener M-A, Conen D, Eichler K, Blaudszun A, Koeck CM. Outcome measurement in the Canton of Zurich: from theory to practice: progress report on six years of development, implementation and experience with routine inpatient outcome measurement. 2003.

13. Kuhn H. Congress should pass legislation to extend protections. *Schweiz Ärztezeitung* 2001; **82**:1394-1403.

14. Motion National Council. Lernsysteme in Spitälern zur Vermeidung von Fehlern müssen geschützt werden. https://www.parlament.ch/de/ratsbetrieb/suche-curia-vista/geschaeft?AffairId=20184210

15. Mellin-Olsen J, Staender S, Whitaker DK, Smith AF. The Helsinki Declaration on Patient Safety in Anaesthesiology. *EurJAnaesthesiol* 2010; **27**:592-597.

16. Jones PM, Cherry RA, Allen BN et al. Association between handover of anesthesia care and adverse postoperative outcomes among patients undergoing major surgery. *Jama* 2018; **319**:143-153.

17. KAV/APC. Positionspapiere. http://www.kantonsapotheker.ch/index.php?id=1197

18. Pearse RM, Moreno RP, Bauer P et al. Mortality after surgery in Europe: a 7 day cohort study. *Lancet* 2012; **380**:1059-1065.

19. Ghaferi AA, Birkmeyer JD, Dimick JB. Variation in hospital mortality associated with inpatient surgery. *NEnglJMed* 2009; **361**:1368-1375.

20. Schwappach D, Hochreutener MA. Das zweite Opfer: Entwicklung eines Handlungsrahmens für den betriebsinternen Umgang mit Zwischenfällen. *Schweizerische Ärztezeitung* 2008; **89**:1404-1408.

21. LAT/DGfO. Interpersonal Competence for Healthcare Professionals. https://www.interpersonal-competence-training.com/

7.2. About the Author

Sven Staender is the Medical Director and Head of the Department of Anaesthesiology & Intensive Care Medicine at Hospital Maennedorf (Zürich). He is running a training course on patient safety for medical students at the University of Zürich and is furthermore involved in various projects and organizations on patient safety, such as…
- Legal liability commission of SGAR-SSAR (chairman)
- Critical incident reporting and reacting network CIRRNET (member)
- European Patient Safety Foundation (vice president)
- European Society of Anaesthesiology (senior consultant patient safety to the board of directors)

Short Report

Safety and quality of psychiatric care in Switzerland

A report for the Swiss National Report on Quality and Safety in Healthcare

Authors:

Dr Thomas Ihde-Scholl, medical director of psychiatric services, Spitäler fmi AG, chairman of Pro Mente Sana foundation

Prof. Wulf Rössler, former director of the University Hospital of Psychiatry Zurich at Burghölzli, professor emeritus of psychiatry at the University of Zurich

Submitted on 15 January 2019

Abstract

Although the density of physicians and psychiatrists in Switzerland is high and there are sufficient financial resources, there is, however, an undersupply of mental health care in some parts of the country and particularly for vulnerable groups such as children and young adults, the elderly, migrants, people living in poverty or without a regular income. While the financial focus is on expensive inpatient treatment, there is a considerable lack of resources for outpatient and intermediary psychiatric care, largely due to the dual financing modalities. Clear indicators of insufficient quality assurance in mental health care are a life expectancy of 10 to 15 years below the average for people with mental health issues, persistent stigmatisation of mental disorders, a disproportionately high number of emergency detentions to inpatient units and a high level of (non-assisted) suicide.

This report focuses on suggestions to improve mental health care in Switzerland, such as redirecting the monetary flow, equal treatment of physical and mental health issues, better prevention and early detection of mental disorders, ensuring an adequate supply of easily accessible intermediary psychiatric care, broadening education regarding mental health topics for general practitioners and care personnel, as well as integrated care for physical and mental problems.

Introduction

This report by the Pro Mente Sana foundation was produced by invitation of the Swiss Federal Office of Public Health (FOPH) as part of the Swiss National Report on Safety and Quality of Healthcare. The Pro Mente Sana foundation is geared to a trialogue (i.e. represents the interests of people with a mental illness, their carers and mental health specialists); the short report authored by Dr Thomas Ihde-Scholl and Prof. Wulf Rössler presents the results of a round table discussion with survivors, mental health specialists, representatives of patient organisations and psychological therapists. Held on 6 December 2018 in Bern, it was moderated by Roger Staub, CEO of Pro Mente Sana, and documented by Christine Klingler.

Question 1

What is known about the safety, quality and efficiency of mental healthcare in Switzerland?

In 2017 there was a total of 281 hospitals with 38,157 beds in Switzerland, of which around 18% (51) were psychiatric care facilities accounting for approximately 17% (6,573) of the total number of beds.[1]

A total of 36,900 doctors were active, an average of 4.3 per 1,000 inhabitants. Among all physicians, specialists in psychiatry and psychotherapy take the second

---

[1] https://www.bfs.admin.ch/bfs/de/home/statistiken/gesundheit/gesundheitswesen/spitaeler/infrastruktur-beschaeftigung-finanzen.html; last accessed on 28 December 2018.

place after general practitioners. According to the OECD, Switzerland has around 42 psychiatrists per 100,000 head of population[2], with a similar number of psychological psychotherapists.

Although this puts Switzerland among the top-ranking industrial nations in terms of the density of outpatient and inpatient care, people are not guaranteed equal access to care. Smaller cantons have access to inpatient facilities run by larger cantons remote from the community (rather than the corresponding wards in their own general hospitals), but they must make compensation payments for this privilege. Psychiatrists and psychotherapists prefer to settle in urban areas. This means that by the standards of modern community psychiatric care, large sections of the population are clearly undersupplied with psychiatric and psychotherapeutic services.

Quality assurance

In the field of outpatient psychiatry and psychology there is a lack of comprehensive quality assurance conducted in accordance with scientific standards. On the inpatient side, the ANQ (Swiss National Association for Quality Development in Hospitals) regularly gathers data on quality.

Data gathering

Obsan and the ANQ regularly gather data. There is, however, no uniform presentation of the system and the long-term use of psychiatric services. Nevertheless, there are certain indicators of a lack of quality and safety.

Indicators of a lack of quality in care in general

Inappropriate care. Resources are not deployed appropriately, with the focus on very expensive inpatient care and on services provided by doctors on an outpatient basis, and on delegated psychotherapy (psychologists cooperating with psychiatrists). At the same time, low-threshold and intermediate care is insufficiently developed. ("Intermediate care" is defined as outpatient and partial hospitalisation services geared to people in acute crisis or people with complex or chronic mental problems. Some of this care is provided on an outreach basis, and as a rule, it is closely networked with other support organisations in the sphere of the people affected.) There is thus a lack of care in the form of the kind of sociotherapy these days taken for granted as part of a modern integrated community psychiatry-based care system, as well as a lack of outpatient (acute) psychiatric services, for example day-clinic care or acute psychiatric home treatment. Virtually all outpatient services depend on patients getting to the service provider.

As well as being very expensive, the current care offerings do not meet the demands of modern care that gives those affected the greatest possible degree of autonomy and co-determination. The present structures are paternalistic and geared to traditional models of medical care.

---

[2] OECD, *Mental Health and Work: Switzerland*. Contributions to the social security series, research report no. 12/13: www.bsv.admin.ch ➔ Praxis ➔ Forschung ➔ Forschungsberichte.

Failure to implement the notion of "outpatient has precedence over inpatient care". The current dual funding set-up runs counter to systematic implementation: the cantons provide 55% of the funding for psychiatric hospitals while all outpatient treatments, including many day-clinic services, are funded exclusively by providers of mandatory health insurance (some cantons finance day-clinic services as a voluntary measure). Health insurers thus have no interest in reducing the number of beds, which is why there is a comparatively high number of beds in Switzerland. Furthermore, partial hospitalisation programs do not have a secured funding since they are not considered essential in health legislation.

Undersupply. This affects children, young people, young adults and the elderly, who often find no place for treatment. Most mental health problems occur up to age 25, which is a particularly sensitive time in terms of people's professional and personal development.[3] Undersupply also affects neglected, vulnerable groups on the periphery: people living in poverty, homeless people, people with addictions, those with chronic mental health problems, people with comorbid problems (suffering physical and mental problems simultaneously), migrants (especially refugees), and so on.

Consequences of a lack of quality in care

Emergency detention. The number of emergency detentions in Switzerland is high. Although there are large differences from region to region, an average of one out of five inpatients is there on the basis of involuntary commitment.[4] Given that sectioned care should only be used as a measure of last resort, this is a clear indication of a lack of properly developed (intermediate) structures.

Life expectancy. As is also the case internationally, the life expectancy of people with mental health problems in Switzerland is 10 to 15 years shorter than average – a fact little known and rarely discussed outside specialist circles. There are many reasons for this. First and foremost is the high suicide rate among people with chronic mental illness who no longer see any perspective in their life. Between 10% and 15% of people suffering from major depression and schizophrenia commit suicide in the course of their illness. Added to this, physical healthcare for people with mental problems is gravely neglected. By the same token, the psychiatric care of people with physical illnesses is similarly neglected. There is abundant evidence that neglect of mental problems suffered by people with physical illnesses (such as diabetes, cardiovascular and oncological diseases) significantly worsens the long-term course of their physical illness. All this is clear proof that the separation of physical and mental healthcare (reflected among other things by the fact that there are psychiatric wards in only very few Swiss general hospitals) results in inequality of treatment, violating the principle of equal opportunity in healthcare.

---

[3] von Wyl, A., Chew Howard, E., Bohleber, L. & Haemmerle, P. (2017). *Psychische Gesundheit und Krankheit von Kindern und Jugendlichen in der Schweiz: Versorgung und Epidemiologie. Eine systematische Zusammenstellung empirischer Berichte von 2006 bis 2016* (Obsan Dossier 62). Neuchâtel: Schweizerisches Gesundheitsobservatorium (page 30).

[4] Schuler, D., Tuch, A. & Peter, C. (2018). *Fürsorgerische Unterbringung in Schweizer Psychiatrien* (Obsan Bulletin 2/2018). Neuchâtel: Schweizerisches Gesundheitsobservatorium.

Suicide rate. Suicide rates in Switzerland are very high, with suicide being the cause of 30 in every 1,000 cases of death (16 non-assisted, 14 assisted suicides).[5] Between 1995 and 2016 there was a steady rise in the number of non-assisted suicides per 100,000 head of population, particularly among the very elderly (aged 85+). In 2015, there were 1,071 suicides in total (792 males, 279 females)[6].

One of the factors contributing to the high number of suicides in Switzerland is the availability of firearms. Switzerland has the second highest rate of suicides with firearms after the United States.

Freedom of choice – autonomy – recovery. The desire of those affected and their families for greater freedom of choice when it comes to treatment is also a result of the lack of low-threshold services. Fundamentally those affected want to be treated as close as possible to where they live with as few restrictions as possible on their personal life. This is precisely why outpatient healthcare should be favoured over inpatient care: because it gives patients as much autonomy as possible, and not because there are potential cost savings.

It is the impression of Pro Mente Sana that societal trends such as self-determination, a rejection of paternalistic structures, a focus on recovery, prevention, involving additional complementary approaches such as phytotherapy, nutrition, etc., are being translated into practice only very slowly and on a rudimentary basis. Financial incentives that would speed up implementation of some of these things are lacking.

Patient rights in clinics

The number of involuntary commitments in Switzerland is high. Added to this, in psychiatric facilities freedom-limiting measures often do not conform with basic human rights, as can be read in detail in the 2016 annual report of the National Committee for the Prevention of Torture (NKVF).[7] This is the case even though there are regulations governing state oversight of psychiatric facilities; this duty is not sufficiently respected.

Also noteworthy are increasing complaints by patients of a lack of language skills among healthcare personnel in a medical discipline whose main therapeutic tool is spoken communication. This is detrimental to the recovery process.[8]

Funding

Psychiatric care in Switzerland is exceedingly well provided with resources by international standards. However, these resources are used primarily for traditional

---

[5] https://www.bfs.admin.ch/bfs/de/home/statistiken/gesundheit/gesundheitswesen/spitaeler/infrastruktur-beschaeftigung-finanzen.html; last accessed on 28 December 2018.
[6] https://www.bfs.admin.ch/bfs/de/home/statistiken/gesundheit/gesundheitszustand/psychische.html#par_headline_1677393895; last accessed on 28 December 2018.
[7] NKVF annual report,
https://www.nkvf.admin.ch/dam/data/nkvf/Berichte/taetigkeitsberichte/2016/taetigkeitsbericht-2016-d.pdf
(pp. 29–53); last accessed on 28 December 2018.
[8] Written communication from Bruno Facci, president of VASK Switzerland (umbrella association for relatives of the mentally ill), 30 November 2018.

services and facilities. In Switzerland, the priority is on building the most expensive component of care, a very good inpatient care system. Compared with other countries Switzerland also has a large number of very cost-intensive institutional assisted living and working environments, where people generally stay a long time or even their whole life. There is a lack of community-based and individualized assisted or supported living and working arrangements, which are also less costly. The goal however should not be to make psychiatric care cheaper, but to use the available resources for a modern, diversified care integrated in the community.

Question 2

What has been done so far to improve the safety, quality and efficiency of mental healthcare in Switzerland?

Here is an overview of improvements in recent years:

- People increasingly see depression as stress-related (which is why it is more frequently referred to as burnout, a less stigmatised term). The stigma attached to schizophrenia, by contrast, has increased.[9]
- The peer model has been expanded. In German-speaking Switzerland, around 200 peers have been trained to date, and a large number of them have found part-time positions (full-time in individual cases) in psychiatric facilities. Peer work, however, is not yet part of standard care.
- The federal disability insurance's (IV/AI) integration programs (early registration and job counselling) are a good start, but they are too short for the recovery process, and procedures jeopardise recovery. Not only that, but mentally ill people receiving disability benefits are stigmatised ("fake" disabled people). Those who do not get a disability pension (with such narrow criteria there are many of them) fall out of the system and are at a great risk of becoming long-term recipients of social welfare.
- The compensation for disadvantages ("Nachteilsausgleich") that has now been put in place gives children and young people with congenital disorders and mental health problems better educational and training opportunities. This is one of the few steps in efforts to achieve equality for people with disability that has been successful.
- Favouring outpatient over inpatient care is basically a step in the right direction, but there is no financial framework to make it happen systematically (closure of day clinics, see above, while numerous inpatient wards are being opened in various cantons).
- Many health policies (for example from the cantons) mention recovery as a principle of healthcare.
- Around ten years ago there was a wave of innovation and good pilot projects (for example in the field of home treatment), but few of them have been implemented because of a lack of funding.
- The FOPH is increasingly commissioning studies and inviting advocacy organisations to contribute their opinions.

---

[9] Angermeyer, M., Matschinger, H., Schomerus, G. (2013). *Attitudes towards psychiatric treatment and people with mental illness: changes over two decades.* In: British Journal of Psychiatry, Vol. 203, Issue 2, pp. 146–151.

- Politicians are more aware of mental health problems and mental health, which is leading to a launch of many projects and reports.
- Many psychiatric institutions now have guidelines to promote empowerment. There are also more open wards, and psychotherapy wards have been set up. There are more specialised day clinics, specialist consultation opportunities as part of outpatient services, and outreach teams.
- Psychopharmacology: There is slightly more openness towards phytotherapy, something primarily desired by those affected, but there is still scope for increasingly combining psychopharmacology and complementary medicine.

Question 3

What have been the obstacles and challenges in terms of attempts to bring about improvements?

Barriers at the social and political level

Lack of equality between physical and mental healthcare. Stigmatisation of mental health problems (despite the change in attitudes towards depression described above) has implications for the funding of the various services. There is no equality in the healthcare planning and health legislation of the different cantons either.

Vicious circle of mental illness and poverty. Mental health problems are a risk factor for poverty, and at the same time poverty is a risk factor for mental problems. This vicious circle could be addressed through integrated health and social care. 40% of all recipients of social welfare suffer from a high degree of psychological stress, which makes occupational reintegration more difficult. Especially counterproductive are cost-cutting measures in social welfare (SKOS) and moving those affected between the various insurance schemes.

Politically motivated agitation. Pro Mente Sana feels that stigmatisation has been increased by certain political groups focusing excessively on the alleged abuse of medical benefit systems. These campaigns have targeted mainly patients with illnesses that are not visible, i.e. primarily mental illnesses.

Societal trends. Everyone is talking about inclusion, but the sustained trend to greater autonomy and individualisation is actually moving society towards greater exclusion. A large number of institutional living and working facilities exclude mentally ill people from participating in society. There are no particular efforts to promote integration in the primary labour market (supported employment). In the secondary labour market, there is a lack of incentive to move away from vested interests.

Barriers at the legislative and funding level

Dual funding of outpatient/inpatient care. Dual funding is counterproductive when it comes to favouring outpatient over inpatient care (see above) and the greatest obstacle to developing a modern mental healthcare system in Switzerland.

Lack of legal regulation for intermediate psychiatry. Intermediate psychiatry is not recognised at the legislative level as necessary for care, which also means no money has to be made available for it.

Prevention. Funds are barely available to promote the mental health of the public in Switzerland. The preventive health act has failed for the time being. There are few sanctions on the consumption of traditional and legal addictive substances (first and foremost alcohol), and substances such as cannabis are to be legalised.

Obstacles at the level of treatment

Gatekeeper role of general practitioners. General practitioners (GPs or family doctors) are the first point of contact for people with mental health problems, and are decisive to achieving the desired equality between physical and mental care. However, psychiatric care is given too little emphasis in training, so GPs are still primarily focused on physical care. There is a lack of incentives to take a holistic view, or the incentives available are counterproductive, for example because longer discussions with patients cannot be billed.

Lack of information on what is on offer. People with mental problems are unable to find out which specialists are competent for what, so it is largely a matter of chance who they end up with.

Psychological psychotherapy other than delegated therapy. Low-threshold access to non-delegated psychological psychotherapy is impeded because there is no model of how it is prescribed and funded, and the service is not covered by basic health insurance.

Separation between physical and mental healthcare. 40% of people with chronic physical conditions also suffer from mental problems, and 60% of those with chronic mental illness also have physical ailments. With such high percentages of comorbid patients, the separation of physical and mental healthcare is not productive, and is probably part of the cause of the low life expectancy of people with mental illness.

Preliminary and follow-up care. The offering of services before and after inpatient care is inadequate. Elective admissions are very rare in inpatient psychiatric care; most are emergency admissions. This in spite of the fact that most admissions are quite foreseeable. In most cases, admissions occur when the social and medical support systems fail, usually at the weekend or shortly before. Many inpatient admissions are unnecessary and could be prevented with structures to provide appropriate help. At the same time, there is a lack of structures for subsequent care to help patients reintegrate after they are released from inpatient treatment.

Question 4

What other improvements do we recommend?

Funding-related measures

Unitary set-up of funding. Services will only evolve if funding is geared accordingly. Dual funding (see above), as it is handled at present, is the greatest obstacle to the development of a modern mental healthcare system in Switzerland. What is urgently required is funding for outpatient and inpatient care borne equally by health insurers and the cantons.

Equality of physical and mental healthcare. Physical and mental health should be recognised as equal and given equal funding. This also applies to training (see above).

Integrated care. There is an urgent need for integrated care for comorbid patients and financial incentives to provide integrated care. However, this demand also covers integrated care with nursing, psychological and psychiatric services in equal measure to enable graduated, diversified care.

Strengthening prevention and early detection/treatment. Prevention, early detection and early therapy have to be made more financially attractive. This also makes (macro)economic sense, because it is a way of preventing treatment from becoming expensive and costs arising in other areas as well.[10]

Reinforcing low-threshold and intermediate psychiatric care. There is a need for more low-threshold, crisis-oriented care provided on an outreach basis, a prescribing model and basic insurance cover for psychological psychotherapy beyond delegated psychotherapy, and more peer work. Desirable would be an arrangement whereby the FOPH steers care by issuing target requirements to the cantonal departments of health.

Improvements in care

Promoting person-centered care. Patients requiring multimodal care need better continuity of treatment based on a human-centric as opposed to an institution-centered approach; rather than patients having to change institutions in the course of their treatment, the required provision of care should adapt to the patients' needs regardless of the institution.

---

[10] Schuler, D., Tuch, A., Buscher, N. & Camenzind, P. (2016). *Psychische Gesundheit in der Schweiz. Monitoring 2016* (Obsan report 72). Neuchâtel: Schweizerisches Gesundheitsobservatorium.

Improve care for minorities. Migrants (especially refugees), elderly people, children and young adults, people without an education, people with addiction disorders, and, above all, polymorbid people, partly with chronic mental illness, must have access to appropriate treatment.

Peer involvement. Peers should be involved across the board at all levels.

Labour market integration. Sustainable integration in the primary labour market should be promoted via supported employment, incentives for employers and the federal disability insurance, which should facilitate the integration on the first labour market.

Social safety net. Society should provide people with serious mental illness with a real safety net in the form of social security and insurance schemes that allow them to live their life in dignity and participate in society, without having to struggle to secure their basic needs.

Improvements in training

General practitioners. Basic and advanced training for GPs should cover physical and mental disease equally so that these doctors can give comprehensive advice to people seeking help with mental health problems, including on medication. Medical training has to include better training in communication skills.

Improvements in quality assurance

Emergency treatment. Involuntary admissions must be regulated in such a way that only specialists in psychiatry can make referrals, or referrals must be authorised by a superior authority (for example the Basel-Stadt model, where referrals are subject to confirmation by the cantonal medical officer). Emergency admissions are a very severe measure restricting peoples' freedom, and should only be applied under very strict and legally regulated criteria. Added to this, coercive measures during inpatient treatment must be defined more precisely and transparently. Procedures should be introduced to ensure that follow-up discussions are held with those affected to explain the reason for and purpose of the treatment against their will.

At the moment there are also no regulatory measures for so-called informal coercion, where the people affected are put under pressure to show good conduct in the desired psychiatric sense in return for specific benefits or deliverables.

Better quality and outcome orientation. First gather data, then link it with funding: this is how funding should be allocated to services that prove to be effective.

Scientific quality assurance. There is a need for comprehensive quality assurance for all forms of psychiatric and psychological treatment and facilities on the basis of health technology assessment (HTA) instruments and the latest scientific insights.

Quality controls on disability insurance experts. Even though they make decisions with immense implications, the medical experts who examine patients on behalf of the IV/AI are in some cases inadequately trained. This is an area where appropriate quality control is urgently needed.

Take on ideas from abroad. Insights from successful attempts to improve provision of care in other countries should be adopted more rapidly.

Improvements in treatment

Respectful approach. It would be desirable for those affected and their families to be increasingly involved at all levels, and for professionals to drop their paternalistic attitudes. This would be an expression of dealing with people on equal terms and respecting their dignity. People with mental health problems should have a say in their own treatment and be able to choose from several treatment options. They should be taken seriously if they complain of physical problems.

Timely referral to specialists. Patients being treated by general practitioners should be referred to specialists in psychiatry if there is no improvement in their psychiatric condition.

Integrated physical and mental healthcare. There is an urgent need for integrated care for comorbid patients. The separation between physical and mental healthcare should be overcome.

Increased combination of traditional and alternative medicine. Alternative medical measures address widespread wishes among those affected.

Swiss National Report on Quality and Safety in Healthcare

Quality improvement in primary care: toward the provision of safe, high value, patient-centered, sustainable, and data-informed care

Authors
Prof Arnaud Chiolero, MD PhD[1,2,3], Prof Nicolas Rodondi, MD MAS[1,4]; 1) Institute of Primary Health Care (BIHAM), University of Bern, Switzerland; 2) Department of Epidemiology, Biostatistics, and Occupational Health, McGill University, Montreal, Canada; 3) Population Health Laboratory, University of Fribourg, Switzerland; 4) Department of General Internal Medicine, Inselspital, Bern University Hospital, University of Bern, Switzerland

Conflict of interest
AC and NR have no conflict of interest to declare.

Abstract
In Switzerland, due to the growth and ageing of population, primary health care needs are increasing, especially for the management of chronic diseases and multimorbidity. Physicians are keen to improve the quality of care for their patients, and several inspiring initiatives have been conducted to monitor or improve the quality and safety of primary care in Switzerland. However, most of these initiatives were local and not funded on a sustained basis. Currently, there is no comprehensive approach of quality improvement (QI) in primary care and the culture of QI remains relatively weak, especially regarding monitoring and external accountability. There has never been a national QI program in primary care. Further, there is no national monitoring of quality and safety in primary care, including to track low value care and linked avoidable healthcare costs. We therefore recommend building a national strategy aiming to (1) set up a monitoring system for the quality and safety of primary care, (2) strengthen a culture of QI in primary care, (3) improve the quality of primary care through evidence-based and monitored interventions, (4) reduce low value care, and (5) support experiments to test QI initiatives. This strategy should be defined with citizens, patients, primary care physicians, allied health care providers (e.g., pharmacists), experts in health monitoring, health insurers, and health authorities, under the aegis of medico-scientific institutions with expertise in primary care as well as healthcare research and monitoring. Such a strategy would be key toward the provision of safe, high value, patient-centered, sustainable, and data-informed care.

1. Context

In Switzerland, due to the growth and ageing of population, primary health care needs are increasing. Indeed, because the frequency of chronic conditions increases with age, the ageing of the population means that a growing number of citizens have chronic diseases requiring primary care. Furthermore, many patients have several conditions. As a result, managing multimorbidity and polypharmacy are a major daily task of primary care physicians [1, 2]. It implies a growing complexity of care, also because primary care physician have to account for patients' social and economic constraints.

In parallel to these demographic changes and related medical issues, there is concern about a shortage of primary care physicians in Switzerland [3]. Indeed, due notably to the ageing of physicians, the increasing proportion of physicians working part time, and the insufficient number of new primary care physicians, the primary care workforce is shrinking. There are some regions in Switzerland, especially in rural areas, where the density of primary care physicians is relatively low. Another major change is the development of group practice and hospital ambulatory care and the disappearance of solo primary care physicians.

Also changing are the roles of patients and the implication of allied healthcare professionals. Patients are indeed becoming key partners, calling for the development of patient-centered care [4, 5], and there is a growing role of pharmacists, nurses, and other allied health professionals for the provision of ambulatory care [6]. Finally, insuring equity in care access are becoming a major issue as a growing share of the population is postponing care for economic reasons [7].

2. Toward a patient-centered, sustainable, and value-based primary care

In Switzerland, healthcare - including primary care - is traditionally physician-centered and essentially based on a fee-for-services funding [3]. Current trends are to shift toward a patient-centered and value-based healthcare system [5, 8, 9]. Patient-centered care focuses on patients' healthcare needs and preferences, through patients' empowerment to become active participants in their care and insurance that their values guide clinical decisions [9]. Shared-decision making defined as "an approach where clinicians and patients make decisions together using the best available evidence" [10] is one tool for patient-centered care.

Value based healthcare "aims to increase the value that is derived from the resources available for a population" [8]. Inadequate use of healthcare resources is frequent, with soaring overdiagnosis, overtreatment, and provision of low value care [11-13]. Due to rising healthcare costs, a better use of resources through a reduction of low value care is necessary to insure the long-term sustainability of healthcare system [3]. Key is to provide the right care to the right patient [13], and primary care physicians are central in this process. In many countries worldwide, "Choosing Wisely" initiatives have burgeoned to identify and prevent use of low value procedures or treatments. In Switzerland, the initiative is led under the aegis of "Smarter Medicine-Choosing Wisely Switzerland" [14].

A pay-for-performance scheme could be one financial way to shift toward a value-based healthcare system [15, 16]. Rather than being paid based on a fee-for-service scheme, primary care physicians are paid accounting for the quality of their service. It requires a monitoring system allowing evaluate performance through (evidence-based) indicators. A pay-for-performance scheme was introduced in the United Kingdom what was a major driver for the

development of QI in primary care [17, 18]. The impact on the quality of care is however highly debated [18], with a growing disenchantment with such scheme [17, 19]. In Switzerland, one trial is ongoing to test the effectiveness of a pay-for-performance program on the quality of care of patients with diabetes [20].

3. Culture of quality improvement in primary care in Switzerland

The field of quality and safety in primary care is broad and multidimensional, and there are multiple areas for quality improvement (QI) [21]. Based on the "Quality Improvement Competencies Framework" proposed by Czabanowska et al. to identify competencies that should acquire future primary care (family medicine) physicians, QI encompasses the following areas: 1) patient care and safety, 2) equity and ethical practice, 3) effectiveness and efficiency, 4) methods and tools (notably for data-informed care), 5) continuing professional education, and 6) leadership and management (for more details, see **Appendix 1**) [21].

In Switzerland, the culture of QI in healthcare remains relatively weak by comparison with countries like the Netherland or United Kingdom [3]. For the provision of care in hospitals, QI culture has slowly grown in the last 20 years, notably through the development of quality of health care indicators at a national level and the implementation of critical incident reporting systems (CIRS) [22, 23]. This development was favored notably by the legal surveillance of hospital by cantonal authorities and the growing competition between hospitals. A key driver was the Swiss National Association for Quality Development in Hospitals and Clinics (ANQ), building a whole set of quality of care indicators [22]. Finally, several national QI programs in hospitals have been supported by the Federal office of public health (FOPH).

By contrast, no such development in QI has occurred at a national level in ambulatory care, and notably in primary care. Primary care physicians are keen to improve the quality of care at an individual level. However, they are less comfortable with e.g. standardization of care, healthcare monitoring, and external accountability, notably due to insufficient training and lack of experience in QI. While there are several -most often local or cantonal- initiatives to improve the quality of ambulatory care (see below), there is no well-defined and sustained QI strategy in primary care at the national level. One major weakness is the lack of monitoring of the quality of care in ambulatory care. Further, the Federal office public health (FOPH) has never supported a national QI program in primary care.

4. Initiatives to monitor or improve the quality and safety of primary care in Switzerland: toward safe, data-informed, and high value care

Assessing the quality of primary care is necessary for QI and for the provision of data-informed healthcare [4, 21]. It is key to distinguish measurements for improvement and accountability. In Switzerland, several inspiring initiatives have been conducted to monitor or improve the quality and safety of primary care, and some of these initiatives are listed below.

4.1. Incident reporting
Incident reporting is a classical tool to improve safety in primary care. It is based usually on voluntary and anonymous reports of physicians or allied health care professionals. There are however several issues related to this type of reporting, notably the difficulty of having a standard and useful definition of incidents, how to insure that all incidents have been reported,

the amount of information about each incident needed, and if this data can be used or not for legal inquiries.

In Switzerland, critical incident reporting systems (CIRS) are used in hospitals [23]. In several cantons, hospitals have to implement CIRS to be on the cantonal hospital lists (for reimbursement). A CIRS for ambulatory care was proposed initially by the Swiss Society of General Medicine (SGIM) in 2002, and subsequently led by the Collège des médecins de premier recours (CMPR) [24]. However, it was successfully implemented. Over several years of activity, only 3-6 incidents were reported annually. Currently, there is no CIRS at a national level in Switzerland for primary health care.

Some studies assessed the frequency of incidents in primary care in Switzerland. In a large physician network including 472 primary care offices in the German part of Switzerland, the frequency of primary care safety incidents and associated harms were assessed in a cross-sectional survey of 630 physicians and nurses [25]. 30% of physicians and 17% of nurses reported that at least one incident occurred daily or weekly in their offices. On average, each responders reported that 92 incidents had occurred in the last 12 months. Documentation of the incident was often lacking. In the same study, medication safety, triaging patient at the initial contact, and drug interaction were the perceived safety threats most often cited [26]. Time pressure and poor office organization process were also identified as important safety threats. Finally, safety climate was perceived as higher in medical center compared to single-handed office, if there was regular team meeting, and if physicians participated to quality circles [27].

Data from Sentinella system were also used to inform patient safety in primary care [28]. Sentinella is a surveillance network of physicians in Switzerland. In 2015, medication incidents were assessed over one year among 180 general practitioners and pediatricians. The mean rate of detected incidents was 2.1 per general practitioner per year, corresponding to a rate of 47 per 100'000 patients' encounter. Among pediatricians, the mean rate was 0.15 per year, corresponding to a rate of 3 per 100'000 patients' encounters. Incidents were more frequent among older and multimorbid patients. Many incidents were linked to communication issues.

4.2. Quality of care monitoring and indicators
Monitoring the quality of care, allowing data feedback and benchmarking through indicators, is a central element of QI including in primary care [29, 30]. The project "Swiss Primary Care Monitoring" (SPAM) aimed to monitor all aspects of the activities and performance of primary care physicians [31, 32]. Through a consensus approach, 56 priority indicators could be defined based on various data sources, including original data collected in a large national network of primary care physicians. SPAM includes several quality of care indicators. Major issues were the heterogeneity in the quality of data to build indicators and the heavy burden to gather this data. While data for structure indicators was of relatively high quality, data for outcomes indicators was almost non-existent [32].

Recently, evidence-based quality of care indicators were produced taking advantage of health insurance claims data from ambulatory care, based on pre-existing foreign clinical practice guidelines and an on informal expert consensus process [33]. Some 24 indicators were developed covering the domains of efficiency, drug safety, geriatric care, respiratory disease, diabetes, and cardiovascular disease. This data is available nationwide and allows both cross-sectional and longitudinal evaluations on different levels (patients, system). However, their validity and implementation in practice remains to be evaluated [33].

Using clinical data of 1781 patients with diabetes extracted from electronic medical records of Swiss general practitioners (as part of the Swiss FIRE project), some quality of care indicators, inspired by the Quality and Outcomes Framework (QOF), could be produced [34]. However, a high amount of missing data made it impossible to evaluate quality of care. Standardization of data collection in electronic medical records would be necessary to use them to build quality of care indicators.

Of growing importance are person-focused assessment of quality rather than disease-focus assessment [4, 35]. Health indicators accounting for patients' perspective, such as patients' reported outcomes measurement (PROMs), are now used in several health care area, including primary care [35]. Tools are available to measure patients' perceived health status, functional status or health-related quality of life. The Swiss Medical Association (FMH) supports the implementation of PROMs [36].

4.3 Quality circle
Quality circle is one major tool for QI in primary care in Switzerland [37, 38]. It consists in small group of 6 to 12 health care professionals (physicians and e.g. pharmacists), working in the same region or locality, and meeting regularly to reflect and improve their practice [39]. They meet on a voluntary basis. In some regions, they share data and indicators, e.g., about prescription patterns and costs, allowing feedback and local benchmarking [40, 41]. They play an important role in QI in primary care. In Switzerland, around 80% of primary care physicians are involved in quality circles [37]. The Swiss Society of General Internal Medicine (SSGIM) supports quality circles [42]. For more information about quality circles, see **Appendix 2**.

4.4 Other initiatives
The certification of heath care activities and process is a standard tool of QI. In Switzerland, the EQUAM (Externe QUAlitätsförderung in der Medizin) foundation proposes certifications for some activities led by primary care physicians (e.g., hypertension management) [43]. For more information, see the chapter devoted to EQUAM in the current national report.

In 2012, the FMH has constituted the l'Académie suisse pour la qualité en médecine (ASQM) to help coordinate numerous QI initiatives [44]. A quality charter was developed with three pillars 1) transparency: make physicians' activities visible to promote quality in medicine and quality of medical services; 2) mandatory: signatory medical organizations develop a quality strategy and regularly review the situation in a quality report; 3) sustainability: the quality strategy is a long-term strategy and quality procedures are an integral part of the pregraduate, postgraduate, and continuous training of doctors.

Quality of care is improved through the reduction of low value care and through a greater involvement of patients. In 2018, the Swiss Society of General Internal Medicine (SSGIM) has defined two priority areas for its quality strategy [45]: 1) smarter medicine-Choosing wisely Switzerland [14] and 2) shared decision-making. Along these areas, pilot projects are planned to improve the care of multimorbid patients and could be tested within quality circles networks.

5. Proposals to foster quality improvement in primary care in Switzerland

Based on evidence and initiatives listed above, and within the QI framework proposed by Czabanowska et al. [21], we make proposals in **Table 1** to foster QI in primary care.

Table 1: Proposals to foster QI in primary care in Switzerland

What?	How to?	Opportunities (O)/Challenges (C)
1) Set up a monitoring system for the quality and safety of primary care	Set up a true health information system for primary care, taking advantage of existing data (e.g., insurance claims data, medico-administrative data, and electronic health records) or data collected ad hoc (including patient reported outcomes measures - PROMs), building on the experiences listed in the current report. Develop a national critical incident reporting system (CIRS) for primary care.	O: Ambulatory data collected by the Swiss statistical office (BFS) O: Health insurance data if made available O: Willingness of the FOPH C: Data protection and access C: Poor data quality, not designed for QI C: Distinguish monitoring for improvement and accountability C: Resistance if led by health authorities or insurances (e.g. data used for performance assessment and payment) C: Funding (e.g. by FOPH)
2) Strengthen a culture of QI in primary care	Support the continuous education of primary care physicians and allied healthcare professionals in QI. Train medical student for QI in primary care. Strengthen citizen and patients implications in all aspects of QI in primary care.	O: Quality circles for implementation O: New training approach for medical student (Profile) C: Aim for data-informed but not data-driven healthcare C: Resistance toward care standardization (engineering vs clinical perspective) and external accountability
3) Improve the quality of primary care through evidence-based and monitored interventions	Identify and support the implementation of evidence-based interventions to improve the quality and safety of primary care. Support quality circles and monitor their activity.	O: Quality circles for implementation C: Agreement on how to define and measure quality C: Fear that patients misunderstand quality indicators
4) Reduce low value care	Track systematically and reduce low value care, within an evidence-based framework.	O: Willingness of physicians to reduce low value care O: Healthcare cost reduction C. Definition of low value care
5) Test new QI initiatives	Support research to test QI initiatives and to reduce low value care.	O: Network of university family medicine institutes C: Funding (unlikely from SNF)

We propose to constitute a working group of citizens, patients, primary care physicians, allied health care providers (e.g., pharmacists), experts in health monitoring, health insurers, and health authorities (notably FOPH) to define, starting from our proposals, a comprehensive national QI strategy for primary care. This strategy should be defined under the aegis of medico-scientific institutions with expertise in primary care as well as healthcare research and monitoring. Such a strategy would be key toward the provision of safe, high value, patient-centered, sustainable, and data-informed care.

Acknowledgment

References

1. Christensen K et al. Ageing populations: the challenges ahead. Lancet. 2009; 374(9696):1196-208.

2. Wallace E et al. Managing patients with multimorbidity in primary care. BMJ 2015; 350:h176.

3. De Pietro C et al. Switzerland: Health System Review. Health Syst Transit. 2015;17(4):1-288

4. Starfield B. New paradigms for quality in primary care. Br J Gen Pract 2001; 51:303-9.

5. Catalyst NEJM. What is patient-centered care? https://catalyst.nejm.org/what-is-patient-centered-care/ Accessed December 4, 2018

6. Santschi V et al. Efficacy of interprofessionnality: evidence and challenges. Rev Med Suisse 2017;13(562):1007-11.

7. Merçay C. Expérience de la population âgée de 65 ans et plus avec le système de santé. Analyse de l'International Health Policy Survey 2017 de la fondation Commonwealth Fund sur mandat de l'Office fédéral de la santé publique (OFSP) (Obsan Dossier 60). Neuchâtel: Observatoire suisse de la santé, 2017.

8. Gray M. Value based healthcare. BMJ 2017; 356:j437.

9. What is value-based health care? https://catalyst.nejm.org/what-is-value-based-healthcare/ Accessed December 4, 2018

10. Elwyn G et al. Implementing shared decision making in the NHS. BMJ 2010;341:c5146.

11. Chiolero A et al. How to prevent overdiagnosis. Swiss Med Wkly 2015;145:w14060.

12. Selby K et al. Creating a list of low-value health care activities in Swiss primary care. JAMA Intern Med 2015; 175(4):640-2.

13. Saini V et al. Drivers of poor medical care. Lancet 2017; 390(10090):178-190.

14. Smarter medicine – choosing wisely Switzlerland. www.smartermedicine.ch/fr/page-daccueil.html; accessed December 16, 2018

15. Porter ME. A strategy for health care reform--toward a value-based system. N Engl J Med. 2009; 361(2):109-12.

16. Catalyst NEJM. Transitioning Payment Models: Fee-for-Service to Value-Based Care https://catalyst.nejm.org/transitioning-fee-for-service-value-based-care/; accessed December 4, 2018.

17. Roland M, Guthrie B. Quality and Outcomes Framework: what have we learnt? BMJ 2016; 354:i4060.

18. Minchin M et al. Quality of Care in the United Kingdom after Removal of Financial Incentives. N Engl J Med 2018;379(10):948-57

19. Khullar D et al. Professionalism, Performance, and the Future of Physician Incentives. JAMA 2018 doi: 10.1001/jama.2018.17719.

20. Meier R et al. The impact of financial incentives to improve quality indicators in patients with diabetes in Swiss primary care: a protocol for a cluster randomised controlled trial. BMJ Open. 2018;8(6):e023788.

21. Czabanowska K et al. Development of a competency framework for quality improvement in family medicine: a qualitative study. J Contin Educ Health Prof 2012; 32(3):174-80.

22. Swiss National Association for Quality Development in Hospitals and Clinics. https://www.anq.ch/en/, accessed December 12, 2018

23. Critical Incident Reporting System (CIRS) www.securitedespatients.ch/recherche-et-developpement/cours-et-conferences/journee-cirrnet-2018/; accessed December 3, 2018

24. Gnädiger M, Henzo E. CIRS – un renouveau? Primary and Hospital Care 2017; 17:382-4.

25. Gehring K et al. Frequency of and harm associated with primary care safety incidents. Am J Manag Care 2012; 18(9):e323-37.

26. Schwappach DL et al. Threats to patient safety in the primary care office: concerns of physicians and nurses. Swiss Med Wkly 2012; 142:w13601.

27. Gehring K et al. Safety climate and its association with office type and team involvement in primary care. Int J Qual Health Care 2013; 25(4):394-402.

28. Gnädinger M et al. Medication incidents in primary care medicine: a prospective study in the Swiss Sentinel Surveillance Network (Sentinella). BMJ Open 2017;7(7):e013658. Erratum in: BMJ Open. 2017;7(9):e013658corr1.

29. Agency for Healthcare Research and Quality. Quality Improvement in Primary Care www.ahrq.gov/research/findings/factsheets/quality/qipc/index.html; accessed January 16, 2019

30. Kiran T et al. Ten tips for advancing a culture of improvement in primary care. BMJ Qual Saf 2018. doi: 10.1136/bmjqs-2018-008451

31. Senn N et al. La médecine de famille en Suisse – Perspectives. Analyse sur la base du programme SPAM. Obsan Bulletin 2016, Neuchâtel.

32. Ebert ST et al. Development of a monitoring instrument to assess the performance of the Swiss primary care system. BMC Health Serv Res 2017; 17(1):789.

33. Blozik E et al; Swiss Quality Indicator for Primary Care (SQIPRICA) Working Group. Evidence-based indicators for the measurement of quality of primary care using health insurance claims data in Switzerland: results of a pragmatic consensus process. BMC Health Serv Res 2018; 18(1):743.

34. Djalali S et al. Swiss quality and outcomes framework: quality indicators for diabetes management in Swiss primary care based on electronic medical records. Gerontology. 2014;60(3):263-73.

35. Weenink JW et al. Patient reported outcome measures (PROMs) in primary care: an observational pilot study of seven generic instruments. BMC Fam Pract 2014; 15:88.

36. Hostettler S et al. La mesure des résultats de santé rapportés par les patients. Bull Med Suisse 2018 ;99 :1348-51.

37. Meyer-Nikolic VA, Hersperger M. Qualitätsentwicklung in der ambulanten Medizin CH: Q-Monitoring-Resultate schaffen Übersicht. Bulletin des médecins suisses 2012; 93:1036-8.

38. Rohrbasser A et al. Exploring why quality circles work in primary health care: a realist review protocol. Syst Rev 2013;2:110.

39. Rohrbasser A et al. Quality circles for quality improvement in primary health care: Their origins, spread, effectiveness and lacunae– A scoping review. PLOS ONE. 2018;13(12):e0202616.

40. Niquille A et al. The nine-year sustained cost-containment impact of swiss pilot physicians-pharmacists quality circles. Ann Pharmacother. 2010; 44(4):650-7.

41. Bugnon O et al. Cercles de qualité médecins-pharmaciens, pour une responsabilité partagée de la liberté de prescription. Rev Med Suisse 2012; 8:1042-48

42. Swiss Society of General Internal Medicine (SSGIM), Cercle de qualité www.sgaim.ch/fr/qualite/qualitaetszirkel.html; accessed December 18, 2018

43. Externe QUAlitätsförderung in der Medizin (EQUAM) www.equam.ch; accessed December 18, 2018

44. Académie Suisse Pour la Qualité de la FMH https://www.fmh.ch/fr/asqm.html; accessed December 18, 2018

45. Swiss Society of General Internal Medicine (SSGIM), Qualité www.sgaim.ch/fr/qualite.html; accessed December 18, 2018

Appendix 1

Framework for quality improvement in primary care

The field of quality and safety in primary care is broad and multidimensional, and there are multiple areas for QI. For the current report, we used the "Quality Improvement Competencies Framework" proposed by Czabanowska et al. to identify competencies that should acquire future primary care (family medicine) physicians for QI in various areas [21]. In this framework, QI encompasses the areas listed in the **Table 2**:

Table 2: Areas for QI in primary care (adapted from Czabanowska et al. 2012 [21]).

Areas	Features
Patient care and safety	Provision of patient centered care; deal with critical incidents and medical error; infection prevention; medication safety; system approach and communication to improve patient safety; health care plan.
Equity and ethical practice	Analysis of equity of practice performance; respect patient autonomy and personal rights; manage patient data safely and ethically; understand intercultural patients' concern; address ethical dilemmas; understand social context; prioritize QI activity
Effectiveness and efficiency	Standardize service delivery to improve timeliness; measure practice performance; implement evidence based medicine; ensure data quality; manage resource efficiently; promote methods of continuous improvement; standardize QI process
Methods and tools	Use the plan-do-check-act (PDCA) quality circle; understand change management; measure performance and use data for improvement and accountability; use benchmark feedback and audit techniques in the context of your practice and region.
Continuing professional education	Use self-assessment; maintain individual continuing learning; pursue systematic practice based learning and improvement; engage in interprofessional learning.
Leadership and management	Work in partnership; work as an interprofessional team, in a practice, in a network, and in the community; understand how to take or delegate leadership for QI; negotiate for change with staff and with patients

This framework is comprehensive and useful to develop a comprehensive QI strategy for primary health care.

Appendix 2

Quality circles in Swiss primary health care

By Adrian Rohrbasser, MD, MSc[1,2,3]; 1) Department of Continuing Education, University of Oxford, United Kingdom.; 2) Institute of Primary Health Care (BIHAM), University of Bern, Switzerland; 3) Medbase Centre Wil, Wil, Switzerland.

AR is a family physician in Switzerland and PhD student at the Department of Continuing Education, University of Oxford, where he studies quality circles in primary health care. He is member of the Swiss Society of General Internal Medicine (SSGIM) committee for quality improvement (QI), and supervises and trains quality circle facilitators.

1. What quality circles are and what they do

Quality circles or similar structured small groups of health professionals are learning environments, sites of continuous professional development, and interventions for QI [1, 2]. They are typically composed of 6 to 12 health care professionals who meet regularly to reflect on and improve their standard practice [3]. In Switzerland, they provide continuous medical education and continuous professional development, which are necessary for QI [4]. Participants choose topics, didactic methods, and techniques to improve targeted aspects of quality. Trained facilitators support quality circles in this process.

Quality circles create a climate of trust and foster a free speech culture. Discussions of everyday problems draw on collective expertise and spark a process of mutual learning. Participants are guided by data in their efforts to improve health care delivery, addressing local problems like inefficient, harmful, or poorly-timed medical services. They are thus a bottom-up system of quality assurance and continuous QI. Participants examine and evaluate processes in their clinics, link evidence to everyday practice, learn to deal with uncertainty, and devise strategies for improving their practice (e.g., improving prescription habits and diagnostic strategies). They discuss and reflect on practice, which may raise their self-esteem. Frequent quality circles participation strengthens team-based strategies for preventing errors [1].

2. The situation in Switzerland

Among the 8290 physicians reporting working in primary health care in 2017 [5], more than 80% reported participating to quality circles as part of QI activities [6]. Since the European Society for Quality and Safety in Family Medicine (EQuiP) delegates introduced the technique in 1996, tutors have offered trainings in QI, including to facilitate quality circles, under the auspices of the SSGIM; some 2500 facilitators have been trained since then. Physicians, physiotherapists, speech therapists, occupational therapists, chiropractors, pharmacists, and practice assistants that adopted quality circles founded the Forum for Quality Circles. Its members organise yearly education meetings for facilitators.

Physician networks in Switzerland are organisations that provide health services tailored to the needs of patients through binding collaborations between physicians and health insurance companies [7]. Some 52% (4278) of primary care physicians were members of physician networks in 2017 [5]. Within these networks, quality circles are used for continuous professional development and QI. Quality circles are integrated quality measures in contracts between physician networks and insurers. Insurers offer plans that require patients first see a physician within their network, except for emergencies. Networks and insurers negotiate and sign contracts over reimbursement for this service. Insurers require networks to show continuous improvement in quality of care they provide to patients and review performance

and renegotiate contracts annually; they rank performance based on predefined measures of quality, which often include quality circles.

In September 2018, the SSGIM conducted a survey to find out how often networks are contractually required to report quality circles to insurers, how many of these quality circles there are, and how many primary care physicians participate in these quality circles. Out of the 50 networks the Swiss Association of Physicians' Networks listed on their home page, 37 (75%) responded. They reported that quality circles are a core element of QI in their practices and key to their members' continuous professional development. In this sample, all physicians belonged to quality circles through their networks. Some 219 networks' quality circles were identified and address a variety of topics. All reported that insurers require networks' physicians to participate in quality circles. Each networks collaborates with 6 to 24 insurers.

3. Conclusion
In Switzerland, physicians commonly use quality circles for continuous professional development and QI. The large number quality aspects that quality circles deal with provides a strong basis for QI in Swiss primary health care.

Acknowledgements

References
1. Rohrbasser A et al. Quality circles for quality improvement in primary health care: Their origins, spread, effectiveness and lacunae– A scoping review. PLOS ONE 2018;13(12):e0202616.
2. Rohrbasser A et al. Collaborative Quality Improvement in General Practice Clusters. Report. Glasgow: Scottish School of Primary Care; 2017.
3. Dahinden A et al. Definition medizinischer Qualitätszirkel – ein Vernehmlassungstext Eine Neuorientierung der Empfehlungen für die medizinische Qualitätsarbeit in der Schweiz [Definition of structured small group work - acknowledged recommendations for quality improvement in Switzerland]. Primary Care. 2005; 5(16):370-2.
4. Czabanowska K et al. Development of a competency framework for quality improvement in family medicine: a qualitative study. J Contin Educ Health Prof 2012; 32(3):174-80.
5. Hostettler S, Kraft E. FMH-Ärztestatistik 2017 – aktuelle Zahlen. Schweizerische Ärztezeitung 2018; 99(1314):408–13.
6. Meyer-Nikolic VA, Hersperger M. Qualitätsentwicklung in der ambulanten Medizin CH: Q-Monitoring-Resultate schaffen Übersicht. Schweizerische Ärztezeitung 2012; 27-28(93):1036-8.
7. Stricker B. Was genau ist ein «Ärztenetzwerk»? Primary and Hospital Care 2005; 5(23):524-5.

Swiss National Report on Quality and Safety in Healthcare:

Medication Safety

Swiss Association of Public Health Administration and Hospital Pharmacists (GSASA)

Authors

GSASA quality & safety committee:

Dr. pharm. Patrik Muff[1] (head of committee), Dr. phil. II. Carla Meyer-Massetti[2,]

Johanna Bouzid[3], Dr. phil. II. Markus Leopold Lampert[4]

Affiliations:
1. Spitalzentrum Biel AG
2. Universitätsspital Zürich, Fachstelle für Qualitätsmanagement und Patientensicherheit
& Universität Basel, Klinische Pharmazie & Epidemiologie
3. Psychiatrische Dienste Aargau AG
4. Solothurner Spitäler AG & Pharmaceutical Care Research Group, Universität Basel

February 2019

Introduction

The issue of drug-related problems came to public awareness in Switzerland ever since the interdisciplinary congress on drug-related risks and safety in hospitals, held in 2001[1].

ADEs affect more than 6% of all inpatients[2]. Pertaining to the causes of ADEs, a clear distinction has to be made between errors in the medication use process (medication errors), which are a problem of medication safety, and undesired drug reactions (ADRs), which are a problem of drug product safety.

Medication errors are the cause of approximately half of all drug-related complications[3] and are in principle avoidable. They occur in more than 5% of all cases where drugs are administered in the hospital setting[2].

In Swiss hospitals and nursing homes, the so-called "qualified person" (i.e. Fachtechnisch verantwortliche Person, FvP), usually a pharmacist, is accountable for the medication use process and its safety[4].

On the following pages the Swiss Association of Public Health Administration and Hospital Pharmacists (GSASA) assesses medication safety in Swiss healthcare institutions based on the degree of implementation of evidence-based recommendations made by the U.S. Institute of Medicine (IOM)[5], supplemented with best-practice strategies for addressing current medication safety issues.

This evaluation of the situation complements the July 2018 report on medication safety in Switzerland published by authors of the Swiss Patient Safety Foundation[6], which addresses both inpatient and outpatient care, offers detailed information on quantitative medication safety data available from Switzerland and is summarized in Box 1.

Box 1: Summary of significant findings and recommendations in the publication of Fishman et al. [6]

In 2018, authors from the Swiss Patient Safety Foundation have published an article detailing Swiss publications on medication safety. Their findings are briefly summarized here:

Available data indicates that more than 27% of patients have an ADR during their hospitalization and that 8-15% of patients are victim of an ADE. A representative international study showed that in 2010, 5.3% of Swiss people were victim of a medication error in the last two years. 4-7% of hospital emergency admissions are caused by ADEs.
During hospital stay, a systematic CIRS analysis showed that preparation and administration of drugs are medication safety hotspots (45% of all medication errors). Other known risk factors in the medication use process are polypharmacy and transitions of care (e.g., hospital admission and discharge). Vulnerable patient groups are children, older and multimorbid patients, especially in nursing homes, as well as patients with language barriers. Empirical research shows that medication safety is an urgent area of concern in the Swiss healthcare system, but overall, there is a lack of actual Swiss data on medication safety, specifically in ambulatory care.
Furthermore, no comprehensive national strategy explicitly dedicated to medication safety exists in Switzerland and health care regulations differ widely between different cantons. In ambulatory care, direct drug dispensing by the prescribing physician is permitted in almost all German-speaking cantons, hampering the interprofessional collaboration between physicians and pharmacists.
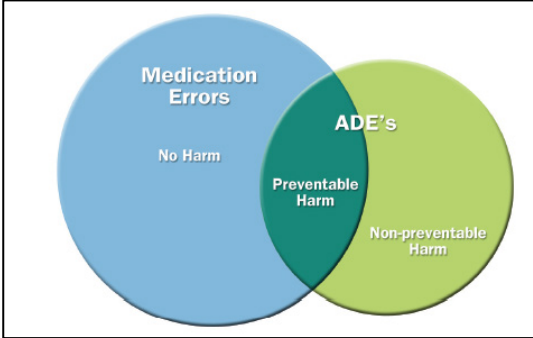
With regard to the aging population and multimorbidity, a proactive comprehensive national medication safety strategy is crucial. National studies, priority setting and subsequent solidly financed improvement projects including effectiveness studies, lead by stable institutions and involving all stakeholders, should be encouraged (e.g. the impact of interprofessional activities like quality circles on medication safety seem promising, but warrant further systematic review).
A framework for interprofessional collaboration is envisioned, integrating digital solutions. And last but not least, patient and medication safety topics should become an integral part in the training curriculum for medical degrees. This might also advance the development of standardised guidelines for medication safety improvement.

Topics not addressed in this report: Adverse drug reactions (ADRs)

Abbreviations, Terms and Definitions

ADE	Adverse Drug Event	A complication resulting from the use of a drug, regardless of whether the drug was used properly or not. [7]
ADR	Adverse Drug Reaction	Any response to a drug which is noxious and unintended which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function[7]. Inherent risk of every drug product. Adverse reactions may arise from use of the product within or outside the terms of the marketing authorisation or from occupational exposure. Use outside the marketing authorisation includes off-label use, overdose, misuse, abuse and medication errors [8].
CDSS	Clinical Decision Support System	An application that analyses data to help healthcare providers make decisions and improve patient care
CIS	Clinical Information System	A large computerized database management system that processes patient data in order to support patient care. This system is used by health care professionals to access patient data and to plan, implement and evaluate care.
CPOE	Computerized (Physician or) Providers Order Entry	Any system that allows registered health care providers to request drugs, laboratory studies or radiological tests by entering those request in an electronic health care record
CIRS	Critical Incident Reporting System	Reporting system which enables hospitals and other health care institutions to record and analyse adverse incidents and near misses with a view to improve patient safety by learning from these incidents
DRP	Drug Related Problem	An event or circumstance involving drug treatment (pharmaco-therapy) that actually or potentially interferes with desired health outcomes. [9] **Figure 1:** Drug-related problems (DRPs): the relationship between different terms (figure adopted from NCC MERP [7])
EPRO	Electronic Patient Record	Systematised collection of a patient's health information in a digital format. These records can be shared across different health care settings.
ME	Medication Error	Failure in the medication use process that leads to, or has the potential to lead to, harm to the patient. MEs are in principle avoidable.
PSAT	Parenteralia Self Assessment Tool	Standardized scheme of hotspots in medication process, and accurately defined interventions enabling the systematic risk assessment in order to reduce the risks associated with the handling of parenteral administrated drugs. [10]

Medication process: safety, quality and efficiency

1. **A comprehensive approach to reducing MEs**

   One way of avoiding MEs is to systematically record and analyse them in an interprofessional environment. While there is no blanket legal requirement to operate a CIRS in Switzerland, many cantons require a CIRS in their care agreements[11]. A 2010 survey of chief pharmacists revealed that 24 of 25 hospitals had a CIRS[12].

   Recording and analysing errors and near misses is particularly important in terms of medication safety, as experience shows that in healthcare institutions overall, reports involving drugs account for 30% to 50% of CIRS reports. Nevertheless, pharmacists at many hospitals are still not systematically involved in the interprofessional appraisal of critical incidents involving drugs.

   Since reports are voluntary, they are not necessarily complete or representative. But experience suggests that a CIRS is a cost-efficient tool which facilitates prioritization of medication safety improvement initiatives[13]. CIRS systems are also a key instrument in raising awareness of risks and possible solutions among hospital and nursing home staff, promoting a systemic and interprofessional approach as well as a positive, open-minded culture of dealing with errors.

   In 2014 the GSASA's quality and safety committee also drew up a checklist to help systematically recognise risks and potential improvements in the handling of parenterals, an entire group of high-risk drugs, and efficiently implement corresponding measures [10]. This PSAT also recommends reporting and regularly evaluating errors and near misses (criteria 4.8 and 8.1).

2. **Ward-specific standardisation of the medication process**

   The IOM has recommended the standardisation of rules and aids for drug prescribing, dosage (including minimum and maximum doses) and administration times, at least on a ward-specific basis.
   Comparably, the PSAT recommends prescribing in writing, using only units and abbreviations officially recognised by the institution, and standardising at the very least minimum the minimum information required for safe drug administration (criteria 4.1 to 4.3).
   Added to this, at many institutions the introduction of a CIS with an electronic prescribing system has enabled the standardisation of aids, master data and prescribing rules (units and abbreviations) across the institution. With regard to the introduction of the EPRO, the GSASA recommends the nation-wide standardisation of abbreviations, units and prescribing rules.
   Moreover, electronic prescribing systems generally have an option for predefining frequent prescriptions (so-called favourites), which can significantly improve the safety and efficiency of the prescribing process.

3. **Computerised physician order entry (CPOE)**

   Many acute care hospitals, and an increasing number of long-term care facilities, already have implemented a CIS with an electronic medical record and electronic prescribing. This trend to digitalisation is boosted by the federal government's decision in 2017 that Swiss acute care hospitals (by 2020) and nursing homes (by 2022) have to commit to transfer relevant data to the EPRO at discharge.

Electronic prescribing systems optimise readability and facilitate central data storage. This in turn increases the ability of different professional groups to simultaneously, flexibly and promptly access the necessary patient data, prevents transfer errors, enables interfaces to be managed efficiently, and thus boosts medication safety.

What remains problematic are insular IT solutions such as for the intensive care unit and anaesthesiology/operating room, where the requirements for clinical information systems differ from those on "ordinary" nursing wards. Using different prescribing systems increases the likelihood of transmission errors at internal interfaces. This means that the next challenge will be to link these specific CISs to the hospital's overall CIS to minimise interfaces and the resulting transmission errors within the facility. This is important because data from the institution's clinical information system also serve as the basis for transfer to the EPRO.

Despite many major advantages, the implementation of a CIS with electronic prescribing is a very complex process that may introduce new (minor) technical risks. CPOE can't provide comprehensive medication safety. It may support the prescribing process but the therapeutic decision making for a given patient still remains the responsibility of the physicians.

4. Facilitating the prescribing process with pharmacotherapeutic programs and decisionmaking aids

These days a number of web-based pharmacotherapeutic dosage and interaction checking softwares are available (e.g. UpToDate®, dosing.de, kinderdosierungen.ch 2.0, SwissPedDose; ABDA-Datenbank, mediQ®).

All the established electronic prescribing systems in Switzerland have a built-in interaction checking software.

More advanced CDSSs are currently at an early stage of implementation, for example for adjusting dosage to kidney or liver function (Documedis® CDS-Check Tool), dosages for children (PEDeDose® from PEDeus), and identifying high-risk medication situations (PharmaClass®).

In oncology almost all Swiss hospitals have established the cato® software solution, primarily designed to support and safeguard the process of centrally preparing cytotoxic drugs in hospital pharmacies. Even so, at most hospitals the prescriptions themselves are not entered directly in cato® or the CIS, which means that the potential for safeguarding prescriptions using stored oncological therapy regimens is not exploited. A Swiss study clearly demonstrated that the integral use of cato® can significantly reduce prescription errors by approximately 60% (4.6% vs 2.0%)[14].

5. Introduction of unit doses

Systems for distributing (solid oral) drugs in unit doses are designed to ensure the safe, patient-specific preparation and administration of drugs. However, so far this type of system has not been established in any acute care hospital in Switzerland.

Projects with this aim have foundered because of the complexity of the clinical routine, the necessity of completely reorganising the medication use process around the new system and the tasks for involved nursing and pharmacy staff and recent challenges as well. In particular, the introduction of Diagnosis Related Groups (DRG) and the shift of treatments from inpatient to outpatient care have forced hospitals to become more reactive in order to reduce the duration of patient stays.

For those reasons, the unit dose system remains primarily an option for long-term care facilities (nursing homes) and outpatient facilities (retail pharmacie and home healthcare) in Switzerland. There are now a number of providers for these areas: institutional hospital pharmacies with blister packaging equipment, and companies such as Medifilm®, Mydose® and Schweizer Blisterzentrum. In retail pharmacies, dispensers are mostly filled manually, for example with the help of Pharmis® or Pyxis®.

Acute care hospitals, by contrast, are increasingly using electronic medicine cabinets (e.g. Pyxis® or Mach-4®) on the wards, which offer a great deal of flexibility at a safety level comparable to unit dose systems.

At institutions with a low level of digitalisation, an alternative approach to assure the safety of the medication use process is the transfer of ward-based medication management activities (stock management, preparation of patient-specific dispensers and parenterals, etc.) from the nursing staff to pharmacy technicians under the accountability of the hospital pharmacy. A survey of 48 hospital pharmacists in 2017 showed that 61% of hospital pharmacies are already involved in managing ward pharmacies, and that these activities are gaining popularity [15]. Separate medication rooms, a needs-appropriate range, neatly arranged drug stocks, active returns management, and measures to avoid look-alike errors and guarantee adherence to the "first expired, first out" principle are all key strategies to ensuring the safe and economical use of drugs.

6. **Preparing high-risk parenterals in the central pharmacy**

   Since the mid-1990s hospital pharmacies have been realigning their approach to drug compounding and preparation. As a result, nowadays the preparation of certain high-risk parenterals (cytotoxic drugs, total parenteral nutrition, etc.) and parenterals for high-risk patients (e.g. neonatology) is centralized in almost all acute care hospitals across Switzerland in the hospital pharmacy, using cleanrooms and applying Good Manufacturing Practice (GMP)[16].

7. **Creating specific processes and written protocols for the use of high-risk drugs**

   The PSAT also recommends standardising the management of high-risk drugs in general and optimising the medication use process along the following lines:

   - Defining a list of high-risk drugs, implementing measures necessary to ensure their safe use and monitoring (criterion 1.2)
   - Reviewing inventory/stockkeeping (criterion 2.2)
   - Using standardised checklists/prescription forms (criterion 4.6)
   - Assuring adequate labelling of prepared drugs, up to the bedside (criterion 5.6)
   - Introducing guidelines on minimum and maximum doses and the corresponding safety barriers (criterion 5.11)
   - Providing tools for calculating infusion rates (criterion 5.12)
   - Independent double-checks for complex dosage calculations and pump programming (criterion 5.13).

Despite the numerous points to be considered, most high-risk parenterals – including electrolyte concentrates for infusion – are still stored and prepared for use on the nursing wards.

So far, it has not been possible to implement the centralised preparation of all high-risk parenterals in hospital pharmacies in Switzerland, primarily because of a lack of personnel resources necessary for 24-hour operation.

In this context, the PSAT recommends at least using solutions for infusion of high-risk drugs in standardised concentrations (criterion 5.4). However, various attempts by the pharmaceutical industry to bring standardized electrolyte solutions for infusion to the market have failed because of the heterogeneity of clinical needs and/or the wishes of nursing wards.

8. **Limiting the different types of infusion equipment**

Intravenous administration of drugs, especially high-risk drugs, is increasingly pump-controlled. The PSAT recommends limiting the number of standard pumps used to a maximum of two models per type (e.g. syringe drivers, infusion pumps, Patient Controlled Analgesia (PCA) pumps) (criterion 1.4), formulating guidelines for their use (criterion 5.14), and regularly inspecting and maintaining all equipment for administering drugs (criterion 8.2).

Even though there is insufficient data to be able to assess the degree to which this recommendation has been implemented throughout Switzerland, a 2015 survey suggests that it has been implemented to a large extent[17].

9. **Clinical pharmacists accompanying care teams on their ward rounds**

Since the 1990s, clinical pharmacy has developed considerably in Switzerland and is now comparatively widespread in larger hospitals. Parallel to this there has been a steady increase in the availability of relevant training (CAS/DAS/MAS programs).

There are major regional differences, however: a study showed that in 2013, clinical pharmacists accounted for approximately 25% of hospital pharmacist jobs in western and southern Switzerland, but only approximately 10% in German-speaking Switzerland (see Figure 2)[18]. These differences correlate strikingly with the drug dispensing system in the ambulatory care sector[10].

Figure 2: Percentage of clinical pharmacy activity (red, in full-time equivalents) versus other hospital pharmacy activities (yellow); survey conducted in 2013; hospitals with several sites are combined in one column
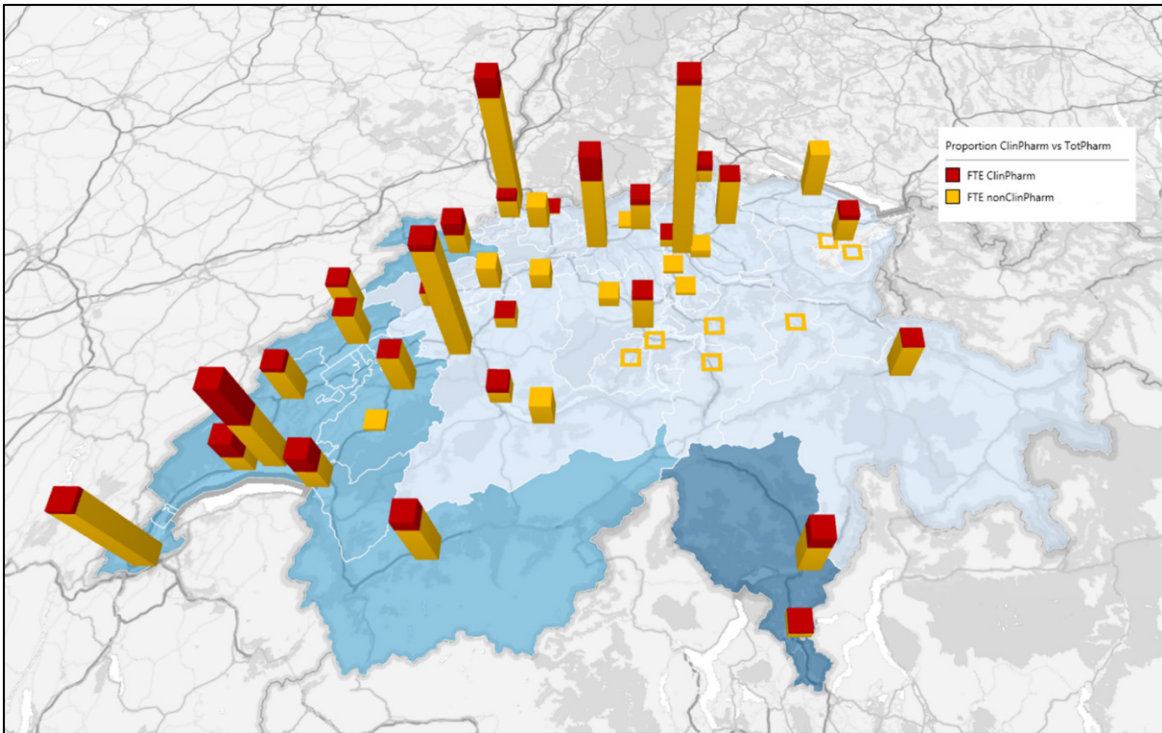
The PSAT also recommends regularly involving clinical pharmacists in monitoring pharmacotherapy and documenting their interventions in the patient record in standardised form (criteria 6.1 and 6.2.1). The GSASA has developed a classification system to record the DRPs identified and handled by clinical pharmacists[19]. An analysis of DRPs recorded at 11 hospitals with an average observation period of 10 months revealed more than 9,500 observed problems. Figure 3 shows how these break down by category[20].

Figure 3: DRP (recorded as per GSASA classification) at 11 Swiss hospitals (total time of observation: 121 months; observation period: Jan 2012 to May 2013) [diagram adapted from Gaufroid [20]]
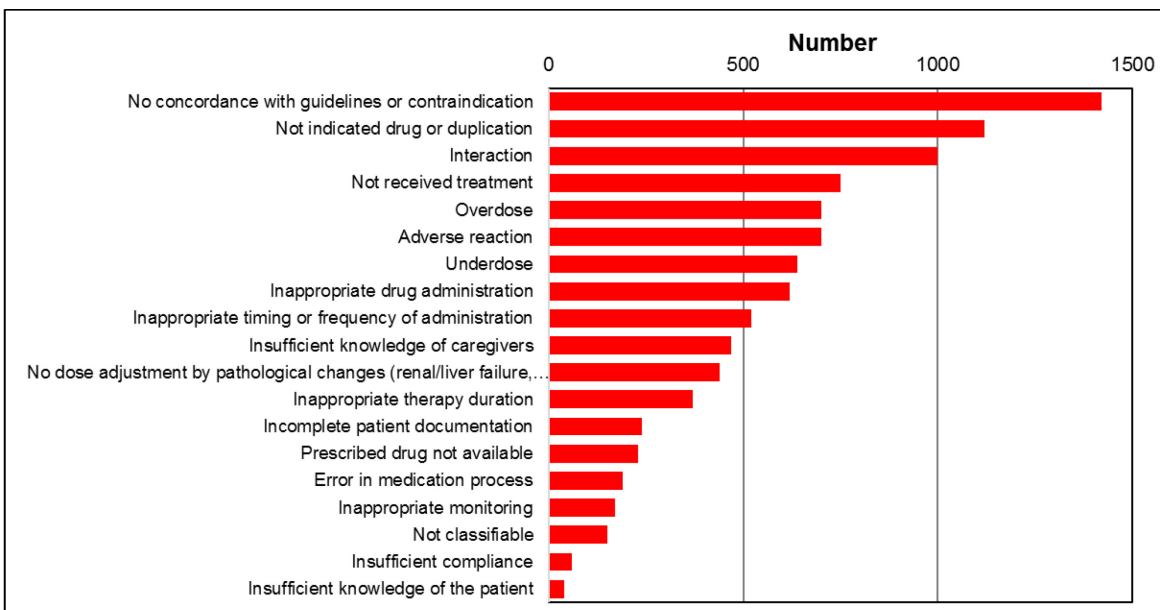
10. Availability of relevant patient information at the patient's bedside

As mentioned above, many acute care hospitals, and an increasing number of nursing homes, already have a CIS in place. Additional patient-specific data like allergies, lab findings, etc. can also be recorded in electronic medical records.

However, several problems remain unresolved: data on allergies are mostly subjectively provided by patients and is rarely entered in CIS in a structured form.

11. Improving patients' knowledge of their drug therapy

Unlike the UK's National Health Service, where "patients should be encouraged and helped to self-administer while in hospital"[21], endeavours to improve patients' knowledge of their drugs while in hospital are still in their infancy in Switzerland.

The primary goal of institutions in Switzerland at present time is to assure that staff uses drugs safely up to the point of discharge. However, an increasing number of programs are being implemented, at least on rehabilitation and long-term care wards, to help patients practice drug management while they are in hospital and thus increase medication safety at home once they are discharged.

The annual survey conducted by the Swiss National Association for Quality Development in Hospitals (ANQ), which includes adult patients in acute care hospitals, gives an indication of the quality of patient training with regard to their drug therapy (question 4: "Were you given a clear explanation of the purpose of the medicines you were supposed to take at home?")[22]. Overall, patients were quite satisfied with the instructions provided (4.47/5), but the heterogeneous results show that there is potential for improvement at many hospitals.

One solution for further improving patients' knowledge of their drug therapies could be retail pharmacies within hospitals. There, patients could be supplied with the necessary drugs upon discharge and be systematically instructed on their proper use[23].

Recent issues and strategies for improving medication safety:

12. Systematic medication reconciliation at transitions of care

So far the focus has been on DRPs during hospitalisation. However, many problems arise specifically on transitions of care, resulting in a negative impact on patient outcomes [24] [25]. Despite this, it is only since 2013 that the issue of medication safety at transitions in care between outpatient and inpatient settings has been widely debated in Switzerland as well[26].

When patients are admitted to a hospital, there is often no systematic medication history taken or medication reconciliation done. This can lead to clinically relevant problems[27] [28].

And when patients are discharged, up to 50% of discharge prescriptions are incorrect or unclear[29]. When patients are transferred to home healthcare (Spitex), more than one third of prescriptions from the hospital were unclear to home care nurses[30].

Professional associations also recommend the introduction of systematic medication reconciliation on hospital admission all across Switzerland[31]. Ideally, this duty should be performed in an interprofessional context[32] [33] (physicians, hospital pharmacist, nurses). However, this is currently standard practice in only one Swiss hospital (Cantonal Hospital Zug).

13. Availability of requisite drugs

In recent years, there has been a significant increase in supply bottlenecks and market withdrawals. The current status of shortages can be viewed at www.drugshortage.ch.

This affects acute care hospitals in particular: according to a 2015 survey, for example, approximately 120 supply bottlenecks with a mean duration of 54 days occurred, including shortages of essential drugs such as parenteral antibiotics and vaccines. While patients feel the effects of such shortages in only approximately 10% of cases, they do lead to a lot of insecurity and uncertainty among staff and considerable extra work for hospital pharmacies (approximately 1.5 hours per shortage)[34].

Federal measures such as the ordinance on keeping compulsory stocks of drugs and the reporting requirement for shortages of essential drugs have proven insufficient (see also https://www.bwl.admin.ch/bwl/de/home/themen/heilmittel/meldestelle.html).

Barriers and challenges

Given the lack of complete data on the implementation of medication safety strategies, it is difficult to comprehensively assess the situation regarding medication safety in Switzerland. In this report we have endeavoured to track down available data and, where these data are missing, to make an expert appraisal. On this basis we can draw the following conclusions:

- Individual IOM recommendations have already been implemented on a widespread basis (comprehensive approach/CIRS, centralised preparation of cytotoxic drugs)
- In recent years, significant progress has been made on other recommendations thanks to the introduction of quality- and safety-relevant measures (electronic prescribing systems, in some cases with pharmacotherapeutic decisionmaking tools; standardised medication processes; clinical pharmacy services; pharmaceutical ward management)
- With some recommendations, however, there is evidence of only modest progress or activity (centralised storage/stocktaking and preparation of high-risk parenterals; introduction of unit dose or equivalent systems; improvements in patients' drug knowledge; systematic medication reconciliation)
- And for some issues, the situation has even taken a step backwards (drug shortages).

We also observe that the degree to which recommendations are implemented depends to a significant extent on how incentives are framed. A few examples:

- CIRSs are sometimes required in cantonal care agreements.
- The centralised preparation of cytotoxic drugs can be remunerated, at least in part, by way of a corresponding tariff. There are also SUVA guidelines on how these substances should be handled [35].
- The federal government's eHealth requirements are facilitating the introduction of electronic CIS. However, the introduction of such systems is made harder by the fact that Switzerland has three languages and therefore offers only micromarkets for providers of IT solutions. This gives the remaining providers more market clout and forces hospitals and homes to adopt standard IT solutions, in most cases from neighbouring countries where the same language is spoken, or develop their own solutions at (too) great expense. This leads to a highly heterogeneous range of electronic medical record and prescribing systems and to the necessity of intensive preliminary training.

- Belief in the cost-efficiency of a competition-driven healthcare system, plus a federal system comprising 26 autonomous healthcare systems and more than 70 different health insurers, is leading to a situation where every stakeholder minimises their costs to the detriment of common, long-term goals. This means that measures that will allegedly cost an individual stakeholder too much are not implemented. Ironically, a recent countermeasure from parliament (the risk equalisation scheme) has led to the discontinuation of the high-quality, cost-efficient Freiburg model for the pharmaceutical management of nursing homes[36].

In many other areas we see voluntary local initiatives on a personal basis, but in most case these activities remain fragmented and fail to cross disciplines or be structurally anchored.

GSASA Recommendations

The following measures would significantly improve medication safety:

1. **A comprehensive national medication safety strategy is requested with <u>binding regulatory requirements</u>.** For health care institutions this should include at least such matters as:
   - Quality assurance systems for hospitals in general and hospital pharmacies in particular covering the entire medication use process
   - Systematic medication reconciliation at all transitions of care to ensure regular up-dating of a patient's drug list as the basis for any following step in the medication use process.
   - Interprofessional structures (medication safety committees / medication safety officers in acute care hospitals and nursing homes) and all sorts of activities to improve medication safety – analogous to those for infection prevention – with the authority to issue institutionally binding guidelines
   - CIRS with interprofessional appraisal, including hospital pharmacists, of critical incidents involving drugs

2. **A national body for medication safety involving all relevant stakeholders and institutions should be entrusted to coordinate activities and research in order to improve medication safety.**
   This would enable the collection of missing data on the scale of the problem on a comprehensive basis and the evaluation of the efficacy, appropriateness and cost-efficiency of improvement measures.

3. **Comprehensive digitalization of the medication use process.**
   This includes CIS, CPOE, CDSS, electronic medicine cabinets on the wards of acute care hospitals resp. unit dose systems for nursing homes, and eHealth/EPRO.

4. **Adequate stock keeping of drugs at all stages, enforced by federal measures and supported by an adequate pricing policy**

5. **General implementation of technical measures, e.g.:**
   - Implementation of separate medication rooms on the wards
   - Standardization of abbreviations, units and prescribing rules across Switzerland
   - Opening of retail pharmacies within/close to hospitals to systematically instruct patients upon discharge on the proper use of their medication

6. **Using the specific knowhow of hospital pharmacy staff, e.g.:**

   - Ward-based medication management by pharmacy technicians

   - Involving clinical pharmacists in pharmacotherapy

   - Implementing specific processes for the use of high-risk drugs, including standardized concentrations

   for infusion solutions or preparing high-risk parenterals in the central pharmacy

7. **All-encompassing incentive systems across institutional and cantonal boundaries**

   e.g. for improving the quality of discharge prescriptions or instructions given to patients prior to discharge

References

1. GSASA/SBK/VLSS. Interdisciplinary conference 2001 on risks and safety: drugs in hospitals. http://www.gsasa.ch/seiten/bildung/gsasa-kongresse/archiv-kongresse/2001

2. Krahenbuhl-Melcher A, Schlienger R, Lampert M, Haschke M, Drewe J, Krahenbuhl S. Drug-related problems in hospitals - A review of the recent literature. Drug Safety. 2007;30(5):379-407.

3. von Laue NC, et al. The epidemiology of preventable adverse drug events: a review of the literature. Wien Klin Wochenschr. 2003; 115(12): 407-415

4. Kantonsapothekervereinigung Schweiz. Regeln der Guten Abgabepraxis für Heilmittel, Version 1. 14 September 2009

5. Kohn LT, Corrigan JM, Donaldson MS, Editors; Committee on Quality of Health Care in America, Institute of Medicine, Washington DC. To Err is Human: Building a Safer Health System. National Academy Press: 1999; p.183-197 (ISBN 978-0-309-06837-6)

6. Fishman L, Brühwiler L, Schwappach D. Stiftung Patientensicherheit Schweiz. Medikationssicherheit: Wo steht die Schweiz? Bundesgesundheitsbl 2018; 61:1152–1158. https://doi.org/10.1007/s00103-018-2794-z ; published online on 24 July 2018

7. National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). https://www.nccmerp.org/about-medication-errors (accessed on 29 December 2018)

8. Guideline on good pharmacovigilance practices (GVP) – Annex I (Rev 4) EMA/876333/2011 Rev 4 https://www.ema.europa.eu/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-annex-i-definitions-rev-4_en.pdf (assessed on 13 february 2019)

9. Pharmaceutical Care Network Europe. https://www.pcne.org/working-groups/2/drug-related-problem-classification (accessed on 20 December 2018)

10. GSASA Parenteralia Self Assessment Tool (PSAT), 2014: http://www.gsasa.ch/seiten/qualitaet-sicherheit/PSAT/?oid=1685&lang=DE

11. Frank O., Patientensicherheit Schweiz. CIRS - Critical Incident Reporting System. www.qualitaetsmedizin.ch/wp-content/uploads/2017/05/3_Frank-Pr%C3%A4sentation_CIRS_Tagung-Qualit%C3%A4tsmedizin.pdf

12. Meyer-Massetti C., Meier CR. Medication safety activities – the role of Swiss hospital pharmacists, EJHP Practice, 16, 2010/6

13. Meyer-Massetti et al. Systematic review of medication safety assessment methods. Am J Health Syst Pharm, 2011 Feb 1; 68(3):227-40.

14. Strub P. et al. Elektronische Verordnung, Standardisierung & Klinische Pharmazie – ein Trio für erhöhte Patientensicherheit in der Onkologie. St. Clara Spital. Poster award in the research award category at the 2011 international patient safety congress – avanti!

15. Pharmazeutisches Stationsmanagement in der Schweiz – eine Standortbestimmung. https://www.gsasa.ch/de/aktivitaeten/pharmazeutische-dienstleistungen/ag-pharma-stationsmanagement/?oid=10137&lang=de (accessed on 29 December 2018)

16. Pharmacopoea Helvetica, Ph. Helv. https://www.swissmedic.ch/swissmedic/de/home/legal/pharmacopoea/pharmacopoea-helvetica0.html

17. Geisser M. Medikamentensicherheit im Spital – der sichere Umgang mit Parenteralia. Masterarbeit Pharmazie, Universität Basel, 2015. https://www.gsasa.ch/de/qualitaet-und-sicherheit/parenteralia-sat/?oid=83&lang=de (accessed on 8 January 2019)

18. Messerli M, Maes KA, Hersberger KE, Lampert ML. Mapping clinical pharmacy practice in Swiss hospitals: a cross-sectional study. Eur J Hosp Pharm SciPract 2016; 23:314–319

19. Maes KA, Tremp RM, GSASA Working group on clinical pharmacy, Hersberger KE, Lampert ML. Demonstrating the clinical pharmacist's activity: validation of an intervention oriented classification system. *Int J Clin Pharm* 2015 Dec; 37(6):1162-71. DOI: 10.1007/s11096-015-0179-z

20. Gaufroid A: Masterarbeit Pharmazie, Universität Basel, 2013 (unveröffentlicht)

21. Audit Commission. A spoonful of sugar: medicines management in NHS hospitals. December 2001. www.audit-commission.gov.uk/SiteCollectionDocuments/AuditCommissionReports/NationalStudies.

22. https://www.anq.ch/de/fachbereiche/akutsomatik/messergebnisse-akutsomatik/step3/measure/1/year/2017/

23. Öffentliche Apotheken in Spitäler: Empfehlungen der GSASA: https://www.gsasa.ch/deliver.cfm?f=0C9192A09B58F8CEB9D597DA043C9CA2933668BE81AA29B98855E49C98EB8A7D2D96A05E80A6B6F4319AD7B8B909A698F2A09FE6A09B92AF968057B7E66EB5B27A6ECC109398B8BAA10A92A6AC069A79DC4FB5AA83AE545852D08E93F1&type=.pdf (accessed on 29 December 2018)

24. Van Walraven C, Oake N, Jennings A, Forster AJ. The association between continuity of care and outcomes: a systematic and critical review. Journal of Evaluation in Clinical Practice. 2010:947-56.

25. Pereira Gray DJ, Sideaway-Lee K, White E, Thorne A, Evans PH. Continuity of care with doctors—a matter of life and death? A systematic review of continuity of care and mortality. BMJ Open. 2018:e021161.

26. GSASA / Patientensicherheit Schweiz. Tagung «Medikationssicherheit an Übergängen – von Schnittstellen zu Nahtstellen», Bern, 23 April 2013

27. Grandjean C. et al. De l'anamnèse d'entrée à l'ordonnance de sortie: continuité des traitements médicamenteux des patients hospitalisés dans un hôpital régional suisse. J Pharm Clin, vol. 28, n° 3, juillet-août-septembre 2009

28. Giannini O. Erfahrungsbericht: Messung des klinischen Impacts (Präsentation an der Tagung «progress! – Sicheres Medikationsmanagement, Bern, Juni 2017). https://www.patientensicherheit.ch/nationale-pilotprogramme/progress-sichere-medikation-an-schnittstellen/#c1672

29. Eichenberger PM, Lampert ML, Kahmann IV, van Mil JWF, Hersberger KE. Classification of drug-related problems with new prescriptions using a modified PCNE classification system. Pharmacy World & Science. 2010;32(3):362-72.

30. Meyer-Massetti C et al: Medication-related problems during transfer from hospital to home care. Baseline data from Switzerland. Int J Clin Pharm 2018; doi: 10.1007/s11096-018-0728-3.

31. Patientensicherheit Schweiz. Der systematische Medikationsabgleich im Akutspital. https://www.patientensicherheit.ch/fileadmin/user_upload/1_Projekte_und_Programme/progress_sichere_med._schnittstellen/progress_sms_d/Toolbox_Fachpersonen_sms_d/1_SR_7_Sichere_Medikation.pdf

32. Carow F, et al. Objective assessment of nonadherence and unknown co-medication in hospitalized patients Eur J Clin Pharmacol (2012) 68:1191–1199

33. Fernandes O, Shojania KG. Medication reconciliation in the hospital: what, why, where, when, who and how Healthcare Quarterly 2012; Vol.15 Special Issue: 42-49

34 Plagge H, Zeggel S. Wie steht es um die Arzneimittelversorgung in Schweizer Spitälern? Schweiz Ärzteztg. 2017;98(33):1040–1042

35 SUVA. Sicherer Umgang mit Arzneimitteln im Gesundheitswesen. https://www.suva.ch/de-CH/material/Dokumentationen/sicherer-umgang-mit-arzneimitteln-im-gesundheitswesen-286918d-5429-5429/ (Zugriff am 1.2.2019)

36 https://www.rts.ch/info/regions/fribourg/9535331-consternation-a-fribourg-force-de-renoncer-a-son-mode-facturation-des-medicaments-en-ems.html

Pharmacovigilance

A contribution to the Swiss National Report on Quality and Safety in Healthcare

Dr. Petra Dörr, Head of Communication and Networking, Deputy Executive Director
Dr. Christoph Küng, Head of Division Drug Safety

Abstract

Pharmacovigilance is an important instrument to collect information on the safety profile of a medicinal product after its initial marketing authorisation. Spontaneous reports on unexpected adverse drug reactions provide valuable evidence to detect new safety signals. Reports are mainly submitted by healthcare professionals and pharmaceutical companies (marketing authorisation holders). Underreporting (by healthcare professionals) is an issue, although legislation mandates reporting.

Suitable IT tools are being introduced in order to facilitate the reporting and make signal detection more efficient. Application of internally harmonised standards such as a common terminology is important in order to ensure comparability of events and enable analysis of data globally. International cooperation and the use of global databases broaden the basis for the detection of new signals. Cooperation with healthcare professional and patient organisations provides useful input for regulatory actions and communication. More and more information – mainly directed to healthcare professionals - is made public, such as public summaries of Risk-Management Plans or Healthcare Professional Communications, which is also integrated into the medicinal product information platform.

Challenges to be addressed include the need to enhance patient reporting of ADRs, how to make use of "big data" in pharmacovigilance, and the ever increasing expectations for (preliminary) data to be made public. In order to address these challenges, new tools need to be implemented for patient reporting, cooperation with healthcare professionals, patients and international partner authorities need to be further enhanced and risk communication needs to be revised.

Swiss National Report on Quality and Safety in Healthcare
Contribution made by Swissmedic on: „Pharmacovigilance – how does it contribute?"

Contents

1. What is known about the safety, quality and efficiency of care in Switzerland in the area of pharmacovigilance?

When applying for a marketing authorisation of a new medicinal product, the applicant has to submit documentation to prove the medicinal product's efficacy, quality and safety. The potential benefits are assessed as well as potential harm to patients. The established benefit-risk profile is the basis for the decision to approve a product for use. As of today, it is based on data from clinical trials, conducted in a controlled environment with a limited number of patients – compared to its use in clinical and medical practice.

It is evident that it is not possible to identify all risks, e.g. in certain patient groups or rare risks, during clinical trials. This is why spontaneous reports on unexpected adverse drug reactions (ADR or Individual Case Safety Reports, ICSR) after the authorisation of a medicinal product provide valuable evidence to detect new safety signals. The recording of individual ADR reports and observational studies in the context of a widespread or long-term use plays an important role in the continued verification of the benefit-risk profile over time. A newly detected risk or even a change in the frequency or severity of a known risk may have an impact on this profile, requiring for example a change in the medicinal product information or other risk mitigation measures.

The current system of collecting ADR is strongly based on reporting by healthcare professionals and companies (marketing authorisation holders). Reporting of ADRs by patients is possible, but numbers are still marginal. Companies report directly to Swissmedic, the national pharmacovigilance centre, whereas healthcare professionals reports are collected and validated by six regional pharmacovigilance centres (RPVCs).
ADR reports collected in Switzerland are stored in a database at Swissmedic and assessed in order to identify potential safety signals. The reports are also shared with the WHO Programme for International Drug Monitoring, the Uppsala Monitoring Centre (UMC)[1,2].
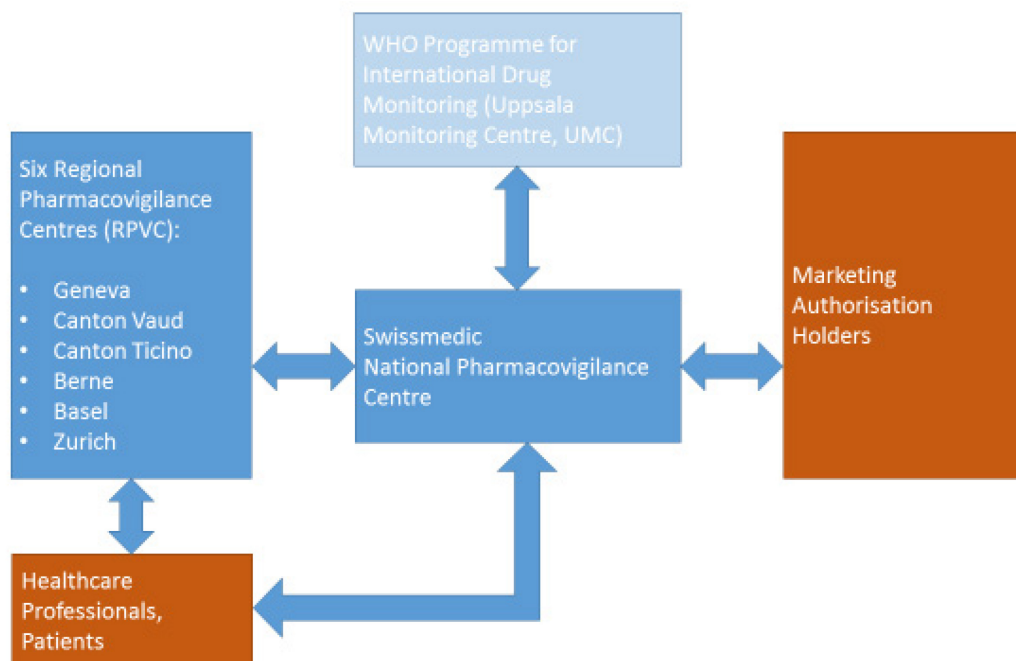
Fig.1: The Swiss ADR reporting system for human medicinal products

Switzerland has one of the highest rates of reporting of ADRs in the world, but there is still serious underreporting[3].

Swiss National Report on Quality and Safety in Healthcare
Contribution made by Swissmedic on: „Pharmacovigilance – how does it contribute?"

According to Assoc. Prof. Stefan Weiler from the Department of Clinical Pharmacology & Toxicology at the University Hospital Zurich, the reasons for healthcare professionals not reporting ADRs include:

- Erroneous assumptions that only safe medicines are on the market and that an ADR is therefore not possible.
- Fear of becoming entangled in a legal dispute or of losing the patient's trust.
- Subjective feelings of guilt that a medicine may have harmed more than helped.
- Personal ambition to collect and publish case reports (publish or perish).
- Unwillingness to report a drug-induced reaction solely on the basis of a suspicion without a definite connection, or simply the lack of time and interest: "The bureaucracy and completion of forms won't help improve my patient's situation." Primary reporters are also not reimbursed for their time and intellectual input[4].

Nevertheless, the number of reports received has increased from 2015 to 2017, as shown in the table below.

	Number of ADRs		
Type of medicinal product	2015	2016	2017
Human medicines	8247	10047	9637
Veterinary medicines	292	253	306
Blood products	2702	3124	3076

Table 1: Number of ADRs received per year (2015-2017)[5]

2. What are the significant and relevant quality and safety improvement interventions that have taken place in Swiss Healthcare in the area of PV?

2.1 Digitalisation

Over the last years, serious investments have been made by Swissmedic to modernise its IT infrastructure. This included basic functionalities such as document management, databases, planning and tracking tools for applications and a web portal offering an increasing number of e-government services[6].

With regard to the reporting of ADRs, two online reporting systems are available today:

- The B2B gateway
- The Electronic Vigilance System (ElViS)

The B2B gateway is a system interface that can be used to electronically send and receive suspected adverse drug reaction reports (individual case safety reports, ICSR) in E2B[i] format. This service is designed to appeal particularly to marketing authorisation holders who send a large number of reports. ElViS also provides a simple, secure and rapid way to exchange ADR reports and documents with the RPVCs.

ElViS is designed for health care professionals (HCP) and marketing authorisation holders who do not use the existing B2B gateway to send ADR reports to Swissmedic. ElViS offers the choice of entering ADR online or uploading an E2B-compatible file.

In addition to the online reporting tools, Swissmedic has also replaced its central IT system for the management of ADRs. The new system allowed to increase efficiency by reducing the

---

[i] E2B refers to the ICH standard on Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports (see also page 6).

administrative burden and managing the ADRs in a paperless process. It also provides for a comprehensive data warehouse for the evaluation of all Swiss reports as well as standardised signal detection processes. The system currently uses the ICH standard E2B version R2, but can also receive and process reports in the latest version (E2B(R3)) of the standard.
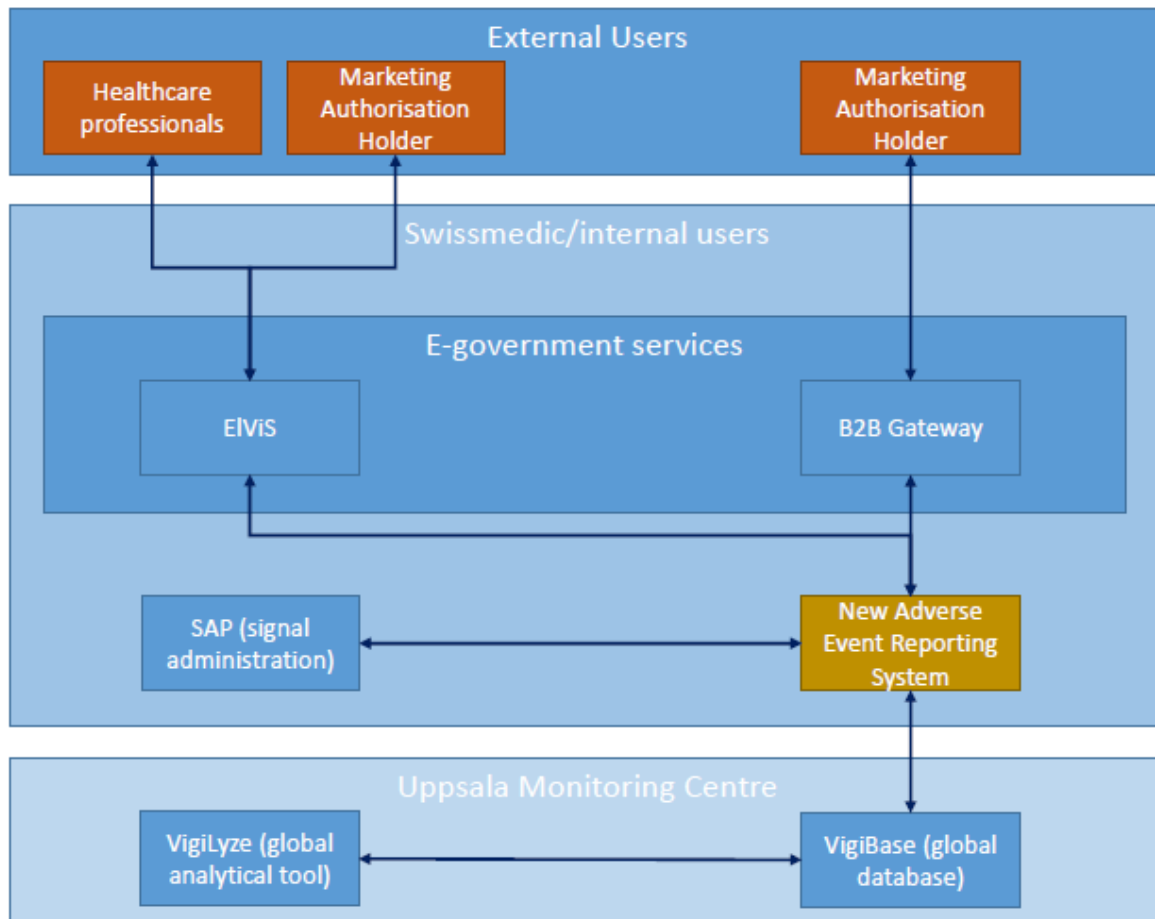
Fig. 2: IT systems used in the context of ADR reporting and evaluation (simplified)

2.2 International harmonisation

ADRs are coded using a common terminology in order to enable comparison and signal detection in databases around the globe. In the past decades, the WHO Adverse Reaction Terminology (WHO-ART), which was developed and maintained by UMC was the terminology for coding adverse drug reactions in the WHO database ("VigiBase")[7]. In the late 1990s, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) developed the Medical Dictionary for Regulatory Activities (MedDRA), a standardised medical terminology to facilitate sharing of regulatory information internationally for medical products used by humans, which over the years became a global standard[8].

In September 2013, Swissmedic decided to switch from WHO-ART to MedDRA. Within the following four months, all Swiss cases were analysed, mapped and re-coded in close co-operation with the Uppsala Monitoring Centre (UMC). On 1 February 2014, all cases in the Swissmedic database were coded in MedDRA and Swissmedic staff started using the new terminology.

In a publication, the benefits of the switch are summarized as follows[9]:

Swiss National Report on Quality and Safety in Healthcare
Contribution made by Swissmedic on: „Pharmacovigilance – how does it contribute?"

The use of an international standard greatly facilitates the exchange of data between Swissmedic and Marketing Authorisation Holders that were already using MedDRA terminology for some time. The cumbersome re-coding from WHO-ART to MedDRA and vice versa has become superfluous for both sides. Furthermore, the use of MedDRA provides for an easier processing of follow-up reports. Additionally, on an international level, sharing of information and comparison of data is facilitated when using the same internationally accepted standard.

2.3   Increased international cooperation

Over the last decade, regulatory authorities, including Swissmedic, have built networks for increased international cooperation. On the one side, authorities have signed numerous bilateral agreements on exchange of information and other cooperative activities, and on the other side multilateral initiatives have emerged or developed[10].

For Swissmedic, in the area of pharmacovigilance, there has been a notable improvement in the cooperation with the European Medicines Agency (EMA) following the signing in July 2015 of an administrative agreement between the EU Commission and the EMA on the one side and the federal Department of Home Affairs and Swissmedic on the other side[11]. Exchange of relevant safety information, early warnings regarding new risk communication and access to the outcomes of discussions of the Pharmacovigilance Risk Assessment Committee (PRAC)[12] and Committee for Human Medicinal Products (CHMP) are useful measures to improve Swissmedic' ability to act and react in a timely and appropriate way and if possible to align with EMA PRAC procedures and recommendations.

The network of bilateral agreements for the exchange of information also forms the basis for the participation of Swissmedic in regular multilateral telephone conferences with partner authorities - such as the EMA, the US Food and Drug Administration (FDA) or the Japanese Pharmaceuticals and Medical Device Agency (PMDA) - on pharmacovigilance issues.

Active participation in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)[13] is one of the key priorities of the international cooperation at Swissmedic. Development and implementation of global standards provides the basis for equivalent regulatory systems and harmonised requirements for the regulated industry. Swissmedic applies ICH standards as a basic principle, considering them as "current state of science and technology". The most relevant ICH standards in the area of pharmacovigilance are listed in Annex 1:

2.4   Enhanced cooperation with healthcare professionals' associations and patient/consumer organisations

In the context of the implementation of a structured engagement with all relevant stakeholders, Swissmedic has developed an approach for enhanced cooperation with health care professional associations in 2016. Looking at the diversity of this stakeholder group, the approach foresees the possibility for ad hoc projects or exchange, combined with annual meetings to discuss topics of common interest. An example for such cooperation that even pre-dates the implementation of the structured approach, is the development of materials for gynaecologists and women with the aim to promote an informed discussion of the benefits and harms of hormonal contraceptives during the consultation visit. This material has been developed in 2013 by the Swiss gynaecologists' association in cooperation with Swissmedic[14].

In May 2014, Swissmedic has established a working group with patient and consumer organisations as a platform for the exchange of information[15]. Pharmacovigilance and the reporting of ADRs has been one of the areas of interest that had been identified early on and

has been discussed repeatedly at meetings of the working group. In addition to the well-established information exchange, a pilot project has been initiated to involve patient representatives in the preparation of the medicinal product information in the course of the process to obtain a marketing authorisation. Such a process has been in place in the European Union for a number of years, and has proven to improve readability of patient information, including information on possible side-effects of a medicine.

2.5   Increased transparency and communication

The Risk Management Plan (RMP) for a medicinal product contains the risk aspects of the product, the planned pharmacovigilance activities and risk minimisation measures. The evaluation of the documentation is an integral part of the marketing authorisation decision. The purpose of the RMP is to describe known and suspected potential risk aspects at the time of marketing authorisation, and to establish strategies on how these can be characterised in future and countered in a risk minimisation approach.

Swissmedic has published RMP summaries of authorised medicinal products since May 2015[16]. Based on the publicly accessible RMP summaries, healthcare professionals and other interested stakeholders can obtain information about the specific measures that have been arranged for the future characterisation and minimisation of risks for the corresponding medicinal product.

The RMP summaries supplement the publicly accessible information for healthcare professionals and patients and are linked to the corresponding medicinal product information via the Swissmedic information platform[17]. In the same way, recent safety updates are made available, such as (Direct) Healthcare Professional Communications ((D)HPC).

HPC / RMP	Fachinformationen (4)	Zulassungsinhaberin	Stand der Info	↑ M/K
HPC	Depakine®	Sanofi-Aventis (Suisse) SA	Aug 2018	M
HPC	Depakine® Chrono	Sanofi-Aventis (Suisse) SA	Aug 2018	K
HPC	Valproat Sandoz®	Sandoz Pharmaceuticals AG	Jul 2018	K
HPC	Valproate Chrono Sanofi®	Sanofi-Aventis (Suisse) SA	Aug 2018	K

Fig. 3: Extract of Swissmedic medicinal product information platform indicating a recent safety communication (DHC) for Valproate-containing medicinal products.

3.   What are the barriers and challenges encountered in the area of PV?

3.1   Patient reporting of ADRs

Compared to other countries, patient reporting of ADRs is still marginal in Switzerland. This may be due to a lack of knowledge about the fact that patients can report such events to Swissmedic or the RPVCs, but also the lack of suitable reporting tools may contribute to the small numbers. It must also be stated that Swissmedic is currently not actively encouraging reporting of ADRs by patients, one of the reasons being the (perceived) lack of quality of such reports.

3.2   Use of "big data" in pharmacovigilance and post-market surveillance

According to a policy paper published by the International Coalition of Medicines Regulatory Authorities (ICMRA), big data refers to "a collection of structured and unstructured data that may be enormous, in the range of several billion gigabytes. In post-market surveillance, structured data may include SRSs, electronic health records (EHRs), electronic medical

records (EMRs), administrative health data (AHD), registries, etc. Unstructured data may include social media like Twitter, Facebook, patient forums, clinical narratives within EMRs, etc."[18]

In the EU a joint Heads of Medicines Agencies (HMA) and EMA Task Force (HMA/EMA Task Force on Big Data)[19] has been mandated to explore a number of issues regarding the emerging challenges presented by big data by:

- Mapping relevant sources of big data and defining the main format in which they are expected to exist
- Identifying the usability or application of big data
- Describing the current state, future state and challenges with regard to;
  - regulatory expertise and competences
  - the need to specify legislation and guidelines
  - data analysing tools and systems needed to handle big data
  - regulators' responsibility for raw data analytics vs sponsor's responsibility
- Designing a big data roadmap
- Generating a list of recommendations as well as evaluating the usefulness of big data in the regulatory setting
- Collaborating with FDA, Health Canada and other third party country stakeholders, including ICMRA, to ensure bilateral insights on big data initiatives

For Swissmedic, it will be essential to follow the progress made and if possible to actively participate in international initiatives on this highly challenging but relevant topic.

3.3   Early information and public databases

As indicated earlier, Swissmedic has taken measures to increase transparency and provide information to the public over the last years. In addition, the revised Act on Therapeutic Products includes provisions for increased transparency such as the possibility to publish information on negative outcomes of marketing authorisation procedures or pending applications. Still, compared to the amount and types of data made public by other regulatory authorities, Swissmedic is lagging behind. Communication of newly emerging risks – even before causality with the use of a medicinal product is confirmed is one of the approaches, the US Food and Drug Administration is applying in its Sentinel initiative. Other regulatory authorities, such as the Australian Therapeutic Goods Administration (TGA) are making their ADR database accessible for patients and healthcare professionals. In Switzerland, such measures are not discussed yet. Still, the positive effects of such transparency measures needs to be shown. It would require a careful analysis of potential upsides and downsides – based on experience gathered abroad - before implementation of such approaches.

4.   What are the recommendations for improvement in the area of PV?

4.1   Further enhance cooperation with healthcare professionals and patients

The cooperation with healthcare professionals has been especially useful in the area of pharmacovigilance. Swissmedic is planning to further enhance this cooperation including the possibility to work with Healthcare professional associations as well as patient and consumer organisations to improve the medicinal product information and risk communication as well as assisting with the dissemination of information. In addition, medical faculties at Swiss universities should be sensitized for the need to strengthen the relevance of pharmacovigilance in the training curriculum of medicine students.

4.2   Improved/modernized risk communication

Appropriate, targeted and timely risk communication is a key element for ensuring patient safety. In addition to the existing tools such as HPCs, the use of social media and the involvement of patient advocacy groups should be explored to provide such information. Explaining the concept of benefit-risk assessment – at time of marketing authorisation and over the whole life-cycle of a medicinal product is another challenge that should be addressed by adequate tools for benefit-risk communication.

4.3   Facilitation of adverse event reporting

Swissmedic has implemented online reporting tools mainly addressed to healthcare professionals and marketing authorisation holders. Patient reporting could be encouraged by providing easy-to-use tools such as an App for reporting of ADRs. In the times of big data, concerns over the quality of patients' reports of ADRs must be put into perspective and approaches for the use of such data must be developed, in line with the outcomes of international initiatives, e.g. from CIOMS.

4.4   Continued/enhanced international cooperation

With a population of more than eight million inhabitants and the already mentioned underreporting of ADRs, it is obvious that a Swiss pharmacovigilance system cannot work in isolation. Safety signals are often detected in larger populations such as the EU or the US. Information needs to be shared and measures need to be coordinated. In this regard, continued or even enhanced cooperation with the EMA is crucial. International cooperation is also required to jointly work on common challenges such as development of regulatory approaches and sharing of best practices with regard to the use big data or real-world data (RWD) in regulatory decision-making.

Annex 1: ICH standards in the area of pharmacovigilance (March 2019)

- The E2A to E2F series of guidelines (Pharmacovigilance)
- E2A Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
- E2B(R3) Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports
- E2C(R2) Periodic Benefit-Risk Evaluation Report
- E2D Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting
- E2E Pharmacovigilance Planning
- E2F Development Safety Update report
- M1 MedDRA Terminology (Medical Dictionary for Regulatory Activities)
- M5 Data Elements and Standards for Drug Dictionaries (ISO IDMP Standards)
- Guideline in development: E19 Safety Data Collection

5. References

[1] Swissmedic Homepage: Pharmacovigilance
https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/market-surveillance/pharmacovigilance.html

[2] Schäublin M. Pharmakovigilanz – Das Spontanmeldesystem in der Schweiz.
Therapeutische Umschau 2015; 72: 743-748.
https://doi.org/10.1024/0040-5930/a000746

[3] Hazel L, Shakir S.A.W Under-Reporting of Adverse
Drug Reactions - A Systematic Review
Drug Safety 2006; 29 (5): 385-396

[4] Vigilance News, Edition 21, November 2018
https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/market-surveillance/pharmacovigilance/vigilance-news.html

[5] Annual report 2017, Swissmedic
https://www.swissmedic.ch/swissmedic/en/home/about-us/publications/current-annual-report/swissmedic-geschaeftsbericht-2017.html

[6] e-Government Portal Swissmedic
https://www.swissmedic.ch/swissmedic/en/home/services/egov-services.html

[7] WHO-ART (UMC)
https://www.who-umc.org/vigibase/services/learn-more-about-who-art/

[8] MedDRA (ICH)
https://www.meddra.org/sites/default/files/messenger/documents/7207-100_messenger_sep_2014.pdf

[9] Swissmedic on MedDRA
https://www.meddra.org/how-to-use/support-documentation/english

[10] International cooperation
https://www.swissmedic.ch/swissmedic/en/home/about-us/collaboration/international-collaboration.html

[11] Agreements on exchange of information
https://www.swissmedic.ch/swissmedic/en/home/about-us/collaboration/international-collaboration/bilateral-collaboration-with-partner-authorities/agreements-on-information-exchange.html

[12] EMA PRAC
https://www.ema.europa.eu/en/committees/pharmacovigilance-risk-assessment-committee-prac

[13] International Council for Harmonisation
https://www.ich.org/home.html

[14] Risque thromboembolique sous contraception hormonale - Nouveaux documents d'aide à la consultation médicale et à la prescription publiés par la Société suisse de Gynécologie et d'Obstétrique

https://www.swissmedic.ch/swissmedic/fr/home/medicaments-a-usage-humain/surveillance-du-marche/fokusthemen/contraceptifs-hormonaux-et-thromboembolies--communications-de-sw/risque-thromboembolique-sous-contraception-hormonale---nouveaux-.html

[15] Collaboration with patient and consumer organisations
https://www.swissmedic.ch/swissmedic/en/home/about-us/collaboration/national-collaboration/collaboration-with-patient-and-consumer-organisations.html

[16] Public RMP summaries
https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/market-surveillance/risk-management--psurs--pv-planning-/rmp-summaries.html

[17] Medicinal Product Information System
http://www.swissmedicinfo.ch/Accept.aspx?Lang=EN

[18] ICMRA Pharmacovigilance Big Data Subgroup: Policy Paper
http://www.icmra.info/drupal/en/strategicinitatives/pharmacovigilance/bigdata

[19] EMA/HMA Big Data Task Force
http://www.hma.eu/509.html

Infection Prevention and Control in Switzerland

Hugo Sax, Stephan Harbarth, Nicolas Troillet, Matthias Schlegel, Jonas Marschall and Andreas Widmer

Swiss Center for Infection Prevention Swissnoso and Swiss Infection Prevention Society

Correspondence:

Prof Dr med Hugo Sax

University Hospital Zurich

Raemistrasse 100 - HAL14

8091 Zurich

Switzerland

hugo.sax@usz.ch

+31 44 255 57 30

Abstract

Word count (max 250): 250

Infection prevention and control (IPC) represents an important part of patient safety with 5.4% of all acute care patients having at least one healthcare-associated infection (HAI) - as measured by a national prevalence survey in 2017. IPC staffing and activity in Swiss hospitals and long-term facilities is diverse according to a recent survey, while a minimal standard is now in development. Historically IPC led the way to standardization in healthcare, a stringent epidemiological approach, monitoring and feedback of relevant results of structure, process and outcome qualities, multi-modal promotion of good clinical practice using behavioral and social sciences, and more recently, human factors engineering. The origins of IPC in Switzerland goes back to the 1960s and is now supported by the Federal Office of Public Health with the two prominent national schemes Strategy NOSO and Strategy against Antimicrobial Resistance (StAR). Various stakeholders are involved, most prominently the Swiss Center for Infection Prevention Swissnoso, the Swiss Society for Infection Prevention (SGSH/SSHH), and the two IPC nursing associations. Several outbreaks have been controlled and preparedness organized with the help of IPC experts on national, regional, and institutional levels HAI surveillance schemes have been established and sustained over years, now a comprehensive HAI surveillance system is being installed. The future of IPC will certainly see an even profounder use of implementation science and digital health, and IPC will continue to play a leading role in the continuous strive for the best health outcomes and resource across all parts of the Swiss healthcare system.

The origins of infection prevention and control in Switzerland

Infection prevention and control (IPC) as formal institutions has its historic roots back in the 1960s that resulted in the foundation of the Swiss Society for Infection Control (Schweiz. Gesellschaft für Spitalhygiene - Société suisse de l'hygiène hospitalière) in 1974, which still exists today. It is an interprofessional society including pharmacists, laboratory specialists, nurses and physicians dedicated to hospital hygiene and infection control.

Two societies for IPC practitioners with a nursing background were founded in the two larger language regions in Switzerland, in 1982 the Spécialistes infirmiers en prévention de l'infection (SIPI; http://www.sipi.ch) and in 1987 the Schweizerische Interessengemeinschaft der Spitalhygieneschwestern (SIGS), now FachexpertInnen Infektionsprävention Schweiz (FIPS: https://fibs.ch).

In 1994 a group of three IPC physicians from university hospitals, Didier Pittet, Patrice Francioli, and Andreas Widmer, founded Swissnoso upon a request by the Swiss Federal Office of Public Health (FOPH) to provide national guidance and leadership in the field of IPC.

A consistent backdrop to this evolution is the fragmented healthcare system reality in Switzerland, consisting in 26 autonomous healthcare systems under the authority of the cantonal governments. Despite this fragmentation of public health decision making, FOPH has always played a central governance role in this evolution.

It was in these early years that IPC led the way into patient safety and quality improvement as we know it today and remained at the forefront of its evolution ever since.

Evolution infection and prevention dimensions over the years

Ever since, IPC has considerably evolved in parallel to international progress in research, implementation and outreach. Several building blocks of infection prevention have been set and improved such as infection surveillance, education of IPC personnel and healthcare providers in

general. Moreover, guidelines have been introduced and improved in parallel with the idea of evidence-based medicine.

Surveillance

In Switzerland, the concept of patient-oriented surveillance of NI was introduced in the 1980s.[1] In 1995, the members of Swissnoso decided to perform a prevalence study of healthcare-associated infections (HAIs), in which 4 of the 5 university hospitals participated.[2,3] Four more such studies followed in 1999, 2002, 2003, and 2004, using the same period-prevalence study method.[4] Insights from these studies included the impact of case-mix rather than quality of care on the higher HAI rate of large hospitals,[5,6] the fact that surgical site infections in operated patients represent an addition to the same prevalence of NI as in the non-operated population,[7] and the fact that only half of all nosocomial urinary tract infections are associated with urinary catheter use.[8] In 2017, Swissnoso re-installed trans-sectional surveillance of all HAI in alignment with the European definitions and method as one-day point-prevalence studies (results see below).

In 2009, Swissnoso started the national surveillance of surgical site infections (SSIs) based on a scheme that was developed and implemented since 1998 in Romandie and Ticino.[9,10,11] This surveillance is financed by ANQ (www.anq.ch) and the results of each participating hospital are made available publicly on their website each year. This represents the first and only open public reporting of HAI rates in Switzerland on a national scale. However, its public impact may be limited; most patients and physicians are not aware of this public reporting of SSI rates stratified by type of surgery, patients' risks and healthcare institution. Comprehensive reports are also published on the [Swissnoso website](https://www.swissnoso.ch/module/ssi-surveillance/resultate/). (https://www.swissnoso.ch/module/ssi-surveillance/resultate/) and in scientific journals.[12,13] A unique feature of this surveillance scheme is the structured assessment of the quality of the surveillance structures and activities in each hospital, which is then published as a score alongside with the results.[14]

At the conjunction between IPC and infectious diseases stands the Anresis (Swiss Centre for antibiotic resistance; http://www.anresis.ch/) platform that has been evolving and expanding its service over the >10 years. Through an internet site everyone can easily get access to resistance profiles (and soon also aggregate-level antibiotic consumption data) stratified by individual pathogens, age groups and Swiss geographical regions.

Guidelines

Swissnoso was originally created to provide guidelines for infection prevention beyond disinfection procedures, publishes as simple Bulletin (https://www.swissnoso.ch/bulletin/) in the three national languages that was added to the main publication of the FOPH and attained a large readership even beyond the national borders. The main content were guidelines that were adapted from international guidelines to Swiss context and still represents the main instrument of expert guidance that has even been the reference for regulation and political discourse. Topics range from instrument reprocessing, environmental cleaning, operating room ventilation, to prevention of specific HAI. In addition, the Swiss Society for Infection Prevention (www.sgsh.ch) created guidelines on endoscope reprocessing and participated in creating several good practice norms.

Outbreaks and pandemic threats

Beside the steady progress in prevention of endemic healthcare-associated infections, national and international epidemic threats have marked the history of IPC in Switzerland.

The first **methicillin-resistant *Staphylococcus aureus*** (MRSA) epidemic in Switzerland was described in 1968 in Zurich.[15] Only 30 years later, MRSA became endemic with a steep rise in the rate of MRSA colonisations and infections especially in the French part of Switzerland, which absorbed a significant amount of resources and became the number one IPC target for years.

The **variant Creutzfeldt-Jakob epidemic** in the UK starting in 1996 with its peak in 2000 triggered a national prevention initiative in Switzerland. Swissnoso was asked to examine the evidence and help to formulate a law on reprocessing multiple-use items.

In 2009, the **H1N1 influenza pandemic** dominated the activity with IPC teams and Swissnoso and issued national pandemic guidelines.

Severe acute respiratory syndrome (SARS) emerged 2003 as a deadly pandemic with an origin in China and a secondary main focus in Toronto, Canada, that vividly demonstrated the potential of transfer of an infection in a single patient over large distances by air travel. Swiss prevention guidelines were published by Swissnoso in 2005, when 20'000 visitors from the epidemic area were attending the world watch and jewellery exhibition in Switzerland

(https://www.swissnoso.ch/fileadmin/swissnoso/Dokumente/6_Publikationen/Bulletin_Artikel_D/
v12_2_2005-06_Swissnoso_Bulletin_de.pdf).

In 2014, the so far largest **Ebola outbreak** in West Africa challenged the fractionated Swiss
healthcare system to organize high-security treatment units and transports of a potentially
infected patient between hospitals. Today two centres are still prepared to treat patients with
highly dangerous pathogens, but a national scheme to finance these preparedness is still
pending.

The **avian influenza H5N1** Human infections were first reported in 1997 in Hong Kong. Since
2003, more than 800 human cases of Asian HPAI H5N1 have been reported from 16 countries
in Asia, Africa, the Pacific, Europe, and the Middle East, though over 60 countries have been
affected. Switzerland never saw an infected patient, but the virus was isolated from birds on
several occasions.

In 2010, two cardiac surgery patients with foreign material implants were detected with the often
fatal *Mycobacterium chimaera* infections in the University Hospital Zurich.[16,17–25] The
investigations revealed in 2013 the source and transmission pathway by aerosolisation from
contaminated heater-cooler units, a stand-alone device containing a water tank and circulation
system used to cool the cardioplegia solution and blood in the extracorporeal circuit. The
cooling fans propelled the contaminated air onto the surgical field. In an investigation that FOPH
mandated to Swissnoso, half of the 18 concerned centres were found to operate contaminated
heater-cooler units. In an astonishingly slow succession, many studies involving modern next-
generation sequencing methods found that contamination happened at the heater-cooler
factories as well as in hospitals from water sources. This outbreak demonstrated a European
wide lack of accountability of medical devices companies.

Burkholderia stabilis associated with contaminated commercially-available washing gloves,
Switzerland, May 2015 to August 2016.[26] Next generation sequencing showed a unique strain
found in patients and new wipe packages - and at the production site of the factory. Overall, 46
patients were colonized or infected by these wipes, one patient died. This outbreak made clear
that the resistance reporting system *Anresis* should also be used as an early warning system for
potential outbreaks.[27]

An epidemiologically successful strain of **vancomycin-resistant *Enterococcus faecium* VanB**
occurred in 2017 in the University Hospital of Bern and then spread to regional hospitals in the

canton and to others hospitals in Switzerland.[28,29] A national taskforce has been created to issue guidance for hospitals, and as of February 2019, the epidemic is not yet stopped. Gaps in screening policies and heterogeneous cluster management were identified as potential cause.[29]

Promotion

The promotion of good IPC practice has always been a pivotal cornerstone of IPC and certainly been present in individual hospitals even before any national initiatives.

On a national level the first large promotional campaign was organized by Swissnoso in 2005/2006 to improve the adequate use of **hand hygiene in healthcare**. The idea was based on the successful multi-modal promotion strategy in the University Hospitals of Geneva[30] and further developed in parallel the WHO Guide for Hand Hygiene in Healthcare was produced in conjunction with the First Global Challenge for Patient Safety based on five avenues of action, systems design, leadership, monitoring and feedback, education, promotion (https://www.who.int/infection-prevention/publications/hand-hygiene-2009/en/). With this activity organisational and individual psychology was taken up by IPC as a tool to achieve the use of best practice in healthcare.[31] Human factors and usability design was applied as a powerful tool to hand hygiene promotion.[32] The Swiss Hand Hygiene Campaign was the largest effort to improve patient safety in Switzerland with over 100 participating hospitals and hand hygiene adherence measured before and after implementation efforts from 53% to 68%.

In the wake of this campaign, Swissnoso introduced a mobile solution to monitor hand hygiene adherence by direct observation, **CleanHands** that was developed and introduced in the Canton St. Gallen and meets a great success with over 170'000 hand hygiene opportunities from 95 institutions with an overall hand hygiene adherence of 75 entered since its launch (https://www.swissnoso.ch/fileadmin/swissnoso/Dokumente/6_Publikationen/Bulletin_Artikel_D/181112_Fulchini_DE_TR.pdf).

In 2015 Swissnoso together with Patientensicherheit Schweiz launched a pilot program to measure and reduce urinary catheter utilization and both **catheter-associated urinary tract infections (CAUTI)** and non-infectious complications of catheters and accompanied this endeavour with healthcare worker surveys on knowledge and practice surrounding catheters.[33] The seven pilot hospitals saw a significant reduction in catheter utilization, more correct indications, more frequent re-evaluation of the need for catheterization, and fewer non-infectious

complications; however, CAUTI were on an already low level and did not drop further. The national roll-out of this surveillance and the intervention bundle is a reasonable next step.

In 2015, a pilot study started to not only survey surgical site infections, but provide Swiss hospitals with a proactive **surgical site infection prevention implementation module**. It contains key elements of the WHO guidelines 2016 with 10 pilot hospitals. The majority of participating hospitals succeeded to decrease the rate of surgical site infections.

Finally, the IPC community is increasingly embracing the power of **social media** and edutainment (https://www.youtube.com/watch?v=zOhwNxgCyZI; https://www.youtube.com/watch?v=wLNJCA7V-B).

Education and knowledge exchange

A formal educational track for nurses to become IPC practitioners has existed in the French and German speaking parts of the country for years, but was established as a certifying national program only in 2010 (https://www.epsante.ch/berufe/hfp-fachexperte-in-fuer-infektionspraevention-im-gesundheitswesen/).

An important means of education opportunity existed in the one-week CDC/SHEA courses with different proficiency levels each year in another location in Switzerland. This opportunity has ended.

After several failed attempts to create an **IPC curriculum and certification for medical doctors** over the past 15 years, a formal subtitle (Schwerpunkt) was accepted by the FMH in 2018. The process to establish corresponding educational pathways and structures is still ongoing.

Outside of certifying education an exchange of knowledge is provided through meetings organized by national surveillance and promotional schemes and conferences such as the joint annual meeting of the Swiss Society of Infectious Diseases and the Swiss Society of Infection Prevention, the so-called Club de Pathologie, the Journée romande d'Hygiène Hospitalière and regional meetings regularly organized by University Hospitals. Since 2011, Switzerland is also the organizing country of the large **International Conference on Prevention and Infection Control (ICPIC)**, taking place every other year and attracting more than 1000 participants from

>100 countries. In 2020, Switzerland will organize the Ministerial Summit on Patient Safety with Health Ministers from 40 countries, focusing on patient safety and HAI.

Policy

On a national level, two laws drove the evolution of IPC in Switzerland, the 1996 revised law on insurances and the 2016 revised law on epidemics that both have their stakeholders in the FOPH. The new law on epidemics laid the foundation for the first national IPC strategy (see below), while the law on insurance led to activities in the field of patient safety outside of IPC.

Several policies regarding IPC requirements for hospitals regarding structure and participation in quality improvement or surveillance activities have emerged on a cantonal level. Financial incentives and requirements regarding IPC topics have also been integrated in contracts between hospitals and insurance companies.

The introduction of per-case reimbursement based on diagnostic-related groups (DRG) and the ownership status of public and private hospitals have led to a commercialisation of Swiss healthcare providers. This has attracted more attention to complications such as HAI that potentially diminish the revenues of hospitals. Additionally, hospitals see themselves increasingly in a competing, market-driven healthcare landscape and consider quality aspects such as IPC efforts and low HAI rates as advertising assets. This increases the status of IPC on the priority list with hospital leadership.

Breakthrough national infection and prevention programs

The fight against HCI is not yet won, the preventable proportion of HAI remains between 30-70% according to a recent review.[34] Two recent assessments paint the picture of the burden of HAI and the state of affairs regarding IPC in Switzerland.

A survey on IPC staffing and the implementation was conducted in which 137 Swiss hospitals (46% of all H+ members) and 125 long-term facilities (37% of all Curaviva members) participated. The results showed a heterogeneous picture of Surveillance, prevention and control of HAI

(https://www.bag.admin.ch/dam/bag/de/dokumente/mt/noso/nosoumsetzung/strategie-noso-ist-analyse.pdf.download.pdf/strategie-noso-ist-analyse.pdf) (see **Tables 1 and 2**; reproduced with permission of the authors). This review of IPC in Switzerland also lists the innumerable actors and their respective roles that are involved on national, cantonal, and institutional levels.

In 2017, Swissnoso re-installed trans-sectional surveillance of all HAI in alignment with the European definitions and method as one-day point-prevalence studies with 96 hospital participating (https://www.swissnoso.ch/forschung-entwicklung/punktpraevalenz-erhebung/resultate/). The overall prevalence of patients suffering from at least one HAI in Swiss hospitals was 5.9% (against 6% in the last European survey). When standardized according to hospital size, prevalence was 5.4%. Surgical site infections accounted for 29%, lower respiratory tract infection for 18%, urinary tract infections for 15%, and primary bloodstream infections for 13% of all infections. As additional values the survey also assessed invasive devices and antibiotic use, and other data associated with infectious risks such as general and IPC staffing and consumption of alcohol-based handrub. **Figure 1-3** display the main results of this surveillance scheme.

Two current initiatives by FOPH tackle the inter-connected fields of prevention of HAI and antibiotic resistance on a national level. These two programs leverage and funnel the existing expertise and historically evolved activity by the many stakeholders among which Swissnoso and the Swiss Society of Infection Prevention play a major role. Importantly, they also provide the necessary finances and make achieving goals realistic.

The **NOSO Strategy** (https://www.bag.admin.ch/bag/en/home/strategie-und-politik/nationale-gesundheitsstrategien/nationale-strategie-ueberwachung-verhuetung-bekaempfung-von-spital-pflegeheiminfektionen.html) is initiated, driven, and financed by FOPH based on the national law in epidemics (article 5 paragraph 1b EpG). It is based on 4 action areas with defined goals: governance, monitoring, prevention and control, and education and research. HAI surveillance is being extended, integrating the existing surveillance modules by Swissnoso.

The strategy includes **long-term care and outpatient settings**. Some cantons (e.g. Valais and Vaud) have already developed programs for IPC in nursing homes and public ambulatory services consisting in the education of healthcare workers, periodic workshops or audits by IPC nurses, and specific guidelines, e.g. for multi-resistant microorganisms. Recently, some cantons from Western Switzerland developed a practical guide for prevention and treatment of infections in nursing homes (https://guide.hpci.ch/) in French and German.

The Strategy against Antibiotic Resistance (StAR;
https://www.star.admin.ch/star/en/home.html**)** takes a One Health approach that seems unique in an international comparison, integrating the veterinary and agriculture domains. Many stakeholders are involved, including the Swiss IPC societies, the Swiss Society Infectious Diseases, and Swissnoso.

Outlook and discussion

The evolution of IPC in Switzerland depicts the evolution of a major movement in healthcare and led the way for patient safety and quality management beyond the infectious risk. It could labelled as IPC 1.0 focussing on reprocessing and disinfection, IPC 2.0 adopting evidence based medicine and epidemiology, and IPC 3.0 integrating the social sciences and human factors engineering.

Infection prevention and control 4.0

In the next 5-10 years it will be crucial to consolidate the heterogeneous range of programs and initiatives to work synergistically and efficiently towards a goal of eliminating preventable HAI in the Swiss healthcare system. It will be a challenge to strike the right balance between regulation and intrinsic motivation by individual hospital leadership and their IPC teams, between standardization on a national level and the necessary liberty to identify local problems and to orient limited resources to achieve maximum benefit on the hospital levels.

A national surveillance system of epidemiologically important pathogens (e.g. based on the Anresis program) should serve as an early outbreaks warning system. This surveillance platform should be open enough to integrate new ways to identify epidemiologically successful or virulent pathogens on the strain level, e.g. using next-generation sequencing.

Despite years of promotion, individual human behaviour in the face of the invisible threat of microorganisms and complex multiple casualties still represents a huge challenge. The integration of human factors design of infrastructures and processes offers low hanging fruit that have yet to be picked. The relatively young science of implementation holds promises if fully leveraged in the complex contexts of healthcare systems.[35] Both approaches overlap and use qualitative inquiry with those involved at the front end, the healthcare workers and their psychological and ergonomic daily reality. Of course, IPC success depends on safety culture in

general and its elements such patient-centeredness, as learning from errors and success, speaking up, etc. Complexity science should be added to useful sources in this respect.[36]

Data science, machine learning and artificial intelligence will see rapid growth in the next years and will have to be integrated in IPC with all the involved challenges such as high investment risks, data privacy and security, and data accuracy at their source. Sensor technology will collect valuable information on transmission pathways and infectious risks. This will allow to produce and understand process quality and HAI rates on a completely new level. 'Forgotten' HAI such as non-ventilator-associated pneumonia can be surveyed and integrated in prevention bundles.

The involvement of patients through their access to medical information through web sources, mobile devices, and social media has to be taken into account. This might also bring surveillance of HAI in the ambulatory and home medicine in arms reach.

The increasing focus on health-economic can have an advantageous or disadvantageous impact on IPC, can foster prevention to increase efficiency or increase infectious risk by decreasing quality of care. Reciprocally, IPC has to be an integral part of an overall governance of healthcare quality to resolve competing goals and achieve the optimal outcome for our patients: to regain and maintain health.

References

1. Pittet D, Francioli P, von Overbeck J, et al. Infection Control in Switzerland. *Infect Control Hosp Epidemiol* 1995; 16: 49–56.

2. Pittet D, Harbarth S, Ruef C, et al. Prevalence and Risk Factors for Nosocomial Infections in Four University Hospitals in Switzerland. *Infect Control Hosp Epidemiol* 1999; 20: 37–42.

3. Harbarth S, Ruef C, Francioli P, et al. Nosocomial infections in Swiss university hospitals: a multi-centre survey and review of the published experience. Swiss-Noso Network. *Schweiz Med Wochenschr* 1999; 129: 1521–1528.

4. Sax H, Swiss-NOSO. [Nationwide surveillance of nosocomial infections in Switzerland-- methods and results of the Swiss Nosocomial Infection Prevalence Studies (SNIP) in 1999 and 2002]. *Ther Umsch* 2004; 61: 197–203.

5. Sax H, Pittet D, Swiss-NOSO Network. Interhospital differences in nosocomial infection rates: importance of case-mix adjustment. *Arch Intern Med* 2002; 162: 2437–2442.

6. Sax H, Hugonnet S, Harbarth S, et al. Variation in nosocomial infection prevalence

according to patient care setting:a hospital-wide survey. *J Hosp Infect* 2001; 48: 27–32.

7. Sax H, Uçkay I, Balmelli C, et al. Overall Burden of Healthcare-Associated Infections Among Surgical Patients. *Ann Surg* 2011; 253: 365–370.

8. Uçkay I, Sax H, Gayet-Ageron A, et al. High proportion of healthcare-associated urinary tract infection in the absence of prior exposure to urinary catheter: a cross-sectional study. *Antimicrob Resist Infect Control* 2013; 2: 5.

9. Staszewicz W, Eisenring M-C, Bettschart V, et al. Thirteen years of surgical site infection surveillance in Swiss hospitals. *J Hosp Infect* 2014; 88: 40–47.

10. Hübner M, Diana M, Zanetti G, et al. Surgical site infections in colon surgery: the patient, the procedure, the hospital, and the surgeon. *Arch Surg* 2011; 146: 1240–1245.

11. Romy S, Eisenring M-C, Bettschart V, et al. Laparoscope use and surgical site infections in digestive surgery. *Ann Surg* 2008; 247: 627–632.

12. Troillet N, Aghayev E, Eisenring M-C, et al. First Results of the Swiss National Surgical Site Infection Surveillance Program: Who Seeks Shall Find. *Infect Control Hosp Epidemiol* 2017; 38: 697–704.

13. Abbas M, Aghayev E, Troillet N, et al. Temporal trends and epidemiology of Staphylococcus aureus surgical site infection in the Swiss surveillance network: a cohort study. *J Hosp Infect* 2018; 98: 118–126.

14. Kuster SP, Eisenring M-C, Sax H, et al. Structure, Process, and Outcome Quality of Surgical Site Infection Surveillance in Switzerland. *Infect Control Hosp Epidemiol* 2017; 38: 1172–1181.

15. Fleisch F, Zbinden R, Vanoli C, et al. Epidemic spread of a single clone of methicillin-resistant Staphylococcus aureus among injection drug users in Zurich, Switzerland. *Clin Infect Dis* 2001; 32: 581–586.

16. Sax H, Bloemberg G, Hasse B, et al. Prolonged Outbreak of Mycobacterium chimaera Infection After Open-Chest Heart Surgery. *Clin Infect Dis* 2015; 61: 67–75.

17. Sommerstein R, Rüegg C, Kohler P, et al. Transmission of Mycobacterium chimaera from Heater-Cooler Units during Cardiac Surgery despite an Ultraclean Air Ventilation System. *Emerg Infect Dis* 2016; 22: 1008–1013.

18. Schreiber PW, Kuster SP, Hasse B, et al. Reemergence of Mycobacterium chimaera in Heater-Cooler Units despite Intensified Cleaning and Disinfection Protocol. *Emerg Infect Dis* 2016; 22: 1830–1833.

19. Sommerstein R, Schreiber PW, Diekema DJ, et al. Mycobacterium chimaera Outbreak Associated With Heater-Cooler Devices: Piecing the Puzzle Together. *Infect Control Hosp Epidemiol* 2017; 38: 103–108.

20. Schreiber PW, Sax H. Mycobacterium chimaera infections associated with heater-cooler units in cardiac surgery. *Curr Opin Infect Dis* 2017; 30: 388–394.

21. van Ingen J, Kohl TA, Kranzer K, et al. Global outbreak of severe Mycobacterium chimaera

disease after cardiac surgery: a molecular epidemiological study. *Lancet Infect Dis* 2017; 17: 1033–1041.

22. Schreiber PW, Köhler N, Cervera R, et al. Detection limit of Mycobacterium chimaera in water samples for monitoring medical device safety: insights from a pilot experimental series. *J Hosp Infect* 2018; 99: 284–289.

23. Sommerstein R, Hasse B, Marschall J, et al. Global Health Estimate of Invasive Mycobacterium chimaera Infections Associated with Heater-Cooler Devices in Cardiac Surgery. *Emerg Infect Dis* 2018; 24: 576–578.

24. Plate A, Kohl TA, Keller PM, et al. Aortic Endograft Infection with Mycobacterium chimaera and Granulicatella adiacens, Switzerland, 2014. *Emerg Infect Dis* 2018; 24: 1700–1704.

25. Schreiber PW, Hasse B, Sax H. Mycobacterium chimaera infections after cardiac surgery-lessons learned. *Clin Microbiol Infect* 2018; 24: 1117–1118.

26. Sommerstein R, Führer U, Lo Priore E, et al. outbreak associated with contaminated commercially-available washing gloves, Switzerland, May 2015 to August 2016. *Euro Surveill*; 22. Epub ahead of print December 2017. DOI: 10.2807/1560-7917.ES.2017.22.49.17-00213.

27. Sommerstein R, Führer U, Lo Priore E, et al. Burkholderia stabilis outbreak associated with contaminated commercially-available washing gloves, Switzerland, May 2015 to August 2016. *Eurosurveillance*; 22. Epub ahead of print 2017. DOI: 10.2807/1560-7917.es.2017.22.49.17-00213.

28. Wassilew N, Seth-Smith HM, Rolli E, et al. Outbreak of vancomycin-resistant clone ST796, Switzerland, December 2017 to April 2018. *Euro Surveill*; 23. Epub ahead of print July 2018. DOI: 10.2807/1560-7917.ES.2018.23.29.1800351.

29. Buetti N, Wassilew N, Rion V, et al. Emergence of vancomycin-resistant enterococci in Switzerland: a nation-wide survey. *Antimicrob Resist Infect Control* 2019; 8: 16.

30. Pittet D, Hugonnet S, Harbarth S, et al. Effectiveness of a hospital-wide programme to improve compliance with hand hygiene. Infection Control Programme. *Lancet* 2000; 356: 1307–1312.

31. Pittet D. The Lowbury lecture: behaviour in infection control. *J Hosp Infect* 2004; 58: 1–13.

32. Sax H, Allegranzi B, Uçkay I, et al. 'My five moments for hand hygiene': a user-centred design approach to understand, train, monitor and report hand hygiene. *J Hosp Infect* 2007; 67: 9–21.

33. Niederhauser A, Züllig S, Marschall J, et al. Nurses' and Physicians' Perceptions of Indwelling Urinary Catheter Practices and Culture in Their Institutions. *J Patient Saf*. Epub ahead of print 29 May 2018. DOI: 10.1097/PTS.0000000000000502.

34. Schreiber PW, Sax H, Wolfensberger A, et al. The preventable proportion of healthcare-associated infections 2005-2016: Systematic review and meta-analysis. *Infect Control Hosp Epidemiol* 2018; 39: 1277–1295.

35. Clack L, Zingg W, Saint S, et al. Implementing infection prevention practices across

European hospitals: an in-depth qualitative assessment. *BMJ Qual Saf* 2018; 27: 771–780.

36. Braithwaite J. Changing how we think about healthcare improvement. *BMJ* 2018; 361: k2014.

Tables and Figures

Table 1. IPC structures in participating acute and long-term care institutions

Tabelle 2 Strukturen im Bereich Infektionen im Zusammenhang mit Spital- oder Heimaufenthalt

	Spitäler (n=137)	Pflegeinstitutionen (n=125)
Hygienerichtlinien vorhanden	100%	100%
Spital- bzw. Heimhygiene vorhanden	97%	95%
Falls ja, am häufigsten angeschlossen bei:	*(n=133)*	*(n=119)*
Pflege	41%	55%
Spitaldirektion bzw. Heimleitung/Administration	18%	9%
Qualitätsmanagement	16%	22%
Infektiologie	13%	--
Hauptverantwortliche Person im Hygieneteam vorhanden	90%	73%
Falls ja, häufigste berufliche Ausbildung(en), Fachabschlüsse:	*(n=123)*	*(n=91)*
Pflegediplom	64%	96%
Medizinstudium	36%	3%
Master/PhD in Public Health oder Epidemiologie	8%	1%
Falls ja, Abschluss in Epidemiologie oder Spital-/Heimhygiene:	*(n=123)*	*(n=91)*
ja	55%	10%
Spital- bzw. Heimepidemiologe/-epidemiologin* vorhanden	44%	13%
Stellenprozente für Spital- bzw. Heimhygienefachkräfte pro 125 Betten bzw. Plätze, Median (IQR**)	39 (14-75)	7 (0-23)
Zusammenarbeitsverträge im Bereich Spital- bzw. Heimhygiene im Kanton/der Region vorhanden	45%[2]	28%[2]

*Arzt, PhD oder Pflegediplom mit Spezialausbildung in Spital- bzw. Heimepidemiologie und Spital- bzw. Heimhygiene

**IQR = Interquartilsabstand

Table 2. IPC-relevant programs in acute and long-term care institutions

Tabelle 3 Programme im Bereich Infektionen im Zusammenhang mit Spital- oder Heimaufenthalt

	Spitäler (n=137)	Pflegeinstitutionen (n=125)
Teilnahme an regionalen, nationalen und internationalen Programmen zur Reduktion von Infektionen im Zusammenhang mit Spital- oder Heimaufenthalt	72%	26%
Häufigkeit einzelner regionaler, nationaler und internationaler Programme		
Swissnoso/ANQ Überwachung postoperativer Wundinfektionen	66%	–
Jährliche Grippeimpfkampagne des BAG	49%	24%
Jährliche WHO Händehygienekampagne	36%	17%
Progress! Sichere Chirurgie	10%	–
Clean Hands (Kantonsspital St. Gallen)	8%	–
KISS (Krankenhaus-Infektions-Surveillance-System)	7%	–
WHO Safe Surgery Saves Lives	6%	–
Eigene, lokale Programme zur Überwachung von Infektionen im Zusammenhang mit Spital- oder Heimaufenthalt	54%	28%
Häufigkeit einzelner lokalen Programme		
Prävalenzstudien	31%	6%
Überwachung von Bakteriämien	24%	6%
Überwachung postoperativer Wundinfektionen (ausserhalb Swissnoso/ANQ)	20%	8%
Überwachung von Harnwegsinfektionen	15%	18%
Überwachung von Pneumonien	11%	6%
Überwachung multiresistenter Bakterien	7%*	14%
Andere spezifische Programme im Bereich Spital-/Heimhygiene	51%	38%
Häufigkeit einzelner spezifischer Programme		
Programm zur Verbesserung der Händehygienecompliance	45%	35%
Programm zur Reduktion postoperativer Wundinfektionen	20%	2%
Programm zur Reduktion von Bakteriämien	11%	5%
Programm zur Reduktion von Harnwegsinfektionen	9%	10%
Programm zur Reduktion von Pneumonien	6%	2%
Verbesserungspotenziale in der eigenen Institution**		
Händehygiene	25%	18%
Personelle Ressourcen	13%	6%
Aus- und Weiterbildung	9%	19%
Überwachung	7%	0%
Richtlinien und Konzepte	5%	9%
Zusammenarbeit und Vernetzung	4%	6%

*Im Fragebogen für die Spitäler nicht vorgegeben (im Freitext erfasst) / **Offene Frage

Figure 1. Prevalence of healthcare-associated infections by hospital size

HAI - prevalence by Hospital Size
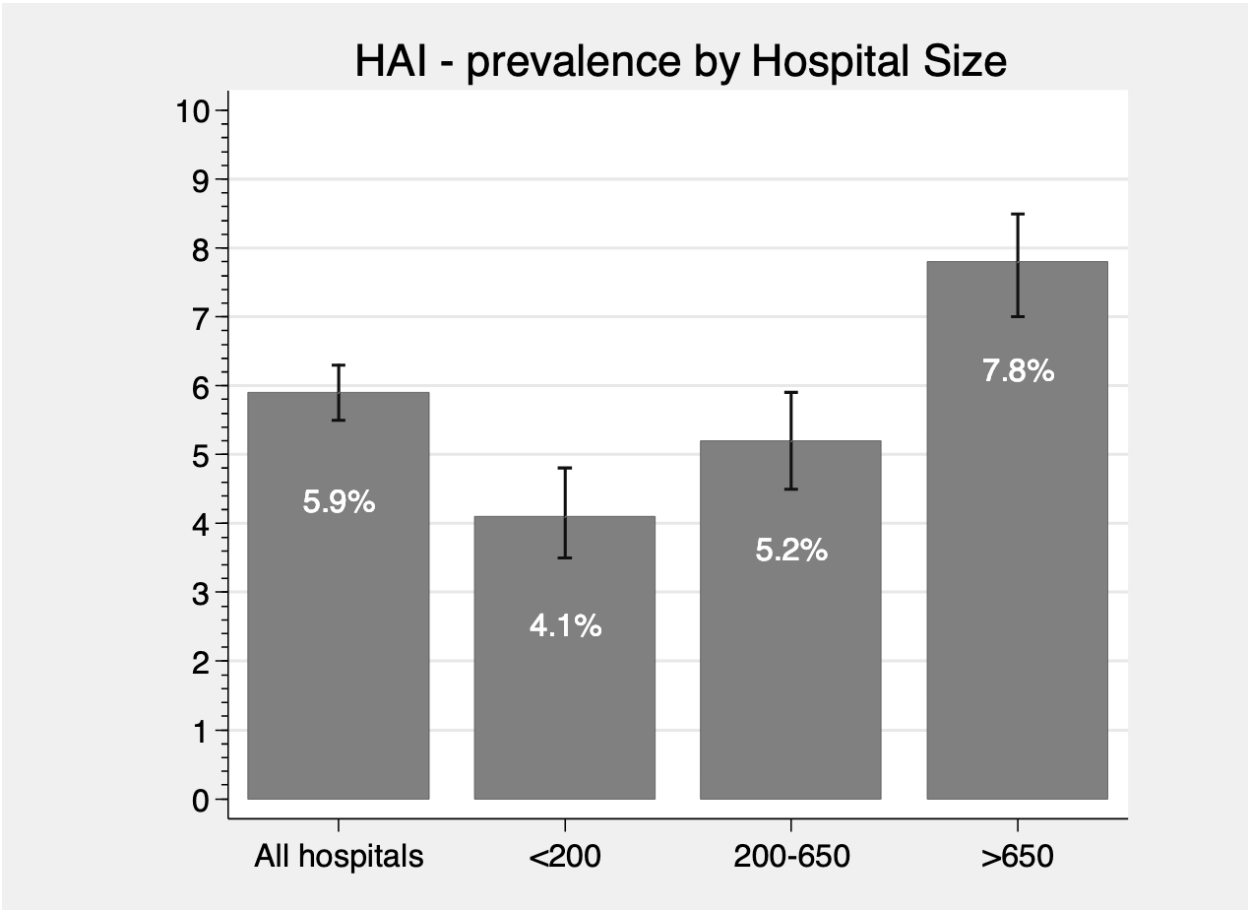
Figure 2. Distribution of infection types (n=835)

Distribution of Infection-Types

29.0% SSI
18.2% LRTI
14.9% UTI
12.8% BSI
9.1% GI
6.1% SYS
3.0% EENT
0.7% NEO
6.1% OTH

Legend of pie chart:
- SSI
- LRTI
- UTI
- BSI
- GI
- SYS
- EENT
- NEO
- OTH
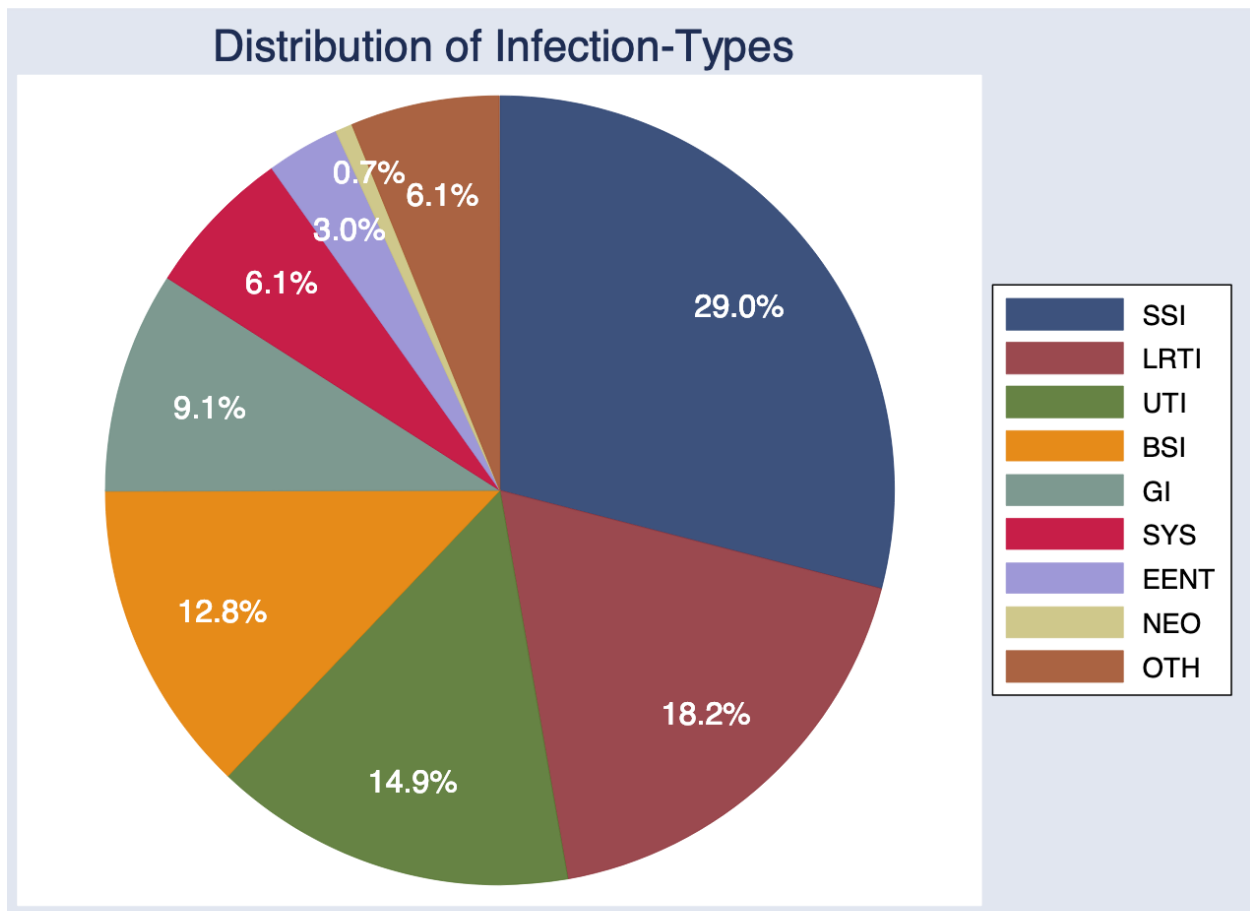
Legend: Distribution of HAI types (835 HAIs): SSI: surgical site infection; LRTI: lower respiratory tract infection; UTI: urinary tract infection; BSI: bloodstream infection; GI: gastrointestinal infection; SYS: systemic infection; EENT: eye, ear, nose, throat, or mouth infection; NEO: specific neonatal case definitions; OTH: other infection.

Figure 3. Prevalence of healthcare-associated infections by hospital type

HAI - prevalence by Hospital Type
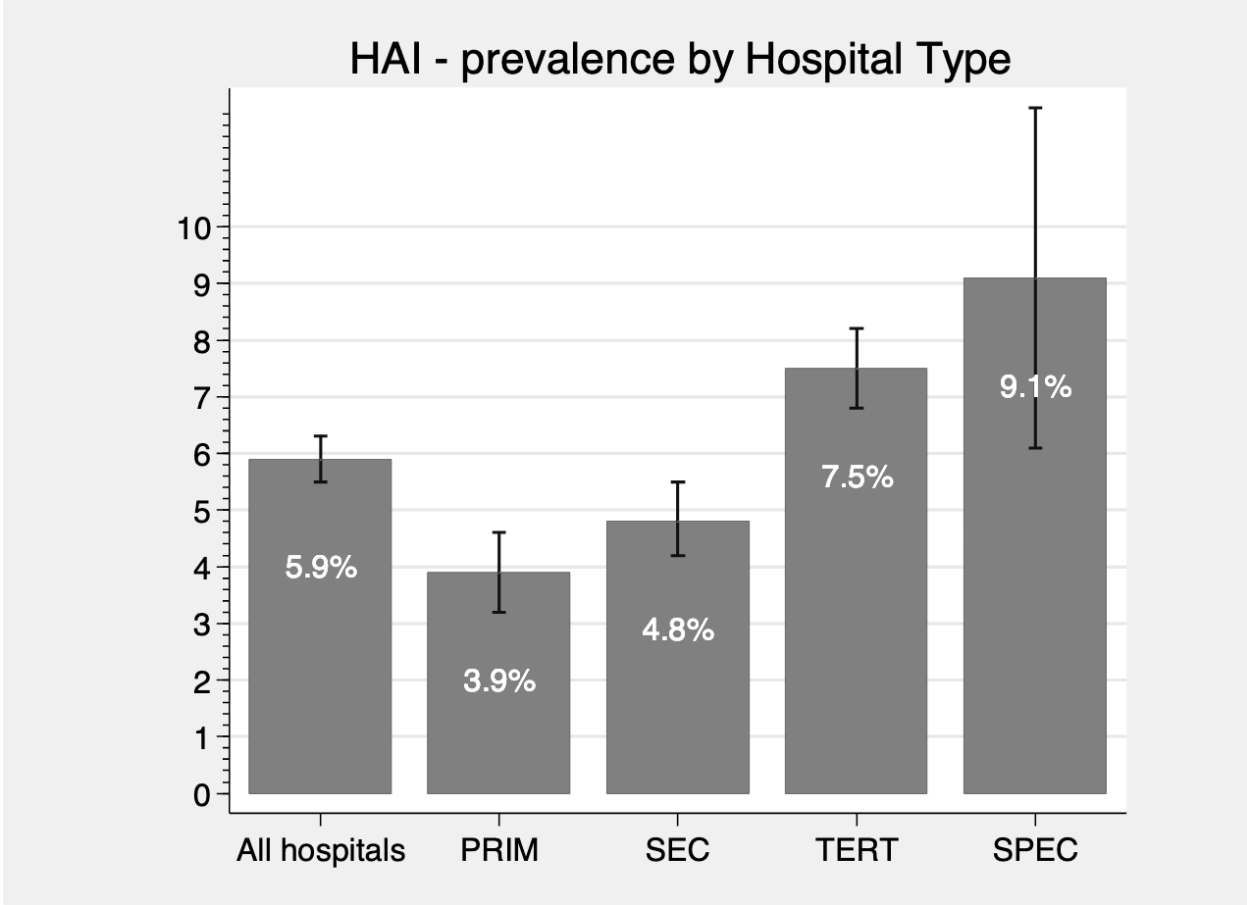
Legend: HAI: healthcare-associated infection; PRIM: primary care; SEC: secondary care; TERT: tertiary care; SPEC: specialized care

Education and training in safety and quality improvement

A short report for the

Swiss National Report on Safety and Quality of Care

Gaëlle Dessard-Choupay[1], Pascal Briot[1], Pierre Chopard[1][2]

[1] Quality of Care Division, Medical Directorate, Geneva University Hospitals,

[2] School of Medicine, Geneva University

January 2019

Abstract

In the past twenty years the education and training of healthcare professional have been adapted to reflect the growing recognition of the importance of safety and quality in the process of care first highlighted nationally in the two reports of the American Institute of Medicine (IOM) in 2000 To Err is Human and Crossing the Quality Chasm. While the IOM recommended a specific framework of actions and transformations to improve safety and quality of care with education and training at its core, the implementation of this framework has varied greatly across systems. Today we note a heterogeneity of the content of these training programs (mainly focus on teamwork, safety and patient centeredness) and of their target audience (mainly healthcare workers). However, to address the challenges that the Swiss health system is facing today and will face tomorrow, we also need to develop other domains of training such as quality management, process variation analysis, statistical process control and to insure that all the actors of the system such as policymakers, executives, operational leaders, clinical leaders, frontline staff are exposed to these education programs. Education and training in quality and safety must become a strategic element of the transformation of our system and it is imperative that a special effort be placed on continuing education to prepare today our professionals to meet the current and upcoming challenges.

Introduction

Since the American Institute of Medicine (IOM) first published in 2000 "To err is human"[1] and "Crossing the Quality Chasm"[2] these two reports have had a profound and global impact on the delivery of care. They highlighted the huge problems of safety and quality in healthcare. Before their publication the debate was limited to more technical and methodological aspects. These reports completely reoriented the debate from "how to measure what is done" to "how to do improve what is done" and they have been progressively adopted by the healthcare delivery systems, the politicians and the public. They described possible strategies, listed in table 1, for health systems to provide safe, effective, patient-centered, timely, efficient, and equitable care. The ultimate goal is to improve "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" [3]. Health care system should be able to manage the six Quality dimensions below and deliver care that is:

o *Safe* - avoiding injuries to patients from the care that is intended to help them.
o *Effective* - providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively).
o *Patient-centered* - providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
o *Timely* - reducing waits and sometimes harmful delays for both those who receive and those who give care.
o *Efficient* - avoiding waste, including waste of equipment, supplies, ideas, and energy.
o *Equitable* - providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.

Table 1: The six dimensions of quality of care [2]

To meet the challenges associated with the implementation of the six dimensions of care health professionals must develop new skills. In 2003 the IOM defined five core competencies that all health professionals should possess, regardless of their discipline, to meet the needs of the 21st-century healthcare system: to provide patient-centered care, to work in interdisciplinary teams, to employ evidence-based practice, to apply quality improvement and to utilize informatics[4].
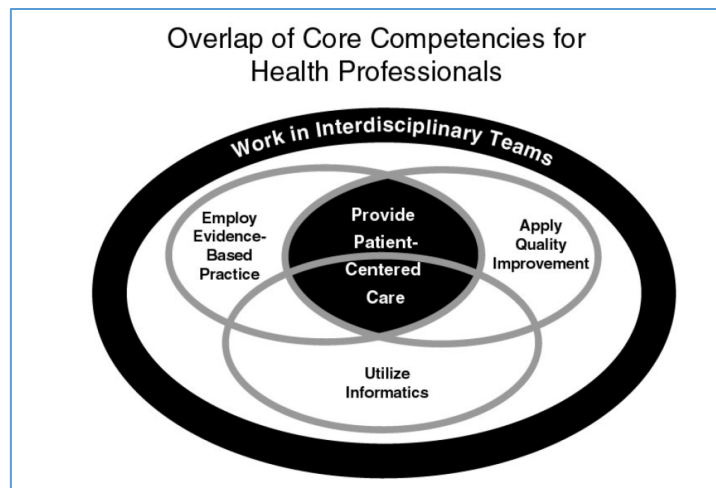
Figure 1. The five core competencies for healthcare professionals to meet the needs of the 21st healthcare system [4]

Over the years the implementation of the six dimensions of quality of care and the teaching and use of the five core competencies of the IOM's recommendations have varied greatly across national healthcare systems and within systems. The attention of the public, experts and governments has been more focused on the issue of safety of care than on the broader issue of quality of care. As a result most international and national organizations adopted strategies to emphasis the "safety" dimension of the delivery of care which had a considerable impact on their approach to transforming their systems.

For example, the World Health Organization (WHO) recognizing the global need for patient safety launched in 2005 the First Global Patient Safety Challenge: "Clean Care is Safer Care". It is followed in 2008 by the Challenge "Safe Surgery Saves Lives" to reduce risks associated with surgery and in 2017 by the Challenge "Medication without Harm" to reduce the level of severe and preventable harm related to medication. In parallel and to help with these initiatives the WHO developed the Patient Safety Curriculum Guide for Medical Schools and the Multi-Professional Patient Safety Curriculum Guide for healthcare professionals.

On the other hand, only a few organizations or health systems have developed strategies based on the six Quality dimensions of care and the five core competencies.

Among these organizations, the Institute for Healthcare Improvement (IHI) is certainly the most influential in the field of quality both nationally and internationally. Since it was started in 1991, it has promoted a systemic approach for Quality Improvement (QI) and it is committed to redesigning healthcare into a system without errors, waste, delay, and unsustainable costs. Since 1996, it organizes the most famous annual conferences on Quality and QI in the world, the "Forum on Quality Improvement in Health Care" held both in the USA and in Europe. Its success is based on a solid theoretical foundation in the field of quality improvement and its ability to carry out projects at all levels of the health system with all stakeholders. IHI has developed a training platform adapted to its different target audiences (clinicians and non-clinicians involved in the healthcare system as well as managers and executives). It has established collaborations on many different topics in Europe with the healthcare systems of England, Scotland, Denmark, Sweden and Portugal.

Among the health systems the Australian Commission on Safety and Quality in Health Care has placed Quality and QI at the core of the transformation of its system since 2006. It works in partnership with patients, consumers, clinicians, managers, policy makers and healthcare organizations to achieve a sustainable, safe and high-quality health system. Its strategic

4

priorities for the next four years are in the areas of patient safety; partnering with patients, consumers and communities; providing quality cost and value; and supporting health professionals to provide safe and high-quality care. In 2010, it launched the Australian Safety and Quality Framework for Health Care which specified three core principles for safe and high quality care: consumer centred, driven by information, and organized for safety. Today it is applied in all parts of the Australian healthcare system. For each target audience (clinicians, managers, health service executives, board members and policy makers) specific "Getting Started" documents are used to facilitate the adoption and deployment of the model via concrete quality improvement projects.

It is important to note with both the experience of IHI and the Australian Commission on Safety and Quality in Health Care the importance of their training program anchored in a holistic approach of quality covering the entire health system and adapted to the specific needs of their target audience.

<u>What about Switzerland?</u>

I.   National agencies

Following the publication of the report "To err is human", the Federal Government created the National Patient Safety Foundation (NPSF) in 2003. It has a broad spectrum of activities on safety such as incident management, medication safety and safety culture. In 2012, the NPSF launched the national programs "Progress!" which were an integral part of the Confederation's strategy for quality. The first pilot program Progress! for surgical safety took place between 2013 and 2015 in 10 Swiss hospitals and was based on the WHO's program "Safe Surgery Saves Lives". The second national program "Medication Safety at the Transition" got implemented in eight hospitals from 2015 to 2016. The third program "Safety with Bladder Catheter" was carried out in seven hospitals between 2015 and 2018. The fourth Progress program is still running and concerns the "Safety of Medication in Medico-Social Establishments (EMS)".

The NPSF also organized two national congresses one in 2007 and another one in 2011 entitled "Patient Safety - Avanti!" which was a resounding success attracting more than 600 participants. It highlighted the many projects carried out throughout Switzerland and showed the real interest of the health professionals to share and learn in the field of safety.

In addition to the NPSF a second agency was created in 2009 the national association for quality development in hospitals and clinics (ANQ) which is in charge of national quality indicators for acute care, rehabilitation and psychiatry. It offers training to professionals focusing on the use of these indicators and the interpretation of their results. However, the ANQ does not offer training in the area of quality improvement.

II.   Universities and other institutions

A.   Source of information and results

We conducted a survey of schools of medicine and nursing, university hospitals as well as other institutions (Hospital Federation of Vaud, Federation of Swiss Physicians, NPSF) to get an overview of the training program offerings in the area of quality and safety of care. We did not take into account the internal training workshops given at hospitals or the activities developed within the medical disciplines for post-graduate training. Although not exhaustive, this survey presents a first overview of the training programs landscape for safety and quality across Switzerland.

The results of our survey show the existence of (see details in the appendix):
1.   Formal structured continuing education programs in quality and safety university based as well as non-university based.
2.   Short training education modules on quality and safety taught within formal continuous education or post-graduate programs in other disciplines.

3. Isolated training sessions on specific topics in quality and safety taught in different organizations.
4. Pre-graduate training taught within the professional schools such as schools of medicine and nursing.

1. Continuing education programs

Four university continuing education programs in the area of quality and safety of care were identified (see Table 2 page 8). Of these programs, only one is targeted at middle managers, the other three are targeted at the frontline staff. The basic concepts and tools for quality improvement are taught in the four programs while those for safety in three of the programs. ***However not all the dimensions or topics of quality and safety are covered in these programs.***

We also identified a non-university continuing education program to train Patient Safety Officer (6 days, three evenings)

2. Short training education modules

These modules are a few hours to a few days in length covering the basic concepts of quality and safety. They are fragmented and housed within different formal programs lacking overall standardization of content.

3. Isolated training sessions on specific topics

These include advanced sessions taught by experts in the field of quality and safety. They last from one to three days and offer a more in-depth teaching of the topics taught in the continuing education programs such as on teamwork, error and risk analysis, and management/strategy.

4. Pre-graduate training

In order for medical students to be better prepared to meet the new challenges, their catalogue of competences was updated in 2017. The new catalogue Profiles is based on the well-known CanMEDS catalogue and defines the seven roles that a physician should have and the level of expertise that a physician must possess in each of these roles at the beginning of his / her postgraduate training [5]. However Profiles focus on safety and does not take into consideration the recommendations of the CanMEDS 2015 report of experts which list the expected competencies in quality improvement and patient safety in the seven CanMEDS' roles [6]. For example in his/her role of manager, the future doctor should have received: "Training and proficiency in quality improvement methodologies important for active engagement in continuous quality improvement". Thus, there does not yet exist a quality and safety curriculum in our medical schools.

The situation appears to be identical with the nursing and other healthcare professional schools even though there exist thematic courses on quality and safety.

However in one of the five core competencies "work in interdisciplinary teams" a curriculum was developed as early as 2013 by the School of Health of Geneva (part of the University of Applied Sciences of Western Switzerland) for nurses, medical radiology technicians, dieticians, midwives and physiotherapists and starting in 2017 medical students were integrated. Pharmacists will join the program in 2019. This inter-professional training program is based on the acquisition of skills in inter-professional collaboration and cooperation through clinical situations with simulated patients. About 500 students are trained per year. To our knowledge this is the only integrated inter-professional curriculum for healthcare students taught over 3 years in Switzerland [7].

There also exists an inter-professional training program started in 2018 in Zurich ZIPAS (Zürcher Interprofessionelle Ausbildungsstation) using also clinical situations with simulated

patients. The target audience is expected to be both students and professionals from a vast range of healthcare specialties.

To be noted some counties are equipped with simulation teaching centres such as in Geneva, Bern, Basel and Zurich.

B. Lessons learned

1. Lessons learned from Swiss experience in the field of continuous training in quality and safety

In 2008, Swiss Patient Safety launched an Error and Risk Analysis course in collaboration with the HUG as a training program in the French speaking part of Switzerland. Ten years later, nearly 500 health professionals were trained. Virtually all public hospitals and private clinics in French-speaking Switzerland used the same concept, the same methods of analysis and the same language. This contributed to the development of a network of collaborators and institutions which favoured exchanges. The same positive experience was made for the CAS-DAS university courses in quality-safety of care as well as for the "Patient Safety Officer" training. The skills acquired by employees as we can observe in our hospitals had significant impacts on organizations in terms of quality improvement but the number of trained professionals remained limited.

Promising programs on the concept of Breakthrough Collaborative developed by IHI[1] have been implemented by the Hospital Federation of Vaud (FHV) for Hand Hygiene Improvement and pressure ulcers with some impressive results in terms of compliance to hand hygiene [8, 9] and risk reduction for pressure ulcers (oral communication).

2. Lessons learned from experience in the pre-graduate field

Among the five core competencies of the IOM (see figure 1) it appears that the "Apply quality improvement" is the least taught in our country. This might be due to the fact that this competency comes from industries far removed from the health sciences and until recently were not used at all in healthcare. In addition, if we want to develop student competencies in Quality Improvement we must also first build faculty capacity.

Some other countries are further along in their implementation of the five core competencies of the IOM. For example the Quality and Safety Education for Nurses (QSEN) project is an initiative to transform nursing education to fully integrate all of the IOM competencies defining specifically the knowledge, skills and attitude (KSAs) for each competency [10]. For the authors, the development of these KSA should "prepare future nurses to continuously improve the quality and safety of the healthcare systems in which they work".

Likewise some medical and nursing schools are in the process to develop curriculums that allow students to learn quality improvement methods and apply them to a clinical quality improvement project [11][12].

Conclusion

Numerous training programs have been set up in Switzerland in recent years in the area of quality of care, which shows a real interest and demonstrates many skills and expertise in this area. The teaching has been adapted and strengthened, particularly with regard to certain dimensions of quality such as patient-centred care and teamwork. New teaching methods have been introduced with simulation and patient-simulated to apply the acquired skills. It seems to have some weaknesses in the domain of quality improvement. These programs remain focused mainly on healthcare professionals. Non-clinician professionals, also indispensable to transform the system, seem "to be left behind". Our experience and the

---

[1] A Breakthrough Series Collaborative is a short-term (6- to 15-month) learning system that brings together a large number of teams from hospitals or clinics to seek improvement in a focused topic area

international literature on the topic points to the need for training all the actors of the health system both in the pre-graduate, postgraduate and professional areas. As well, the content of the training must be adapted to each target audience for the five core competencies.

The national, regional and local initiatives discussed are promising but remained fragmented and limited. To transform the Swiss healthcare system and engage its 250 000 workers will require that education and training must become a national and strategic priority. The skills acquired can then be mobilized in clinical QI initiatives such as to improve the management of patients with chronic illness or to reduce the adverse events associated with a technical procedure.

<u>Recommendations</u>

1. Education and Training in Quality and Safety should become a strategic priority for the Federal and County Governments:
   a. Pre-graduate : A quality safety curriculum must be established for each pre-graduate program with formal evaluation of students' acquired skills/competencies
   b. Post-graduate : even if we didn't assess the post-graduate training for doctors, QI skills/competencies should be included in the medical societies' requirements
   c. Continuing-education: QI trainings should be developed for target audiences such as top managers (executive boards, boards of trustees), middle managers and the frontline. MAS level programs must be developed to train future QI experts
2. A national platform of communities of practices should be created to:
   a. Provide healthcare workers with QI training content
   b. Share knowledge and experience about QI initiatives
   c. Launch national challenge for clinical improvement initiatives
3. A national congress "quality and safety of care" should be created and could serve to announce and start the deployment of this strategic priority

Bibliography

1. Kohn LT, C.J., Donaldson MS, ed. *To err is human: Building a safer health system*. The National Academies Press 2000.
2. medicine, I.o., ed. *Crossing the quality chasm: A new health system for the 21st century*. 2001, The National Academies Press: Washington, DC.
3. Lohr, K.N., ed. *Medicare: a strategy for quality assurance*. Vol. 1. 1990: Washington.
4. Medicine, I.o., *Health Professions Education: A Bridge to Quality*. 2003: Washington DC.
5. Frank, J., Snell L, Sherbino, J, *Canmeds 2015. Physician competency framework.* 2015, Royal College of Physicians and Surgeons of Canada: Ottawa.
6. Wong BM, A.-S.S., Bukowskyj M, et al *The CanMEDS 2015 Patient Safety and Quality Improvement Expert Working Group Report*, T.R.C.o.P.a.S.o. Canada, Editor. 2014: Ottawa.
7. Meche, P., et al., *Design and implementation of an interprofessional education course for undergraduate students at the University of Applied Sciences Western Switzerland: the Geneva experience.* J Interprof Care, 2015. **29**(3): p. 279-80.
8. Staines, A., et al., *Hand Hygiene Improvement and Sustainability: Assessing a Breakthrough Collaborative in Western Switzerland.* Infect Control Hosp Epidemiol, 2017. **38**(12): p. 1420-1427.
9. Staines, A., et al., *Sustained improvement in hand hygiene compliance using a multi-modal improvement programme at a Swiss multi-site regional hospital.* J Hosp Infect, 2018. **100**(2): p. 176-182.
10. Cronenwett, L., et al., *Quality and Safety Education for Nurses.* Nurs Outlook, 2007. **55**(3): p. 122-31.
11. Ogrinc, G., D.W. Nierenberg, and P.B. Batalden, *Building experiential learning about quality improvement into a medical school curriculum: the Dartmouth experience.* Health Aff (Millwood), 2011. **30**(4): p. 716-22.
12. Ferguson, C.C. and G. Lamb, *A Scholarly Pathway in Quality Improvement and Patient Safety.* Acad Med, 2015. **90**(10): p. 1358-62.

Program	CAS[2] Qualité et sécurité des soins : dimensions opérationnelles	DAS[3] Qualité et sécurité des soins : dimensions managériales	CAS Qualité des soins et conseils	CAS Patientensicher--heit – *end in 2019*	CAS Qualität in der Medizin – *start in 2020*
Length	15 days	33 days	24 days	17 days	18 days
Who	Faculty of Medicine, University of Geneva and Faculty of Biology and Medicine, University of Lausanne	Faculty of Medicine, University of Geneva and Faculty of Biology and Medicine, University of Lausanne	HES-SO Valais-Wallis (University of applied Sciences and Arts Western Switzerland)	HES- Bern (Bern University of Applied Sciences)	FMH (Foederatio Medicorum Helveticorum) / HES-Bern
Teaching language	French	French	French	German	German
Target audience	Frontline Multidisciplinary	Middle-managers and experts Multidisciplinary	Nurses or related professionals	Frontline Multidisciplinary	Frontline Multidisciplinary
Certification	Diploma 12 ECTS[4]	Diploma 30 ECTS	Diploma 15 ECTS	Diploma 10 ECTS	Diploma 12 ECTS
Web-site	CAS Qualité et sécurité des soins	DAS Qualité et sécurité des soins	CAS Qualité des soins et conseils	CAS Patientensicher--heit	-
Topics					
Quality improvement*	■	■	■	■	■
Evidence based practices	■	■	■		■
Patient-centered care	■	■	■		■
Safety	■	■		■	■
Teamwork/ Collaboration/ Communication		■		■	
Leadership		■			
Strategy		■			
Information systems		■			
Quality assurance					

Table 2 Continuing (lifelong) education university programs (topics in blue are taught)
* The QI training is focused on the fundamental principles of Quality (PDSA-Cycle, improvement-methods)

---

[2] CAS : Certificate of Advanced Studies
[3] DAS : Diploma of Advanced Studies
[4] ECTS : European Credit Transfer System

Appendix
Overview of education and training in safety and quality of care in Switzerland

1. University based continuing education programs on safety and quality of care

[5]CAS Qualité et sécurité des soins : dimensions opérationnelles (Faculty of Medicine, University of Geneva and Faculty of Biology and Medicine, University of Lausanne)
[6]DAS Qualité et sécurité des soins : dimensions managériales   (Faculty of Medicine, University of Geneva and Faculty of Biology and Medicine, University of Lausanne)
CAS Patientensicherheit (HES-Bern : Bern University of Applied Sciences) will end in 2019 and will be replaced by the CAS «Qualität in der Medizin» (Federation of Swiss Physicians / HES-Bern)
CAS Qualité des soins et conseils (HES-SO Valais-Wallis - University of applied Sciences and Arts Western Switzerland)

Patientensicherheitsmanagement: Grundlagen is a session of 3 days training. It is the result of a collaboration between the Universität St Gallen, German Universities and H+ Bildung.

2. Non university based continuing education programs on safety and quality of care

Patient Safety Officer (collaboration between Hospital Federation of Vaud – Geneva University hospitals- University Hospital of Lausanne)

3. Quality or safety training modules which are part of other programs

- **Continuing education programs**
    - Module « Quality of care » of the CAS in management of health organizations (Geneva School of Economics and Management)
    - Modules « Patient safety » of the training program offered by Espace Compétences
    - Modules « quality management, process management, lean management » of the training program offered by H+ Bildung

- **Post-graduate programs**
    - Optional module "Quality and patient safety in healthcare" of the Master of Public Health (offered by Swiss patient safety)
    - Course « Qualité, risques et sécurité des soins » of the Master of Science in nursing sciences (collaboration Unil/HES-SO -University of applied Sciences and Arts Western Switzerland)

4. Continuing education sessions in quality and safety of care
    - TeamSTEPPS® (inter-professionnality) : forum francophone and formation des formateurs (Hospital Federation of Vaud) - French speaking Forum and training of the trainees
    - Role of the executives and supervisory authorities of health institutions in the quality and safety of care (collaboration CHUV-FHV-HUG)
    - Trainings offered by the National Patient Safety Foundation
        - "Error and Risk Analysis (ERA)", different formats ranging from 1-3 day course (target group: inter-professional health care staff), offered together with the HUG for the region of Romandie.

---

[5] CAS : Certificate of Advanced Studies

[6] DAS : Diploma of Advanced Studies

- "Patient safety in cancer care", offered by the Swiss Oncology Nursing Society 1 day (target group: advanced and specialized oncology nurses practitioners)
- "Speak up for safer care", offered together with Careum, 1 day course (target group: inter-professional health care staff),
- "Second victim", 1 day course (target group: inter-professional health care staff)
- "Safe surgery". E-learning course (target group: inter-professional health care staff working in the OR), developed together with university hospital Basel

5. Pre-graduate education program
- Isolated thematic courses on the fundamentals of quality and safety of care offered by universities and professional schools of health, but no curriculum identified as such.
- Pre-graduate inter-professional (IP) curriculum in Geneva (School of Health of Geneva and Medical faculty of Geneva) since 2013
- Zipas inter-professional (IP) curriculum in Zürich for pre-graduate students and continuing education since 2018

Note we decided to exclude hospital based specific training sessions

Nationaler Verein für Qualitätsentwicklung in Spitälern und Kliniken
Association nationale pour le développement de la qualité dans les hôpitaux et les cliniques
Associazione nazionale per lo sviluppo della qualità in ospedali e cliniche

ANQ Quality Measurements in Hospitals and Clinics -
A pioneering Swiss achievement

A contribution to the National Report on Quality and Security in Swiss Healthcare

Author: Dr. Petra Busch
Organisation: Swiss National Association for Quality Development in Hospitals and Clinics (ANQ)
Date: 19 February 2019

Summary:

The Swiss National Association for Quality Development in Hospitals and Clinics (ANQ) co-ordinates and conducts quality measurements in acute somatics, rehabilitation and psychiatry. The results permit transparent and nationwide comparisons. Based on these results, hospitals and clinics can specifically develop measures for improvement of their quality.

ANQ members include the Spitalverband H+, santésuisse, curafutura, the Swiss social insurances, the cantons, the principality of Liechtenstein and the Swiss health directors' conference. Thus, all payers and service providers of Swiss health care are represented in the ANQ. The association's work is based on the health insurance act (Krankenversicherungsgesetz; KVG); the ANQ is not profit-oriented.

The ANQ does internationally pioneering work: The partnership-based agreements, the consensus-oriented cooperation of all tariff partners with a bottom-up approach and the mandatory nationally comparative quality measurements that are consistent throughout the country and being published transparently are an international success and serve as a positive example.

Opportunities: The ANQ quality measurements using scientifically accepted survey methods permit fair comparisons between the institutions within the meaning of best practices. They raise awareness among the institutions for quality subjects and serve the payers (cantons/insurers) as indicators for the dialogue with the service providers (hospitals/clinics).

Thresholds: The ANQ quality indicators were chosen in order to promote quality development - the measurement results do not reflect the overall quality of an institution. Accordingly, they are neither suitable for quality-dependent remuneration (pay for performance) nor for sanctions against institutions with bad measurement results or ranking/hospital classifications.

The future challenges lie in the extension of the quality measurement into the outpatient area of hospitals, financing of inpatient services in connection with development of outpatient before inpatient, further development of the measuring plan and timely communication of the ANQ measurement results. Optimisation potential is present in intensification of the coordination and networking between the parties and in responding rapidly to health-political developments.

1) Swiss National Association for Quality Development in Hospitals and Clinics (ANQ)

Corner points of the ANQ

The Swiss National Association for Quality Development in Hospitals and Clinics (ANQ) co-ordinates and conducts quality measurements in acute somatics, rehabilitation and psychiatry. The results permit transparent and nationwide comparisons. Based on these results, hospitals and clinics can specifically develop measures for improvement of their quality. ANQ members include the Spitalverband H+, santésuisse, curafutura, the Swiss social insurances, the cantons, the principality of Liechtenstein and the Swiss health directors' conference. Thus, all payers and service providers of Swiss health care are represented in the ANQ.

The ANQ does internationally pioneering work: The partnership-based agreements, the consensus-oriented cooperation of all tariff partners with a bottom-up approach and the mandatory nationally comparative quality measurements that are consistent throughout the country and being published transparently are an international success and serve as a positive example.

Initiative of the healthcare area

The ANQ activities are based on the Swiss health insurance act (Krankenversicherungsgesetz; KVG) from 1994 which stipulates that the service providers (hospitals and clinics) and the payers (insurers and cantons) incorporate contractually agreed quality assurance procedures including periodic performance reviews. Hospital and clinic comparisons must also be carried out, in particular with regard to costs and the quality of the results.

As a consequence of the KVG revision at the time, the Spitalverband H+, the industry association of the health insurances santésuisse, all Swiss cantons and the Swiss social insurers (accident, military and disability insurance) founded the ANQ association in 2009. The main objective of the association was defined as consistent implementation of outcome measurements in the inpatient area of acute somatics, psychiatry and rehabilitation. In early 2018, the health insurance curafutura joined the association.

Efficient structures

The most important association bodies of the ANQ are the members' assembly and the board. As the highest committee, the *members' assembly* approves, among others, the strategy, the budget and the annual statement and elects the board members.

The *board* manages the business of the ANQ. It has equal representation and consists of twelve persons: six represent the hospitals/clinics, three the cantons, three the insurances. One representative of the Swiss Federal Office for Health (BAG) joins as an observer without voting right. The board develops the strategy. In particular, it specifies rules on transparency and handling of data. Furthermore, it determines the quality indicators and measurement tools. When selecting them, it ensures internationally and scientifically accepted survey methods so that the results can be compared to those from other countries.

The *office* is subject to the board and supports it. The office can rely on the expertise and experience of quality committees and ANQ expert groups. The *quality committees* are formed according to ANQ subject areas or interdisciplinary according to measuring subjects, and help implement the measurements and develop them further. *ANQ expert groups* reinforce current questions of ongoing quality measurements and intensely deal with central aspects.

Quality measurements, communication and support as main tasks

The ANQ coordinates and implements quality measurements in inpatient acute somatics, rehabilitation and psychiatry based on the ANQ measuring plan and the quality indicators defined in it. It communicates the measurement results to the ANQ partners and the public. In its activities, the ANQ is committed to the greatest scientific care and transparency.

The ANQ regularly supports the persons responsible in the hospitals and clinics in the interpretation and use of the data by trainings and topic-specific workshops. The ANQ symposium Q-Day enables technical exchange within the meaning of best practice. Many representatives of the service providers and payers use the practice-oriented discussion and networking platform around the ANQ measurements.

Financing through members and annual contributions

The expenses for the *ANQ association structure* (office, committees, member administration) are financed by the annual membership contribution.

The *measurement and evaluation costs of the ANQ* are financed via the annual contributions of the hospitals and clinics. They depend on the number of inpatient stays in the respective area (in 2017, per discharge: acute somatics 2.70 CHF, psychiatry 9.88 CHF, rehabilitation 11.30 CHF). In return, the hospitals and clinics receive the measurement tools, the measuring logistics, the evaluated results and the national comparative reports.

The ANQ is not profit-oriented.

2) ANQ quality measurements

ANQ measuring plan and quality indicators

The ANQ compiles concepts for measuring result-relevant national quality indicators in the three ANQ subject areas of inpatient acute somatics, psychiatry and rehabilitation on the order of the tariff partners (Spitalverband H+, santésuisse, curafutura, the Swiss social insurances, the cantons, the principality of Liechtenstein and the Swiss health directors' conference). The quality indicators are specified in the ANQ measuring plan, which is part of the national quality contract.

ANQ bodies with experts from hospitals, clinics and ANQ partner organisations continually develop the measuring plan. New quality indicators must be particularly relevant, clearly comprehensible, practically useful and suitable for fair quality comparisons between the institutions according to the transparently published criteria catalogue[1]. Experiences and feedback from the hospitals and clinics are considered in the best manner possible. The measuring plan is widely supported and nationally accepted thanks to this procedure.

The ANQ pursues a practical approach: The measurement results are to directly benefit the patient and the attending hospital staff. Another central item is that the institutions are able to use the data collected for quality measurements as a basis for the increase of their quality.

The ANQ focuses on measuring selected and important quality aspects. The overall quality of an institution therefore cannot be assessed based on the ANQ measurement results.

The currently valid ANQ measuring plan indicating the quality indicators, methods and measurement tools per ANQ subject area is enclosed.

Swiss pioneering achievement

The most notable features

The ANQ has done a lot of development and conviction work in the ten years since its founding. Its achievements to date are internationally pioneering: The partnership-based agreements, the consensus-oriented cooperation of all tariff partners with a bottom-up approach and the mandatory nationally comparative quality measurements that are consistent throughout the country and being published transparently are an international success and serve as a positive example.

National quality contract – a partnership-based agreement

The national quality contract from 2011 forms the basis for successful implementation of consistent quality measurements in the three ANQ subject areas. All Swiss hospitals and clinics, all cantons and all insurances acceded to this contract. They thus committed to participating in all ANQ measurements and financing them. Thereby, they also agreed to careful evaluation and transparent publication of the data. Implementation of countrywide and consistent quality measurements in hospitals and clinics is unique in the international context.

---

[1] Cf. Criteria catalogue for new measuring subjects respectively quality indicators (document in German)

Partners in constant dialogue

All tariff partners are continually in dialogue via the ANQ. This raises awareness for some different opinions and promotes a solution-oriented manner of action across the individual stakeholders and the different interests.

Consensus-oriented procedures lead to high acceptance

With the national quality contract, all important partners of healthcare, without exception, commit to the target of quality measurement and quality development, and to a shared approach. This is a basic prerequisite for a national measuring system. Therefore, not only the statutory specifications are implemented, but targeted and pragmatic solutions are jointly developed, implemented and supported additionally.

The procedure with equal say in the implementation of the measurements and the publication of results offers better prospects of success than regulations passed by the authorities. For example, the evaluation and publication concepts for the individual indicators are developed under inclusion of the basis and reviewed by the ANQ partners. This shared consensus-oriented procedure in the meaning of a bottom-up approach, coupled with as much expert knowledge as possible, creates a high acceptance of the developed solutions among all parties.

Transparent publication with fair hospital and clinic comparisons

ANQ mandates independent organisations, usually institutes of universities or colleges, with processing and evaluation of the collected data. They evaluate the results scientifically and according to international standards. The data are subjected to a risk adjustment. Hospitals and clinics may differ considerably in their service offer, their infrastructures and their patient collectives. Risk adjustment can consider these differences and render the measurement results comparable. Since reality never can be mapped entirely, the ANQ always reminds of such differences and possible interpretation freedoms when communicating measurement results.

Fairness is not only an absolute requirement in data evaluation, but also in communication of the measurement results. They are presented in a graphically comprehensible manner, while reading aids and references to opportunities/risks of the ANQ measurements contribute to a correct interpretation of the results. The ANQ does not highlight any hospitals or clinics, neither positively nor negatively, since accessibility of the measurement results to the public promotes competition anyway.

The ANQ welcomes it if the results of the quality measurements are publicly discussed – but this should be done factually and according to the motto of "dialogue instead of pillory".

Opportunities and limits

Opportunities: Quality development, raising awareness and dialogue

The indicators selected by the ANQ are primarily suitable for *quality development* in Swiss hospitals and clinics. They supply the basics in order to trigger and implement targeted improvement measures in the institutions.

They permit *fair comparison of the results* between the individual institutions with respect to a specific indicator. Publication of the measurement results per hospital or clinic promotes competition among each other. Thanks to the transparent publication, it is now possible to make differentiated comparisons and to learn from each other – in the meaning of *benchmarking and best practices*. The nationwide consistent measurements are to permit, as far as possible, *international comparison* and corresponding benchmarking as well.

The quality measurements *raise awareness* among the persons responsible in the hospitals and clinics for the respective quality subjects. This triggers learning processes. The individual measurement results offer hospitals important internal argumentation aids, e.g. for investment in quality development, for process analyses, trainings, etc.

The payers (cantons and insurances) use the ANQ quality measurements as indicators for the *dialogue* with the service providers (hospitals and clinics).

Thresholds: Pay for performance, sanctions and hospital rankings

The ANQ quality indicators were chosen explicitly in order to promote quality development - the measurement results do not reflect the overall quality of an institution. Accordingly, they are neither suitable for *quality-dependent remuneration* (pay for performance) nor for *sanctions* against institutions with bad measurement results. The focus of the tariff partners should be mostly on whether the service providers actually use the ANQ data in their quality management.

For the same reasons, the ANQ measurement results are also not suitable for rankings or hospital classifications, which are intended to serve patients as a basis for decision-making when choosing a hospital: the ANQ measurements measure only the quality of a very specific indicator and not the overall quality. The ANQ disapproves of unauthorised, reduced or improper use of the measurement results by third parties and attentively monitors the development in the field of hospital search and comparison portals.

Basics of quality development in institutions

The responsibility for derivation, development and implementation of quality development measures based on the ANQ measurement results is deliberately kept with the hospitals and clinics. They know their operational processes best and are able to efficiently and specifically determine where they need to start improvements.

The ANQ is not legitimated to take sanctions against the service providers or to apply any controlling mechanisms. The payers (cantons and insurances) are responsible for quality control and possible interventions.

3) A lot has been achieved in ten years

Development and conviction work

In the ten years of its existence, the ANQ has done plenty of development and conviction work: The structures of the ANQ with many different partners have been created and the demanding question of financing of the association and quality measurement has been answered. The core of this work is the national quality contract, in which the shared understanding is recorded and the cooperation is stipulated. Initial resistances among the hospitals and clinics have mostly been overcome. Today, the hospitals and clinics share the intention of the nationally comparing, transparent ANQ measurements and are motivated to use the data gained for patient treatment and for quality development.

Creation and further development of the ANQ measuring plan

The ANQ measuring plan was developed in a consensus procedure among all ANQ partners. Implementation of the measuring concepts took place gradually between the three subject areas. The farthest progress today is found in acute somatics, which has been implementing and developing the measuring concepts since 2011 already. In psychiatry, the measuring concepts have been implemented since mid-2012 and in rehabilitation since early 2013. As of the end of 2018, the measurement results from rehabilitation have first been transparently published - so that measurement results from all three areas on hospital/clinic level are now available.

Improvement of data quality

Good data quality is a prerequisite for the measurement results being published transparently, i.e. including hospital and clinic names. The data quality has improved in all three specific areas across the years. The increasing experience of the hospitals and clinics in data collection, clinic-specific reports on data quality, optimisation of the processes and offered ANQ trainings for quality managers contribute to this development.

Outcome: 2009 to 2019

As of today, 16 nationwide measurements across all three ANQ subject areas are comparatively evaluated, with 12 of them transparently per hospital/clinic. The most important results are summarised below. Comparisons with the prior year are not possible everywhere for various reasons (adjustments in the measurement tools, insufficient data quality, first transparent publication).

Outcome inpatient acute somatics:

- Acute somatics have measured *patient satisfaction* since 2011, using short question-naires on the satisfaction with relevant core areas. The results from 2011 to 2017 show a consistently high patient satisfaction across all survey items and across all years.

- The measurement of *postsurgical wound infections* in now 12 different types of intervention has been performed by Swissnoso, national centre for infection prevention, on the order of the ANQ since 2009. Since the beginning of the transparent publication in 2011, the following infection rates reduced statistically significantly: Appendectomy (removal of the appendix), elective hip joint prosthesis, hernia surgery (inguinal hernia surgery), cardiac surgery/all interventions, laminectomies with and without implant (spinal surgeries), stomach bypass surgeries. Rectum surgery, in contrast, showed a significant increase of the infection rate. Hospital infections, in particular postsurgical wound infections, are generally connected to the service quality of hospitals and clinics – due to which transparent publication is of great interest for the population and for the media.

- Since 2011, the ANQ has been measuring the *potentially avoidable rehospitalisations (readmissions);* since 2017, it has published the rates of the individual acute hospitals in a transparent manner. In 32% of the hospitals/clinics (basis: Federal Statistical Office data year 2016 with publication 2018), there were more readmissions than would have been expected based on the patient mix. It must be observed that potentially avoidable readmissions can only be influenced within limits by the hospitals; accordingly, a conclusion to treatment quality in the hospital is only partially possible. The rate of *potentially avoidable re-surgeries* is not disclosed for method-related reasons.

- Data on *falls and decubitus ulcers (bedsores)* is collected once per year. Among adults, the total decubitus ulcer rate has remained relatively stable for several years; it is at about 4%. The fall rate among adults also remains virtually stable across the year; it was 3.8% in 2017. Among children, a clear and significant reduction of the total decubitus ulcer rate has been found since the measurements began: Between 2013 and 2017, it reduced significantly and continually from about 15% to about 7%. These results show that the hospitals became strongly aware of the decubitus ulcer risk in children in the last years.

- Since September 2012, data on implanted *hip and knee prostheses* has been recorded in the *implant register SIRIS*. Since inclusion of the register in the ANQ measuring plan, all hospitals and clinics have been obligated to record hip and knee implants in the register. From 2012 to the end of 2016, the register has consistently documented more than 162,000 hip and knee prostheses (primary and revision surgeries). At the end of 2016, SIRIS achieved a participation ratio of 96%. Specific statements on long-term behaviour and function duration of the implants will not be possible before the register has been operated for at least ten years. The same applies to possible quality comparisons.

- Recording of the *spinal implants* is to be included in the measuring plan in future – the corresponding development work and implementation plans are underway.

Outcome inpatient psychiatry:

- In psychiatry, *patient satisfaction* has been consistently measured nationwide since 2017. The first transparent publication will take place in 2019, based on the data from 2018.

- The *symptom burden* has been measured since mid-2012 in adult psychiatry and since mid-2013 in child and youth psychiatry. These ANQ measurements with self- and third-party assessment document that the psychiatric treatment reduces the symptom burden among patients between the admission and discharge. The load values at admission have slightly increased across the years (this means, the patients are increasingly burdened a little more at admission), but the psychiatric treatment also has been able to reduce the symptom burden more strongly by discharge over time. All in all, the results confirm that the clinics have a high treatment quality.

- Since mid-2013, the proportion of freedom restricting measures *(Freiheitsbeschränkende Massnahmen; FM)* has been recorded in adult psychiatry and child and adolescent psychiatry. Progress across the years shows a continuous slight increase of the share in cases with at least one FM in the total number of cases in both areas – we consider this due to improved documentation in the first years. In 2017, adult psychiatry showed the first slight reduction. These figures must be assessed under consideration that fewer FM does not necessarily equal higher quality, since the application of FM can be very different in practice. In clinics that use more FM than others, they may be applied for shorter periods than in those that use fewer FM. This depends on the individual clinic concepts and patient collectives. Direct clinic comparisons therefore are not possible.

Outcome inpatient rehabilitation:

- Rehabilitation has measured *patient satisfaction* since 2013, using short questionnaires on the satisfaction with relevant core areas. Evaluation of the results from 2013 to 2017 shows a positive overall image: Patient satisfaction is relatively stable on a very high level across the years.

- According to the measuring plan for rehabilitation, different methods and measurement tools are used (*documentation of participation target and assessment of target achievement, function in everyday activities, physical performance capacity, quality of life, general health status*) depending on rehabilitation area (musculoskeletal, neurological, other, cardiac, pulmonary rehabilitation). The indicators are collected for every patient both at admission to rehabilitation and at discharge from it. The difference measures treatment success. In November 2018, the results measured in rehabilitation were first published transparently based on the data measured in 2016. The evaluations showed that all clinics achieved an average improvement of function in everyday activities, performance capacity and quality of life, as well as the general health status, between admission to and discharge from rehabilitation.

4) Future challenges and potential for optimisation

The future challenges of the ANQ are diverse:

- *Expansion of quality measurement into the outpatient hospital area:* ANQ quality measurements are focused on the inpatient area only at the moment. In the medium- and long-term, measuring indicators for the outpatient hospital area are to be defined and included in the ANQ measuring plan.

- *New financing of the inpatient performance in connection with development of outpatient before inpatient:* The ANQ measurements are calculated via annual contributions of hospitals and clinics, based on the number of inpatient discharges. With development of "outpatient before inpatient" (easier cases are increasingly treated outpatient), the annual contributions for the ANQ are dropping. Financing of the ANQ quality measurements must be adjusted accordingly.

- *Further development of the current measurement plan:* The ANQ and its expert bodies continually check how the measuring plan can be optimised and effectively developed further. The three subject areas acute somatics, psychiatry and rehabilitation currently proceeded independently of each other. One imaginable development is increasingly targeted at patient-oriented result measurement (alignment with the increase of well-being from the patient's point of view).

- *Faster communication of the ANQ measurement results:* the elaborated processes of data collection until transparent publication and the many interfaces between the partners and persons involved lead to the measurement results being ready for publication only one or two years after completion of data collection at the moment. The tendency is towards reduction of the overall duration.

The ANQ currently finds optimisation potential mostly in the following areas:

- *Intensifying cooperation and networking:* Cooperation and exchange between all actors in healthcare is good, but has space for further intensification.

- *Faster political action:* Healthcare is changing, many health-political questions influence the activities of the ANQ. It is desirable to quickly deal with the developments with suitable structures.

Other current developments in healthcare with implications for the ANQ activities:

- Ongoing KVG revision on quality and economic efficiency

- Introduction and further development of SwissDRG, TARPSY, ST Reha and outpatient tariff systems

Further information on the ANQ, including detailed ANQ measurement results: www.anq.ch

There are no potential conflicts of interest for the ANQ.

ANNEX

ANQ measuring plan with quality indicators

The ANQ measuring plan (as of January 2019) shows the quality indicators, methods and measurement tools defined for each specific area.

Acute care

Indicator	Method	Tool
Adults		
Patient satisfaction	Survey	ANQ short questionnaire
Wound infection after surgeries	Swissnoso programme	SSI surveillance module
Potentially avoidable readmissions	SQLape	Data from FSO medical statistics
Falls and pressure ulcers	Prevalence review	LPZ International
Knee and hip implants	Registration	SIRIS implant register
Spinal implants*	Registration	SIRIS implant register
Children		
Patient satisfaction	Parent survey	ANQ short questionnaire
Wound infection after surgeries Appendectomies	Swissnoso programme	SSI surveillance module

* Undergoing clarification/in progress

Psychiatry

Indicator	Method	Tool
Adults		
Patient satisfaction	Survey	ANQ short questionnaire
Symptom severity	Data collection method: self-assessed	BSCL
	Data collection method: externally assessed	HoNOS
Coercive measures	Documentation	EFM
Children and adolescents		
Symptom severity	Data collection method: self-assessed	HoNOSCA-SA
	Data collection method: externally assessed	HoNOSCA
Coercive measures	Documentation	EFM-KJP

Rehabilitation

Indicator	Method	Tool
Adults		
All areas of rehabilitation (Module 1)		
Patient satisfaction	Survey: self-assessed	ANQ short questionnaire
Musculoskeletal, neurological, other* rehabilitation (Module 2)		
Participation goal (ICF)	Documentation of participation goal & Evaluation of goal attainment	ANQ goal documentation
Functioning in activities of daily living	Data collection method: externally assessed	FIM® or EBI
Cardiac (C), pulmonary (P) rehabilitation (Module 3)		
Physical capacity	Review of capacity Review of capacity	6-minute walk test (C/P) Cycle ergometry (C)
Quality of life	Survey: self-assessed Survey: self-assessed	MacNewHeart (C) Chronic respiratory questionnaire CRQ(P)
General health	Survey: self-assessed	Feeling thermometer (P)

* Geriatric, internal, oncological, paraplegic and psychosomatic rehabilitation

The economic case for quality and safety

A contribution to the Swiss National Report on Quality and Safety in Healthcare

February 2019

Jean-Blaise Wasserfallen, MD MPP

Vice-medical director at the University of Lausanne (CHUV)

Tenured Professor at Lausanne University (Unil)

Faculty of Hautes Etudes Commerciales

Lausanne, Switzerland

Phone: +41 21 314 18 02

Mobile: +41 79 665 16 56

Email: jbw@chuv.ch

The economic case for quality and safety

Abstract

Cost of delivering health care are made of fixed costs (infrastructure, equipment, personnel) and variable costs (procedures delivered, made of time of health care workers, equipment and medical goods used). Billing procedures bring revenues, and sustainability requires that revenues match fixed and variables costs.

Procedures carry an intrinsic risk of complications and/or adverse outcomes. Preventive and surveillance measures use health care resources, and lead to additional costs. Despite precautions, errors happen, detected before or only after they hurt the patient. Correction implies additional procedures and costs.

The cost to obtain quality (COQ) is the most reasonable balance between prevention/surveillance and correction costs, on top of production cost.

Quality or risk management systems are expensive, requiring resources for set up, running and maintenance.

Savings occur by decreasing variation of practices, segmenting patients by severity, avoiding duplications of procedures, and errors and complications. Their direct consequences are reductions in hospital length of stay and/or number of outpatient visits. Documenting savings makes return on investment visible.

Economic studies in quality and safety are scarce, particularly in Switzerland.

Quality and safety initiatives should include success factors and an economic analysis. They heavily depend from the information system.

Changing healthcare workers' behaviour is difficult, and financial incentives not always successful. Two recent initiatives (ERAS and Smarter Medicine) encourage a critical assessment of quality and safety of delivering care. Savings come as a by-product, and could be seen as the contribution from health care workers to decreasing the high cost of the Swiss health care system.

The economic case for quality and safety

Introduction

Quality and safety in health care are very disputed subjects in all countries. Quality initiatives have soared and represent a huge market, with many methods proposed for use, and plenty of consultants advertising their services. However, health care managers are very reluctant to pay for these initiatives, because they are sceptic about their effectiveness, although they acknowledge that quality of care is of paramount importance for their institution. Finally, payers claim that they will not pay more for better quality, while at the same time, in most health care systems, they still reimburse procedures with complications, and thus poor quality.

Surprisingly, data about the economic aspects of quality and safety systems and their impact on health care are scarce, particularly in Switzerland. This paper will describe the economic aspects linked with delivering health care procedures, as well as setting up and running quality and safety systems. It will describe in some details two recent initiatives associated with savings by optimising delivery of care and eliminating waste. Finally, it will identify success factors, as well as barriers and challenges, for setting up and running quality and safety systems, and issue some recommendations for improving the present situation in Switzerland.

Cost of delivering health care

In any health care system, costs can be divided into 2 main categories:

- Fixed costs: infrastructure (building), equipment (investment), and personnel costs (the latter making up about 75% of the fixed costs, when the infrastructure costs are excluded). These fixed costs are not dependent from the number of procedures delivered, but linked with the decision to set up and deliver a given type of health care procedures.

- Variable costs: any diagnostic and/or therapeutic procedure implies a production cost made of 3 main components: time of health care workers needed (measured by their wages), cost of equipment used (through its maintenance and depreciation share), and costs of medical goods (laboratory tests, drugs, implants, etc). They are linked with the number of procedures delivered, and

bring revenues, when they can be billed to a payor (state, insurance, or patient
(as deductible, co-payment or out-of-pocket)).

A given health care system is only sustainable, when revenues match fixed and variables costs.

<u>The "cost to obtain quality" (Coût d'Obtention de la Qualité = COQ) for an individual diagnostic and/or therapeutic procedure</u>

As most procedures are complex and invasive, they carry with them an intrinsic risk of leading to complications and/or adverse outcomes. Therefore, some additional measures are usually taken in order to prevent this risk from occurring, and still others to detect early the occurrence of complications. All these additional measures lead to using health care resources, and thus to additional costs, increasing the bare production cost mentioned above. Some of these preventive measures are mandatory by law (for example screening blood donation for several virus), while others are recommended by guidelines of good medical practice (such as testing for blood groups and/or antibodies against some blood antigens), and still others are left to the health care worker's or institution's choice or experience (in this example, the type and frequency of controls carried out by the nurse during the blood transfusion infusion time). These preventive costs can be highly variable and sometimes sizeable. In the example of blood transfusion, one bag is billed in Switzerland about CHF 225, including virus screening. Testing for antibodies adds 30% or 53% to this price, depending on whether the blood group of the patient is known or not, respectively. If the patient has special antibodies, testing for them further increases the price of the bag by 84% or 107% for the same reason, respectively.

Despite all these precautions, an error can happen, which can either be detected before it hurts the patient (for example a wrong blood transfusion bag is detected at the time of concordance checks carried out immediately before it is infused), or unfortunately only after the procedure was completed (the same blood transfusion bag was effectively administered to the patient) without detecting it was not appropriate for this patient. The error must then be corrected, and this implies additional procedures, and hence additional costs, which can be sizeable, depending of the severity of the harm caused by the error.

As both extreme positions (taking all preventive measures to avoid any error from occurring, and taking no preventive measure and paying for the damages when they occur) are unsustainable because of their associated costs, the "COQ" is the most reasonable balance between prevention/surveillance and correction costs, which has to be added to the bare production cost (1). Plotting costs versus probability of error for any procedure gives a "U-shaped" curve, and the "COQ" of this procedure is the point on the curve where the costs are lowest.

As patients are heterogeneous, because they have individual characteristics (such as age, and gender, or antibodies in the example of blood transfusion above), and a unique health history (summarised by comorbidities, and past surgeries), the balance just described is different for each of them, and can be assessed through severity scores. Therefore, the "COQ" for a given procedure can vary between patients.

The cost of quality systems

Quality systems available on the market for health care institutions are either inclusive (ISO (2), EFQM (3)), or partial, focusing only on some aspects of care (Sanacert (4)). Specific systems also exist for physicians in private practice (Equam (5)), and for different categories of physicians (ASQM (6)).

In all cases, setting up the system is expensive, as it requires a lot of work for describing procedures in writing, diffusing them and having them applied. Running the system implies a formal process of continuous improvement, able to analyse observed results and compare them with expected ones, and legitimate to take measures to correct the gap, if one is present. Finally, maintenance costs can be sizeable as well, with external audits required at regular intervals to keep the accreditation label.

A systematic review, published in 2015 (7), of 7 studies published between 2005 and 2012, on the effect of ISO 9001 (4 studies) and EFQM models (3 studies) on hospital performance showed that both models improved patient satisfaction and safety, reduced average length of stay, improved waiting lists for invasive procedures, and decreased unplanned readmissions. However, only one study (8) involved cost issues, and showed a 6.1% drop in the cost of medical goods, and a 35.2% savings in laboratory cost.

There are no data in the literature claiming that an inclusive system leads to better results than a partial one, and no specific data are available for Switzerland.

The cost of risk management systems

To focus on risk management can be an alternative to a formal quality system. It improves the health care system only in specific fields, where an intervention was shown or is known to be effective (for example hand hygiene), or where an ex-ante risk analysis showed particular vulnerability (for example at the operating theatre), or on the basis of recorded errors or near-misses within a specific health care institution. If this approach can appear to require fewer efforts than the previous one, it nevertheless implies the same types of work and costs, including the cost of external (SanaCERT (4)) or internal audits (home-made system). It also requires that errors be detected, which is difficult when the health care system is made of several partners with loose links between them. This situation represents a particular challenge for physicians in private practice.

In most institutions, both quality and risk management systems co-exist, and are run by the same people, allowing savings of scale.

The savings from quality and safety systems

Savings in health care are linked with a decrease in the amount of resources used to deliver a diagnostic and/or therapeutic procedure. This can occur in 4 different ways:

- By decreasing the variation of practices between the different actors, through standardization of the procedures. It implies adopting and applying procedures, pathways, guidelines, or other tools of the same nature, measuring the compliance of the different actors to these tools, and taking steps to suppress deviance from the agreed procedures.

- By segmenting patients by severity of risk and/or of illness, and adapting the intensity of both preventive and therapeutic procedures applied to them accordingly. For example, for a given patient, the risk of developing a pressure ulcer will depend from his/her nutritional status, as well as from the duration and type of surgery contemplated. Similarly, the treatment of a grade 4 pressure ulcer will necessitate more intensive treatment measures than those needed for a grade 1 ulcer (9).

- By avoiding duplication of laboratory and/or radiologic diagnostic procedures, or multiple drug treatments, because the information is not available when needed,

or because the patient is treated by multiple physicians not coordinated between them.

- By avoiding errors and complications, which require additional diagnostic and/or therapeutic procedures to correct them. Well-documented examples are avoiding blood stream infection by hand hygiene, or pressure ulcer by early mobilization.

The most important direct consequences of these 4 types of actions are the reductions of the hospital length of stay (LOS) and/or of the number of outpatient visits, both planned or in emergency, needed to take care of the patient. Avoiding using expensive diagnostic procedures and drugs or implants is an additional consequence in some cases. Documenting these observed savings is very important to convince managers to invest in quality and safety procedures, because they can concretely see a return on investment, that might even by far offset the additional resources needed to get this kind of results, depending on the domain under study.

<u>International examples of systematic reviews of economic analyses on quality and safety</u>
Published examples exist in different domains, both in hospital and in private practice. The following 4 examples will provide an illustration of the subject, and of the difficulties to document some of the savings, as compared with the easily available cost of the interventions.

- Central venous catheters insertion: a systematic review of 15 studies, with data from 113 hospitals, showed that the practice recommended by the Agency for HealthCare Research and Quality for inserting central venous catheters reduced the risk of bloodstream infection by 57%, and resulted in net savings of $1.85 million per hospital. Net savings offset additional program cost by $3.15 for each $1 invested (10).
- Antibiotics: a systematic review of 5 studies on programmes of antimicrobial stewardship showed that their implementation may be cost-effective from a hospital and/or payer's perspective (11).
- Hospital readmissions: a systematic review of 50 studies, half of them with patients suffering from heart failure, showed that in this patient population, interventions resulted in average net savings of $972 per patient, whereas in patients suffering from other conditions, interventions resulted in an average net

loss of $169 per patient. However, if the intervention engaged both patients and caregivers, net savings were greater (12).

- Diabetes: a systematic review of 46 studies of diverse designs showed that non-randomized controlled studies were associated with more favourable results. In the 19 randomized-controlled studies, glycaemic control, as measured by HbA1c, was improved by 0.26%, or 3 mmol/l, at an incremental net cost of $116 per patient annually. Long-term incremental cost-effectiveness ratios ranged from dominant (i.e saving money) to costing up to $100'000/Quality-Adjusted Life-Year (QALY) gained (13).

Swiss examples of economic analyses in quality and safety

Very few examples of economic analyses of interventions to promote quality and safety have been carried out in Switzerland. Three examples from Ticino, the most active Canton in this field, are summarised below.

- Implementation of guidelines on routine pre-operative testing: a 6-month strategy of meetings with health care professionals from 6 hospitals of Canton Ticino showed a statistically significant reduction in the probability of patient undergoing some routine pre-operative tests (81% for coagulation tests, 73% for glycemia, 62% for azotemia, 57% for chest x-ray, 49% for creatinine, and 43% for chest x-ray), translating in costs savings of about CHF 68'000 for 3 months in 1998 (14).
- Economic burden of unjustified medications at hospital discharge: on a sample of 318 out of 577 patients, 619 out of 3691 prescriptions were deemed unjustified, for a mean monthly cost of €32 per patient or about €19'000 per month. Gastrointestinal agents amounted to 46% of the total costs, of which 34% were related to proton pump inhibitors (15).
- Prescription practices for antibiotics in a medium-sized Swiss hospital: over a 6-months period, 129 patients' antibiotics prescription was reviewed. Overall, adherence to guidelines was 71%, and 58% had delayed switch from intravenous to oral form (mean delay of 5 days), resulting in additional pharmacy costs (the intravenous form being about 10 times more expensive than the oral form), and additional hospitalisation costs (16).

These examples were published between 2002 and 2009, and no information is available about their long-term impact. It is dubious that these studies had a widespread impact, as these fields are still in the top-lists of unnecessary prescriptions today.

Recent initiatives in Switzerland

Two recent initiatives can be ascribed to quality and safety measures, leading to potential important savings. The first one focuses on surgical care and is called "Enhanced Recovery After Surgery" (ERAS), and the second is more widespread in medicine and called either "Choosing Wisely" or "Smarter Medicine".

ERAS

This initiative was launched in the late 1990s. It aims at optimising patient's preparation to surgery, decreasing surgical and anesthesiological trauma during surgery, and optimising post-operative recovery, through 20 measures grouped into care bundles (17). The initial improvement in clinical outcome (18) could be replicated in colorectal surgery at a Swiss tertiary hospital, and translated into savings amounting to CHF 1'981 per patient, mainly through a decrease of nearly 50% in LOS in abdominal surgery, which offset the additional specific cost of ERAS of CHF 1'213 per patient (19). The same findings could be observed in thoracic surgery, with savings amounting to CHF 3'686 per patient, through a nearly 60% decrease in the numbers of complications, translating into a 43% decrease in LOS, again offsetting the additional specific cost of ERAS of CHF 729 per patient (20).

Smarter Medicine

Smarter Medicine was launched in 2012 in the USA and spread to Canada and Europe. It is based on the fact that some diagnostic and/or therapeutic procedures are routinely prescribed, by habit or tradition, but are not associated with any benefit for the patient. As some of these procedures are invasive, or likely to give false positive results, they might even harm the patient. As a consequence, they represent wasted resources, and can be eliminated without adverse consequences. Each society of specialists was asked to provide a list of the 5 procedures that might be suppressed without adverse consequences (Top-5 lists). These lists were published on Internet and in the specialised literature, as well as in the media.

In Switzerland, a Smarter Medicine Society was launched in 2014, and up to date, 8 societies of specialists published a Top-5 list on the web (21). This initiative is very interesting, as it has some features in common with the theory of lean management, which focuses on eliminating waste, without altering the quality and safety of the underlying procedure. As a consequence, some of the tools and practices of lean management could be adopted in Smarter Medicine (22).

This initiative might eventually lead to the effective implementation of findings published, with their cost consequences, by Swiss authors in the last 15 years (14-16). Both ERAS and Smarter Medicine are original and might be effective, because they do not focus on cost issues, and thus do not meet resistance from health care professionals, who are most responsive to the aspects of quality of care and safety of their patients.

Success factors

One of the key incentives for setting up a quality and safety system is the available evidence that some improvement is possible in the structure, processes and/or outcome of a given health care institution. In the Swiss health care system, the regular publication of quality indicators by the Federal Office of Public Health (23) and the National Association for the development of Quality in hospitals and clinics (ANQ(24)), with the identity of individual hospitals, is a very potent stimulus in this field.

A second key factor is to have the executive board of the institution understand the importance of paying attention and devoting resources to quality and safety because of the impact that accidents in this field can have on the image of their institution, with potentially disastrous financial consequences.

A third key factor is the ability to identify an internal champion, able to carry out the role of ambassador. He/she should first show that the system works in his/her own field, and then convince his/her colleagues to adopt the same system in their respective field. Quality and safety are in this respect highly contagious diseases.

One last key factor is the ability to identify savings linked with quality and safety interventions, because it will attract the interest of administrators, and made it easier to get the required investment to set up the quality and safety system.

<u>Barriers and challenges</u>

One of the key challenges for monitoring hospital or private practice performances is the availability of data. If they are not routinely collected, as for example included in the dataset that hospitals are required to send yearly to the Federal Office for Statistics, any additional data retrieval needs additional resources. Studies available in the literature on this subject are heterogeneous both in types of data and methods, so that the results of a systematic review including 8 studies "weakly indicate that collection of hospital data and improvement in data recording can be cost-saving" (25).

A second challenge is to be able to fulfil the success factors described above, in order to push the institution into this move and effort, as the inertia in the health care system is really important.

A third challenge is linked to the fact that many health care professionals are needed in the care of a given patient. This makes information transfer and availability critical for efficiency, and implies a well developed and interconnected information system (26). Unfortunately, in the Swiss health care system, legal requirements for an electronic patient chart are different between the hospital and outpatient sectors. This represents a huge barrier against efficiency of care, as well as quality and safety, which will be very difficult to overhaul.

Finally, some actors complain that quality and safety initiatives need additional funding to be launched and sustained. Some countries have tried to introduce financial incentives for physicians and hospitals to provide care of good quality and in adherence to clinical practice guidelines. This initiative, called "Pay-for-Performance" (P4P) showed mixed results in the USA and UK, both in hospital (27) and private practice settings (28). Studies in the field of behavioural economics have recently shown that, contrary to the traditional economic view that money is the only or main motivator for observed behaviours, "monetary reward can undermine motivation and worsen performance on cognitively complex and intrinsically rewarding work, suggesting that pay-for-performance may backfire" (29). Therefore, introduction of P4P in Switzerland is probably not the solution for improving quality and safety of care.

<u>Recommendations</u>

Changing healthcare workers' behaviour is difficult, as it is shaped early at medical or nursing schools, and later moulded in clinical wards by contact with senior physicians and nurses, not always aware of the latest medical development in their field. Hospital

management cannot necessarily suppress heterogeneity of practice within the institution, and guidance implementation on best practice by simple dissemination is ineffective. In this field, it is essential that lessons learned from other countries be replicated in Switzerland. The National Institute for Excellence (NICE) in UK has recently published some recommendations for achieving high-quality care (30), which could be adapted to the local healthcare system.

Quality and safety initiatives should therefore include the following characteristics:
- Include all actors involved in the field under study
- Identify champions as ambassadors for the project
- Use routinely available data or as few data to be acquired as possible
- Include an economic arm to the project in order to identify and compute both additional costs and expected saving
- Win the support of the executive board of the involved institutions

In this perspective, the 2 recent initiatives (ERAS and Smarter Medicine) are probably the best way to encourage a critical assessment of quality and safety of procedures of care, and should be encouraged. The savings incurred come as a by-product, and could be seen as the contribution health care professionals can bring to decreasing the high cost of the Swiss health care system.

References

1. Izoland. La démarche qualité, hygiène, sécurité, environnement (QHSE). http://nathalie.diaz.pagesperso-orange.fr/html/qualite/4controlerlaqualite/coq/indexcoq.html.

2. Organisation Internationale de Normalisation (ISO). https://www.iso.org/fr/popular-standards.html.

3. European Foundation for Quality Management (EFQM). Le modèle d'excellence EFQM. http://www.efqm.ch/modele-efqm.html.

4. Schweizerische Stiftung für die Qualitätssicherung im Gesundheitswesen. (SanaCERT). www.sanacert.ch.

5. Fondation EQUAM : Promotion externe de la qualité des prestations médicales. https://www.equam.ch/fr/.

6. Académie Suisse pour la Qualité en Médecine (ASQM). https://www.fmh.ch/fr/asqm/a_propos_de_asqm/taches.html.

7. Yousefinezhadi T, Mohamadi E, Safari Palangi H, Akbari Sari A. The effect of ISO 9001 and the EFQM model on improving hospital performance: a systematic review. Iran Red Crescent Med J 2015;17:e23010.

8. Beholz S, Konnertz W. Improvement in cost-effectiveness and customer satisfaction by a quality management system according to EN ISO 9001:2000. Int J Health Care Qual Assur Inc Leadersh Health Serv 2005;4:569-573.

9. National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and treatment of pressure ulcers: Quick Reference Guide. Emily Haesler (Ed.) Cambridge Media: Perth, Australia; 2014.

10. Nuckols TK, Keeler E, Morton SC, et al. Economic evaluation of quality improvement interventions for bloodstream infections related to central catheters: a systematic review. JAMA Intern Med 2016; 176:1843-1854.

11. Ibrahim NH, Maruan K, Mohd Khairy HA, et al. Economic evaluations on antimicrobial stewardship programme: a systematic review. J Pharm Pharm Sci 2017;20:397-406.

12. Nuckols TK, Keeler E, Morton S, et al. Economic evaluation of quality improvement interventions designed to prevent hospital readmission: a systematic review and meta-analysis. JAMA Intern Med 2017;177:975-985.

13. Nuckols TH, Keeler E, Anderson LJ. Economic evaluation of quality improvement interventions designed to improve glycemic control in diabetes: a systematic review and weighted regression analysis. Diabetes Care 2018;41:985-993.

14. Barazzoni F, Grilli R, Amicosante AM. Impact of end-user involvement in implementing guidelines on routine pre-operative tests. Int J Qual Health Care 2002;14:321-327.

15. Perren A, Donghi D, Marone C, Cerutti B. Economic burden of unjustified medications at hospital discharge. Swiss Med Wkly 2009;139:430-435.

16. Di Giammarino L, Bihl F, Bissig M, et al. Evaluation of prescription practices of antibiotics in a medium-sized hospital. Swiss Med Wkly 2005;135:710-714.

17. Lassen K, Soop M, Nygren J, et al. Consensus review of optimal perioperative care in colorectal surgery. Arch Surg 2009;144:961-969

18. Gustafsson UO, Hausel J, Thorell A, et al. Adherence to the enhanced recovery after surgery protocol and outcomes after colorectal cancer surgery. Arch Surg 2011;146:571-577

19. Roulin D, Donadini A, Gander S, et al. Cost-effectiveness of the implementation of an enhanced recovery protocol for colorectal surgery. Br J Surg 2013;100:1108-1114

20. Gonzalez M, Abdelnour-Berchtold E, Perentes JA, et al. An enhanced recovery after surgery program for video-assisted thoracoscopic surgery anatomical lung resections is cost-effective. J Thorac Dis 2018. Doi: 10.21037/jtd.2018.09.100

21. Smarter Medicine: Choosing Wisely Switzerland. www.smartermedicine.ch.

22. Crema M, Verbano C. Lean Management to support Choosing Wisely in healthcare: the first evidence from a systematic literature review. Int J Qual Health Care 2017;29:889-895.

23. Swiss Federal Office of Public Health. Indicateurs qualité des hôpitaux suisses de soins aigus. https://www.bag.admin.ch/bag/fr/home/zahlen-und-statistiken/zahlen-fakten-zu-spitaelern/qualitaetsindikatoren-der-schweizer-akutspitaeler.html.

24. Association Nationale pour le développement de la Qualité dans les hôpitaux et cliniques (ANQ). https://www.anq.ch/fr/domaines/soins-aigus/.

25. Jones C, Gannon B, Wakai A, O'Sullivan R. A systematic review of the cost of data collection for performance monitoring in hospitals. Systematic Reviews 2015;4:38.

26. Chaudhry B, Wang J, Wu S, et al. Systematic review: impact of health information technology on quality, efficiency, and costs of medical care. Ann Intern Med 2006;144:E12-E22

27. Flodgren G, Eccles MP, Shepperd S, et al. An overview of reviews evaluating the effectiveness of financial incentives in changing healthcare professional behaviours and patient outcomes. Cochrane Database of systematic Reviews 2011, Issue 7, Art. No. CD009255

28. Scott A, Sivey P, Ait Ouakim D, et al. The effect of financial incentives on the quality of health care provided by primary care physicians. Cochrane Database of systematic Reviews 2011, Issue 9, Art. No. CD008451

29. Himmelstein DU, Ariely D, Woolhandler S. Pay-for-performance: toxic to quality? Insights from behavioural economics. Int J Health Services 2014;44:203-214.

30. Leng G, Partridge G. Achieving high-quality care: a view from NICE. Heart 2018;104:10-15.

Jean-Blaise Wasserfallen MD MPP

Vice-medical director at CHUV

Tenured Professor at Lausanne University

Faculty of Hautes Etudes Commerciales

Abstract: 250 words

Text: 3433 words (without references)

Incident Reporting & Safety Learning

patientensicherheit schweiz
sécurité des patients suisse
sicurezza dei pazienti svizzera

Systems for reporting medical errors and treatment incidents

in the Swiss healthcare system: an overview

Article for the Swiss National Report on Quality and Safety in Healthcare

Author: Dr Olga Frank

Contents

Zusammenfassung

Bericht- und Lernsysteme (CIRS-Systeme) sind im Schweizer Gesundheitssystem schon seit vielen Jahren Bestandteil des klinischen Risikomanagements. Die ersten Anfänge gehen auf das Jahr 1996 zurück, in dem das Universitätsspital Basel mit dem Departement für Anästhesie das «CIRSmedical» einführte. Der angenommene direkte Nutzen der CIRS-Berichte für Verbesserungsmassnahmen zur Fehlervermeidung führte dazu, dass in den folgenden Jahren Bericht- und Lernsysteme in nahezu allen akutstationären Einrichtungen implementiert wurden. Zudem wurden unterschiedliche Netzwerke aufgebaut, allen voran das nationale Netzwerk «CIRRNET» der Stiftung Patientensicherheit Schweiz. Die anfängliche Euphorie im Betreiben von Bericht- und Lernsystemen wich der Erkenntnis, dass die freiwillig erfassten Daten keinen Rückschluss auf die medizinische Behandlungssicherheit einer Gesundheitsinstitution zulassen und aufgrund ihrer vielfältigen Verzerrungen nur mit Vorsicht quantitativ zu interpretieren sind.

Das zentrale Problem beim Betreiben von CIRS-Systemen bestand von Anfang an darin, dass es in der Schweiz, im Unterschied zu anderen Ländern mit inzwischen gesetzlicher Schutzgarantie für CIRS-Systeme, keinen gesetzlichen Vertraulichkeitsschutz für das Berichten über kritische Ereignisse gibt. In Ermangelung anderer, verlässlicher Daten werden Begehrlichkeiten geweckt, Einsicht in CIRS-Systeme zu nehmen und damit die zentralen Erfolgsfaktoren zum Betreiben von Bericht- und Lernsystemen zu gefährden.

Für das weitere Betreiben von Bericht- und Lernsystemen im Schweizer Gesundheitssystem besteht Handlungsbedarf auf Seiten der Gesetzgeber. Eine Zweckbindungsgarantie für CIRS-Systeme ist dringend nötig um ein angstfreies Lernen aus Fehlern im Schweizer Gesundheitssystem zu ermöglichen.

Executive summary

Critical Incident Reporting Systems (CIRS; sometimes referred to as reporting and learning systems) have been incorporated in the Swiss healthcare system's clinical risk management protocols for many years. This dates back to 1996, when the University Hospital Basel and its department of anaesthetics introduced "CIRSmedical". The assumed direct benefit of CIRS reports – improvements resulting in the prevention of errors – led to the adoption of CIRSs by almost all acute inpatient facilities in the ensuing years. A variety of networks also emerged, above all the national CIRRNET network initiated by the Stiftung Patientensicherheit Schweiz (Swiss Patient Safety Foundation). Initial euphoria over the operation of CIRSs gave way to the realisation that data gathered on a voluntary basis does not permit conclusions about the safety of a healthcare institution: the multiple bias in the data means any quantitative analysis must be treated with caution.

The main problem that has always affected CIRS in Switzerland is that the confidentiality of incident reporting does not enjoy legal protection here, unlike in other countries. The absence of other, more reliable, data creates an appetite for opening up CIRS, which puts at risk the very basis for its success.

Legislators need to act if CIRS is to continue being deployed in the Swiss healthcare system going forward. A guarantee of confidentiality in respect of CIRS is urgently needed in the Swiss healthcare system to foster learning from mistakes without fearing the consequences.

1 The early days of critical incident reporting systems (CIRSs)

In the 1970s the Australian Patient Safety Foundation became the first in the world to lay the initial foundations for the introduction of cross-disciplinary national CIRS systems with the Australian AIMS Programme[1]. In Europe, Switzerland took its first step in operating CIRS systems in 1996.

1.1 Pioneers of the CIRS in Switzerland (1996)

In 1996, the Department of Anaesthesiology at the University of Basel introduced the internet-based Swiss Critical Incident Reporting System (CIRS). To create a uniform system for reporting critical incidents in the Swiss healthcare system, in 2001, on the basis of many years of experience and in collaboration with the FMK, the SBK/ASI and NASA psychologists, a data set was defined for a generic anonymous CIRS to develop CIRSmedical, a system that could be used for the entire range of clinical medicine, making it available to a wide range of healthcare institutions.

CIRS systems were implemented at many hospitals as the importance of patient safety for Swiss healthcare continued to grow. Even though many questions in relation to the liability of people who report errors and incidents were not fully clarified, CIRS systems with different objectives were implemented and operated.

2 Further development of CIRS systems after the early days (2000–15)

As things developed further, CIRS systems became a vital component of clinical risk management systems. They were most widespread in acute inpatient care facilities; less so in other sectors of care in the Swiss healthcare system. The level of implementation was very heterogeneous, and remains so to this day. No nationwide overview of healthcare establishments that have implemented a CIRS exists to date.

The early euphoria gave way to a debate, lasting many years, on the obligatory use of CIRS systems. Initially great credence was given to the utility and effectiveness of CIRS systems. For example an expert survey on patient safety in Switzerland conducted in 2008[2] concluded that introducing a CIRS was one of the most useful measures for improving patient safety. The idea that anyone operating a CIRS was automatically doing clinical risk management and living a culture of safety and learning prevailed for a long time, even in specialist circles – until an increasing amount of practical experience became available.

2.1 Swiss study on clinical risk management (2008)

The year 2008 saw the first study of clinical risk management in Switzerland. It was conducted by ETH Zurich's Centre for Organisational and Occupational Sciences[3] in collaboration with the Lucerne University of Applied Sciences Institute of Business and Regional Economics. The goal of this practice-oriented research project was to investigate the current situation and planned development in clinical risk management at Swiss hospitals. The findings showed that at that time (2008), systematic/clinical risk management was still a new field for many hospitals, although it had already gained in importance. Among other things, the national survey covered aspects related to CIRS systems. Around half of the hospitals taking part in the survey (n = 138) had a person responsible for the central coordination of clinical risk management activities. Hospitals were using a relatively broad spectrum of measures to enhance patient safety. One of these measures was operating a CIRS. In 2008, around 40 per cent of the hospitals that responded had a CIRS and were analysing the origins of error reports. In charge of running the

CIRS in most cases were decentralised personnel resources who were responsible for operating the local CIRS in addition to their routine clinical work as doctors or nurses.

2.2 Swiss CIRRNET® network (2006)

In line with the idea that it was not only possible to learn from one's own mistakes, but that critical events at other locations could also be of key importance, there was a growing trend to establishing networks. A wide range of different types of network emerged, most notably the CIRRNET®. In 2006 the Critical Incident Reporting & Reacting NETwork (CIRRNET®) was established by the Swiss Patient Safety Foundation in cooperation with the Swiss Society of Anaesthesiology and Reanimation (SGAR-SSAR) with the support of the Federal Office of Public Health (FOPH). CIRRNET® is the network of local CIRS systems in Switzerland. The network enables affiliated healthcare institutions to forward anonymised CIRS reports to the CIRRNET® database and thus make them available on a password-protected basis to all the network partners for internal learning purposes. The goal is to learn from mistakes and identify cross-regionally and/or nationally relevant problem areas of patient safety. Along the lines of "from reporting to reacting", problem areas identified are worked on with experts at different healthcare institutions and organisations, and practical recommendations (so-called Quick-Alerts®) are published on a broad basis.

During the pilot phase from 2006 to 2010, 12 hospitals and their anaesthesiology clinics participated in CIRRNET®. After a successful evaluation in 2010, CIRRNET® was opened to all Swiss healthcare establishments and all medical disciplines. In 2018 a total of 82 healthcare establishments, predominantly in acute inpatient care, were affiliated with CIRRNET®. CIRRNET® is funded by the Swiss Patient Safety Foundation, the cantons and network participants.

2.2.1 Quick-Alerts®

As a result of the processing of cross-regionally/nationally relevant problem areas in patient safety, from 2006 to 2018 a total of 46 Quick-Alerts® were formulated and published by the Patient Safety Foundation. Quick-Alerts® are concisely worded recommended improvements and warnings on the basis of individual, relevant, topical and easily definable problems in patient security. These problem areas of pan-regional relevance are identified from the CIRRNET database. Quick-Alert recommendations are developed in collaboration with various experts and made available to all healthcare professionals with an interest.

To look into the propagation of Quick-Alerts® within healthcare establishments and get an idea of how these practical recommendations are passed on within them, in 2013 the foundation held a written survey of quality and risk managers at all Swiss hospitals. This survey[4], conducted with the psychology of work in organisations and society research group at ETH Zurich, was designed to evaluate the use and practical utility of Quick-Alerts® at healthcare institutions. The quality and usefulness of Quick-Alerts® were deemed to be positive. Quick-Alerts® raise employee awareness of specific hot spots in patient safety, and provide concrete tips on how to improve and avoid errors. In most cases they are passed on to different professional groups within an institution, and are often discussed with the medical service. Quality and risk managers see reading the Patient Safety Foundation's Quick-Alerts® and forwarding them to "affected" staff and departments within their organisation as one of their duties.

Given that Quick-Alerts® receive formal approval from Swiss professional associations, these practical recommendations enjoy a high level of acceptance in professional circles, and are also cited internationally.

3   Current snapshot

More than 20 years after the introduction of a CIRS at a Swiss hospital, different experience has been gathered, and various developments can be observed. The pivotal problem in relation to operating CIRS systems is still that there is no statutory confidentiality safeguard when it comes to reporting on critical incidents, and that negative consequences for the culture of learning and safety and a decline in people's willingness to report can therefore be expected. Added to this, a justifiable interest on the part of the public and patients, insurers and government regulators (the federal, cantonal and municipal authorities) with respect to healthcare safety data cannot be satisfied with CIRS systems. The misconception that CIRS systems allow conclusions to be drawn about the safety of treatments persists in many places, and leads to false expectations of CIRS data.

3.1   Legal framework for operating reporting and learning systems

Confidentiality protection and protection from prosecution are the key to the successful operation of a CIRS, and crucial to the culture of safety and learning at Swiss healthcare establishments. The problem, however, is that unlike other countries, Switzerland has so far had no legal regulations governing the way reports in reporting and learning systems are dealt with. Therefore, notifiers in these systems are not protected from the possibility that their notifications could be consulted and used in criminal proceedings. There is a yawning gap in the law that is disconcerting for people reporting incidents and reduces their willingness to do so. As long as a CIRS can be utilised for criminal proceedings, people working for Swiss healthcare establishments will have to fear harmful consequences for themselves, their colleagues or the healthcare establishment if they report incidents and errors. The patient rights legislation in Germany[5], for example, shows that reporting that is not subject to prosecution does not conflict with prosecution in cases of gross negligence. Similar rules would be welcome in Switzerland.

It is high time that Switzerland introduced legal regulation in the form of a guarantee that the output of CIRS systems will only be used for specific purposes. Efforts to bring about such a change in the law have been under way since back in 2001.[6]

3.2   Obligatory CIRS systems

There is no legal obligation at federal level to operate a CIRS. On the basis of the cantonal regulation of the Swiss healthcare system, however, there are cantonal laws and agreements between departments of health and healthcare establishments. Since 2014, for example, Canton Valais has imposed a reporting requirement on its hospitals by way of an ordinance on healthcare quality and patient safety.[7] The same applies for Canton Ticino, which has also established a duty to report medical incidents in its cantonal healthcare legislation.[8] By way of the Zurich hospital list and its annex, Canton Zurich obliges its acute inpatient facilities to operate a CIRS.[9] Other cantons, within their quality and patient safety policies, urge healthcare establishments to operate a CIRS, but do not explicitly require them to do so. Canton Graubünden, for instance, in its ordinance to the healthcare act, requires its public-law hospitals to participate in the CIRRNET network, which presupposes that hospitals operate a local reporting and learning system.[10]

Reporting incidents in the CIRS is basically voluntary, but healthcare institutions are no longer free to choose whether that operate a CIRS. CIRS systems and the resulting learning steps are very important, and given that this information is indispensable in terms of assuring patient safety, are part of the core duties of any healthcare institution. For this reason, all healthcare establishments should be obliged to operate a CIRS system, and the requisite legal protective provisions should be initiated.

4   Lessons learned after more than 15 years of CIRS systems in Switzerland

Incident reporting and learning (CIRS) systems are not the only form of system for generating reports on undesired medical incidents. From the moment the Swiss healthcare system started implementing them, their ability to generate reliable data on medical incidents has been overestimated. They are not an appropriate tool for the quantitative capture of treatment errors. They are neither sensitive nor specific. This fact was recognised many years ago, prompting an ongoing discussion around suitable, more sensitive systems for capturing such information.

Up until now, CIRS systems have had to contend with the problem that there is often no clear evidence of the efficacy of improvement measures, but at the same time, the complexity and the need to develop and establish the importance of a culture of safety and learning mean they are a key component of any clinical risk management system.

Quantifying treatment errors in the healthcare system is a matter of great concern for healthcare policymakers (federal and cantonal), insurers, the public at large and other stakeholders. This is basically understandable. For this reason, with all the different, justified interests involved, the goal and interest in obtaining insight must always be defined first before the appropriate tool or procedure for gathering data is decided. Practice to date shows that for want of systematic, mandatory reporting systems for defined incidents in the context of the medical treatment of patients, expectations of reporting and learning (CIRS) systems are aroused that do not tally with the purpose of CIRS systems. Given the under-reporting, the findings of analysis must be viewed with extreme caution. The operation of reporting and learning systems has to be seen from two points of view: in the context of a healthcare establishment's operations, and in the overall context of healthcare provision and managing patient safety.

5   Need for action and recommendations for CIRS systems in Swiss healthcare

Continuous monitoring by way of regular national surveys of officers responsible for clinical risk management is a key measure when it comes to promoting awareness of forward-looking, systematic risk management and supporting healthcare institutions in their ongoing efforts to develop. However, as long as there is no legal regulation governing the compulsory gathering of data on treatment safety, data will be captured unsystematically and for different purposes that are not primarily intended or suitable for managing Switzerland's healthcare system.

The Swiss Patient Safety Foundation draws attention to the necessity and urgent need for action in terms of ensuring that data on treatment safety are captured systematically (see chapter 5 of "Harm to patients in Switzerland – an overview", contribution to the Swiss National Report on Quality and Safety in Healthcare by S. Züllig) and preventing a situation where CIRS systems are relied on for want of appropriate data. It is worth protecting CIRS systems and the reports they generate on medical incidents from the authorities' subpoena for production of evidence; they should only be used for the purpose of identifying and analysing problem areas in patient safety and devising and implementing improvements. As long as the law fails to provide rules protecting the operation of reporting and learning systems in Switzerland, the Swiss Patient Safety Foundation recommends that healthcare institutions reduce the legal risk as far as possible by taking organisational measures such as anonymising and destroying original critical incident reports.

Recommendation of the Swiss Patient Safety Foundation

1. The management of any healthcare establishment should clearly define what should be reported in the local reporting and learning (CIRS) system. All employees should be made aware of this definition. Incidents involving damages and/or potential damages should not

be reported in reporting and learning systems. Reporting and analysis techniques should be taught and trained.

2. Every CIRS should make it possible to report anonymously. In concrete terms, this means that the identity of the person reporting (and the patient) must not be passed on to third parties. It can, however (at least initially) be known to the team operating the reporting system.

3. There must be no cross-references between reporting and learning systems and patient dossiers/medical records and other medical documents.

4. All incidents and persons reported in a reporting and learning system must be systematically anonymised and de-identified. No personal data may be viewed or saved within the framework of a CIRS report. If necessary, reports must be further anonymised and de-identified before they are processed, forwarded or published.

5. Incidents involving damages and/or potential damages must be deleted from the CIRS and if necessary reported and documented in a separate system for damage cases.

6. Employees must not suffer any disadvantage for the incidents they report. In particular, they must not be held responsible for system errors.

7. If a healthcare institution is subpoenaed by the judicial authorities to produce evidence, after careful consideration sealing of the evidence must be demanded.

Literature

1 Wilson RM, Runciman WB, Gibberd RW et al. The Quality in Australian Health Care Study. Med J Aust 1995;163:458-71.

2 Rose N., Ortner MA., Meyenberger C. et al. Die Patientensicherheit in der Schweiz. SÄZ 2009;90:48.

3 Briner M, Kessler O, Pfeiffer Y et al. Erste Schweizer Erhebung zum klinischen Risikomanagement im Spital. SÄZ 2009;90:-16.

4 Pfeiffer Y, Schwappach DLB: Learning from national safety alerts to change practice in hospitals: the perspective of healthcare quality and risk managers. *ZEFQ* 2016; 110-111: 26-35

5 Sozialgesetzbuch (social security statute book) V, § 135a zum Patientenrechtegesetz (protection of patient rights). https://www.sozialgesetzbuch-sgb.de/sgbv/135a.html

6 Kuhn HP. Patientensicherheit: Lehren der Luftfahrt für den Gesetzgeber. SÄZ. 2018;99(13-14):419-421.

7 Canton Valais Council of State. Verordnung über die Versorgungsqualität und Patientensicherheit (healthcare quality and patient safety ordinance). Art. 11 Meldungen von Zwischenfällen (reporting incidents). https://lex.vs.ch/frontend/versions/2059

8 Legge sulla promozione della salute e il coordinamento sanitario (Legge sanitaria, LSan)". Article 68. https://m3.ti.ch/CAN/RLeggi/public/index.php/raccolta-leggi/legge/num/270

9 Canton Zurich Government Council. Annex to the 2012 Zurich hospital lists for acute care, rehabilitation and psychiatric care: general requirements (Version 2018.01; effective 1 January 2018. https://gd.zh.ch/dam/gesundheitsdirektion/direktion/themen/behoerden/spitalplanung/strukturbericht/strukturbericht_september_2011/akut_zuercher_spitalliste_gueltig_ab_1.1.2018/Generelle%20Anforderungen%20Version%202018.pdf.spooler.download.1504161647683.pdf/Generelle+Anforderungen+Version+2018.pdf

10 Verordnung zum Gesundheitsgesetz (Canton Graubünden health ordinance, VOzGesG). https://www.gr.ch/DE/institutionen/verwaltung/djsg/ga/dienstleistungen/aufsichtbewilligungen/Gesundheitsgesetz/Verordnung%20zum%20Gesundheitsgesetz.pdf

Short Report for Swiss National Report on Quality and Safety in Healthcare

Healthcare from the point of view of patients

DVSP (the umbrella association of Swiss patients' organisations)

Abstract:

The Swiss healthcare system has major advantages for members of the public, but also certain disadvantages that can have serious implications for patients. One great advantage is that the entire population has access to healthcare. One great disadvantage, on the other hand, is the fact that there are gaps in the quality and safety of the healthcare provided to patients. These gaps are due to the fragmented nature of the healthcare system and the dual levels of authority and responsibility (the cantons and the federation). But they are also due in no small measure to the fact that Switzerland has no comprehensive, binding quality assurance approach that is subject to control.

The healthcare system is on the whole very good, but there are serious gaps evident in a number of areas. There is a particularly urgent need for action when it comes to the quality of, for example, medication, the individual benefits of treatment, invasive procedures, defining indications, identified sources of error, interfaces between inpatient and outpatient care, hygiene, etc. In many of these areas, there have long been important insights and proven solutions just waiting to be implemented.
The federalist structure of the healthcare system will only work from the patient point of view if powers and responsibilities are tied more closely to the federal authorities and made subject to binding regulation across the country, particularly in the context of quality assurance, which should be coordinated and monitored by a single body.

The status of patients in Switzerland is poor compared with neighbouring countries. While the bodies representing them are involved in various working groups run on a federal, cantonal, municipal and private basis, there is no funded, delegated co-determination for patients at the federal level such as exists, for example, in the Netherlands. The rights and duties of patients are set down in various federal and cantonal laws and ordinances. The result is that these can even differ from canton to canton.

Healthcare from the point of view of patients

The Swiss healthcare system has major advantages for members of the public, but also certain disadvantages that can have serious implications for patients. One great advantage is that the entire population has access to healthcare. One great disadvantage, on the other hand, is the fact that there are gaps in the quality and safety of the healthcare provided to patients. Some of these gaps are due to the fragmented nature of the healthcare system and the dual levels of authority and responsibility (the cantons and the federation). But they are also due in no small measure to the fact that Switzerland has no comprehensive quality assurance approach. While areas such as health insurance, the protection of health, and research involving humans are regulated at the federal level, responsibility for healthcare is in the hands of the cantons. At the same time both levels coordinate and run joint projects on the federal/cantonal platform, for example via the cancer and e-health strategies, or the framework agreements set down between the Swiss Federal Department of Home Affairs (FDHA) and the Swiss Conference of the Cantonal Ministers of Public Health (GDK) on the implementation of the electronic patient record. From the patient's point of view, although this federalist structure can lead to differences in the ways laws are implemented and different payers, it can also facilitate the rapid launch of projects in areas such as prevention, as numerous current initiatives demonstrate. The federal and cantonal authorities bear the main responsibility for healthcare, with municipal authorities and private actors also contributing by way of different projects.

The consequences of a federalist structure

The result of the federalist set-up of Swiss healthcare is a fragmentation into 26 cantonal healthcare systems. We believe Switzerland is too small for that to represent patients and insured people. While the federal constitution and federal legislation set down the framework for the cantons to provide healthcare to the public, responsibility for implementation rests primarily with the cantons. This means that each canton is obliged to assure the entire population access to high-quality healthcare in the event of illness and accident. While each canton for its part is a member of the Conference of the Cantonal Ministers of Public Health, the power to decide and the responsibility for decisions ultimately rests with the canton alone. This federalist set-up has also led to a system lacking in transparency, which results in legal inequality and duplication of effort – on the one hand because powers and responsibilities are concentrated in such small areas, in most cases ending at the cantonal border, and on the other hand because a system of this sort cannot guarantee quality and quality assurance, despite the fact that quality assurance has been a legal requirement ever since the introduction of the Federal Health Insurance Act in 1996. When assessing the suitability of this federalist system as an instrument in healthcare from the point of view of patients, we have to focus primarily on quality and quality assurance. For this reason, this is also the area we focus on in the following pages. It includes the rights of patients and their status.

No central body for quality and cost-efficiency

Quality and quality assurance are established by law in the Federal Health Insurance Act. The cantons are in charge of implementation. Even though the legal position is clear, in many cases nobody feels really responsible, and often the very opposite seems to be the case. Many of those responsible, from hospital directors to doctors, say that quality measurements and controls are much too complicated and bring little besides administrative work. This may be true in certain areas, but there are many quality standards, including international standards, that would enable both compliance and control. This also applies to the broadly available insights into known sources of error which could be minimised with targeted measures. There have long been calls for transparency in quality-related data, but this has not been given priority either. It was only after the Federal Office of Public Health (FOPH) published its first report on quality indicators in Swiss acute hospitals in 2006 that a broad debate got going on this topic. Even though the FOPH's approach came in for heavy public criticism, this led many of those responsible to rethink their position. Despite the criticism, some hospitals even followed suit and are now also publishing quality data on their websites. Overall the debate has resulted in quality improvements and more transparency at some hospitals. The federal government's endeavours to coordinate quality and quality assurance are very welcome. Outstanding work is being done at various levels on quality and quality assurance – work that should be authoritatively coordinated by a central body, preferably the federal government, and which should be extended across the whole of Switzerland for the benefit of patients.

The status of patients

The status of patients in Switzerland is very poor compared with neighbouring countries. While the bodies representing patients are involved in various working groups run on a federal, cantonal, municipal and private basis, there is no funded, delegated co-determination for patients at the federal level such as exists, for example, in the Netherlands. The rights and duties of patients are set down in various federal and cantonal laws and ordinances. Canton Zurich, for example, has taken a pioneering role with its own special patient legislation, while the rights and duties of patients in other cantons are generally set down in cantonal healthcare law. While some of these laws regulate these rights and duties very well, patients are in a weak position, particularly in liability law, and there is a lack of political will among most parliamentarians to change this state of affairs. When it comes to alleged breaches of duty of care and the resulting health damage, the burden of proof lies with the person affected or their legal representative. This means that in most cases a layperson in medical terms has to substantiate an error and the resulting health damage to a specialist. They also have to bear the costs of investigation themselves, unless they have taken out legal expense insurance. Once the proof has been successfully demonstrated, damages are paid and the case is closed. It is up to the person or institutions responsible alone to take individual cases further, unless criminal proceedings are instituted – something which in our judgement is necessary only in very rare cases. Experience at the patients' organisations suggests that this is only very rarely the case in real life, especially because

errors are supposed to induce a learning effect rather than resulting in the criminalisation of physicians.

While we reject the criminalisation of doctors, we do call for a different approach to handling and processing mistakes that immediately leads to learning effects beyond the individual case. Added to this, the consequences and learning effects derived from errors should be presented transparently so that learning does not simply remain at the individual level. We also call for more quality requirements and controls which are binding across Switzerland and which must eventually involve sanctions. Ultimately, the legal requirements have to be modified in such a way that the burden of proof on those affected is at least reduced. We also call for transparency on matters of quality. A patient must be able to choose a hospital or doctor on the basis of quality criteria.

Lack of quality in healthcare

Quality and quality assurance in healthcare have top priority, not just because they can save a lot of suffering for patients, but also because they can enable massive cost-savings. But quality assurance in particular has its shortcomings. So far there has been no binding system for the whole of Switzerland for either inpatient or outpatient care. To a large extent quality assurance is done on a voluntary basis. The lack of quality of control is particularly serious. Care providers can give quality the status they deem to be appropriate. This can result in exemplary pilot projects and initiatives, but it can also lead to the complete negation of existing shortfalls in quality. There are many reasons for this: a lack of standards, coordination, legal basis, sanctions and insight, but also the fact that shortfalls in quality are not always obvious. Often they only become evident in isolated cases where there are complications in treatment or a potential breach of duty of care. For some time inappropriate care has been the subject of intense debate. This is because there have long been question marks in terms of whether only treatments are provided which have a benefit for the patient in question. For this reason, there is a growing focus on quality assurance with respect to medical indication. Medical indication as a component of quality assurance also feeds into the number of case statistics, for example in the context of cantonal contracts for hospital services, but also in the context of so-called overtreatment. This term refers to services which are not absolutely necessary, or which are even unnecessary and in our belief better defined in terms of inappropriate care. Medical indication is also closely bound up with the statutory provision of information to patients. Inappropriate care has particularly serious implications for individual patients when a risk taken unnecessarily actually materialises, or when a treatment is carried out without information having been provided to the patient as stipulated by law and the treatment subsequently turns out to be inadequate or even wrong. As research shows, inappropriate care has now assumed serious proportions, and this complex problem is intensifying all the time. Economisation and economic interests combined with the lack of binding quality assurance in medical care are key factors in this issue.

Quality projects still few and far between

For patients to be able to participate in quality assurance they need to be given the relevant tools and knowledge. In the federalist set-up the cantons cannot influence the care provided under basic insurance. If a canton sees a need for action in this respect it can try to bring about reforms by way of a pilot project or by casting its sights beyond the cantonal border. In terms of health literacy, Switzerland is underdeveloped by comparison with other countries. This prompted the Canton Zurich department of health to join forces with a private institution to launch a health literacy project. Its sponsors include the Zurich patient organisation, which supports various projects designed to promote health literacy among members of the public, and patients in particular. Particularly important in this respect is the provision of information to patients by law, including information in the course of preventive examinations. The DVSP is addressing this issue explicitly.

We favour the shared decision-making (SDM) model, which defines the way patients and doctors participate in decisions on further treatment or treatment steps. This form of information and education cannot prevent inappropriate care in individual cases, but it does facilitate holistic treatment.

The findings of scientific studies on quality assurance are regularly published, but they have not resulted in guidelines that are binding across Switzerland. The Patient Safety Foundation also publishes regular quick alerts and papers of the month, each of which highlights a source of error in a particular area and the corresponding measures. In response to our enquiry, a representative of the foundation said that while these publications create lively interest, it is not known – and no effort is made to find out – whether hospital managers, or those involved in general, disseminate these recommendations and declare them binding on their establishment, for example by way of directives. The same lack of authoritativeness also prevails when it comes to study findings.

Hospital (nosocomial) infection represents a major problem. Experts reckon that around one third of infections could be prevented if hygiene measures were implemented systematically and consistently. Various bodies, including the ANQ, conduct measurements of infections. Although there are numerous specialists devoted to hygiene and measures to reduce rates of infection are known, no comprehensive, binding hygiene standards have been established with corresponding controls and sanctions for non-compliance. This possibly has to do with the fact that the burden of proof that an error was made and resulted in health damage also lies with the patient in the case of hospital infection. These things are difficult to prove, among other things because the FMH expert panel does not issue opinions in the event of infection and there is no hygiene legislation that would require compliance with such an opinion. Neither the findings of the Patient Safety Foundation, the measurements carried out by the ANQ nor the findings of studies have led to comprehensive, binding quality and quality assurance measures. While this cannot be blamed entirely on the federalist system, it is difficult to coordinate activities if there is no single body in charge. If quality and quality assurance are done inconsistently and only selectively, comparable transparency cannot be established either. But this comparable transparency is crucial.

The sovereignty of the cantons

The Conference of the Cantonal Ministers of Public Health (GDK) might give the cantons recommendations in all areas of healthcare, but it does not have the authority to issue directives. Binding inter-cantonal cooperation has to be regulated specially. While this is the case for highly specialised medicine, for which the cantons are also responsible, it does not yet happen across the board. It can also happen that Switzerland is often too small for rare procedures, treatment of sufficient quality, or for certain studies, which makes it necessary to cooperate internationally in some areas. For quality to be assured in the event of complex interventions, for example, there needs to be a minimum number of cases. This is demonstrated in the quality report accompanying the Federal Office of Public Health's pilot project, and also in a study recently published by University Hospital Zurich. Specialised procedures conducted without the requisite number of cases often result in serious complications and prolonged suffering. This is also one of the reasons why the cantons have joined forces in a concordat for the provision of high-end medicine. If this concordat succeeds, high-end medicine will remain at cantonal level; if not, it will be delegated to the federal level.

Different payers

The benefits paid under health insurance are the same for the whole population. Everyone is entitled to them regardless of whether they live in a canton with a university hospital or in a small peripheral canton. These services account for around one third of the costs of healthcare. Premiums contribute a share of the costs of healthcare provided under basic insurance. However, premiums do not give direct entitlement to a direct benefit of equal value; not claiming on basic insurance constitutes an act of solidarity with sick people. Premiums cover a reasonable share of the funding required to provide the infrastructure for things like emergency care, training, administration and ultimately also research. This benefits everyone in the event that they need care.

With the new hospital planning and funding legislation, in many places acute care has been separated from long-term care. A result of this can be that via the law on the funding of nursing care the responsibility for long-term care now lies primarily with local authorities. The canton, however, is responsible for overseeing home nursing services and long-term care institutions, as well as defining the framework for the funding of long-term care. Responsibilities in this area are thus spread over three levels: federal, cantonal and municipal. This leads to a great deal of non-transparency and legal inequality. The implementation of the law on the funding of care also exemplifies the different ways in which the cantons exploit their room for manoeuvre. Each canton decides for itself who has what responsibilities. Sometimes it's the municipalities and sometimes it's providers who have a say; sometimes there is hybrid responsibility for long-term care. This creates major uncertainty among residents and patients in long-term care institutions as regards the care they are entitled to and, above all, how it is funded. When it comes to funding, legal inequality and uncertainty prevails; amendments to the funding law are urgently required to remedy the situation.

Progress in medicine

Another consideration is the rapid pace of medical progress. While this has undisputed advantages, it also creates the risk that medical care with no proven added value for patients will be covered and paid for under basic insurance. This is because Switzerland, unlike other countries such as the UK, does not systematically evaluate the value added by highly specialised medicine. In Switzerland there are no structures or institution for doing so. To this end, in 2005 Canton Zurich launched a pilot medical board; it has since gained a new and broader group of sponsors and become established as the Swiss Medical Board. Health technology assessments (HTAs) are used to assess the value added by specific care. The Swiss Medical Board, whose sponsors include the GDK, is now to be developed further or established at federal level in a different form – primarily to ensure that the results and insights gained from the evaluation of care will also impact treatment and funding. If this does not happen, the project will remain on a non-binding, cantonal footing, and potential solutions that would be worth looking into will be put on the shelf.

Concrete proposals:

- Create and establish a centre of quality and cost-efficiency to guarantee quality assurance across the board
  - Ensure central coordination of quality assurance measures
  - Define binding quality requirements, controls and, when necessary, sanctions
- Improve transparency of treatment and quality-related data
- Strengthen inter-cantonal and national cooperation
- Give patients the right of codetermination at federal level
- Adopt a different approach to handling and processing mistakes
- Implement integrated care
- Adopt measures to prevent inappropriate care, under- and overtreatment
- Promote public health literacy
- Define binding standards of hygiene (hygiene legislation)
- Unify the different funding systems and the different payers

Conclusion

The present healthcare system is on the whole very good, but there are clear gaps evident in a number of areas. There is an urgent need for action in many of these areas, especially when it comes to the quality of, for example, medication, invasive procedures, defining indications, identified sources of error, home and in-house nursing interfaces, the benefits of treatment, hygiene, etc. In some of these areas there are already important insights and proven solutions.

The federalist structure of the healthcare system will only work from the patient point of view if powers and responsibilities are newly demarcated in areas such as quality assurance, which should also be coordinated by a single body. Responsibilities in

highly specialised medicine and the oversight of institutions also have to be reorganised. Another proposal is that periods of limitation and forfeit in liability cases should be harmonised across Switzerland. The rights and duties of patients also need to be defined more uniformly to better benefit them.

For those affected, the healthcare system is generally lacking in transparency and subject to a great deal of legal inequality. Ultimately, quality and quality assurance are not possible on a nationwide basis. Overall, the federalist structure tends to drive up costs. Few things, apart from the suffering of patients, are as costly as shortcomings in or a lack of quality.

The OECD's healthcare statistics show our system to be more expensive but no better than in comparable countries such as Austria and Canada. Both these countries have fewer consultations and higher life expectancy. The federalist system still has to meet a minimum requirement: it must be anchored in a comprehensive legislative framework for healthcare at the federal level. The most urgent requirement from the point of view of patients: a central body for quality and cost-efficiency must be established at the federal level.

Erika Ziltener, Lic. phil., Diploma in Nursing
President of the umbrella association of Swiss patients' organisations (DVSP)
Umbrella association of Swiss patients' organisations (DVSP)

Literature sources:

DVSP (2012): Revisionen in Abklärung: Motion zur Umkehr der Beweislast und Motion für ein Hygienegesetz.

Federal Office of Public Health (2012): "Qualitätsindikatoren in Schweizer Akutspitäler 2006" report. Accessible at www.bag.admin.ch/kvspi.

Swiss Patient Safety Foundation (2012): Paper of the Month. Medienanalyse der öffentlichen Berichterstattung über Medikationsfehler. Accessible at https://www.patientensicherheit.ch/agenda/detail/news/paper-of-the-month-29-medienanalyse-der-oeffentlichen-berichterstattung-uber-medikationsfehler/.

Richtlinien der FMH-Gutachterstelle Bern (2011): Ablehnung eines Gesuchs der Patientenstelle Zürich

UniversityHospital Zurich (2011): "Komplikationen nach Operationen sind Kostentreiber" study.

Support for victims (patients, families, and staff)

A short report prepared for the Swiss National Report on Quality and Safety in Healthcare.

Dr. Stuart McLennan
Institute for Biomedical Ethics, University of Basel, Switzerland.

Date of Submission: 11 January 2019

Disclosure: The author has no conflicts of interests to declare.

Abstract

While the need to support patients and staff involved in adverse events has been recognised in Switzerland, there are a number of interconnected barriers and challenges that exist in the Swiss health care system that can undermine support, including variations in hospital safety culture, a lack of systematic programs and staff training, and legal barriers. To improve the support of victims after adverse events in Switzerland, this short report recommends that consideration should be given to the following:

Support for patients and families:
1) That the training of staff in relation to "open disclosure" is enhanced via the implementation of a broad-based educational initiative and that all Swiss health care organisations establish a core group of "just-in-time" disclosure coaches.
2) That there is greater harmonization of open disclosure guidance across Swiss hospitals and that this guidance is made more patient-centred so that patients are asked what their needs are to allow their priorities to guide the disclosure conversation.

Support for staff
1) That an evidence-based tool kit is developed to assist Swiss health care organisations in developing and implementing a systematic support program, and that organisations financially invest in these support programs due to both ethical and financial reasons.
2) That the implementation of systematic support programs is combined with multipronged educational efforts to increase awareness of the problem, the availability of support programs, and that they are beneficial and safe to use.

1. Introduction
Medical injury has been a central concern to health systems since international research was published highlighting the significant harm that adverse events cause to thousands of patients each year [1]. While efforts to reduce adverse events and harm continue, heath systems are also increasingly considering how the "victims" of medical injury can be better supported.

1.1. Support for patients and families
The "first victims" are the patients who are harmed. Available international data suggests that medical errors cause disabling injuries or death to nearly one in ten patients and that the economic cost of errors is substantial, with prolonged hospitalisation, loss of income, disability and litigation costing some countries many billions of dollars a year [2]. The support of patients and families following an adverse event is inextricably linked to "open disclosure"; the prompt, compassionate, and honest communication with patients and families following a healthcare incident that has resulted in harm [3-5]. Indeed, the disclosure of errors has evolved in recent years from a strategic response to rising legal costs focusing on organisational risk minimisation, to an ethical practice seeking to re-establish trust by meeting patients' needs and expectations following an incident. While the open disclosure process can vary, it typically includes an acknowledgment; providing a factual explanation of what happened; an expression of regret or an apology; ***an offer of practical and emotional support***; and explaining the steps being taken to manage the incident and prevent recurrence [3-4]. Open disclosure is thought to potentially have a number of positive benefits, including assisting the recovery of harmed patients by "redressing a power imbalance, restoring dignity, achieving closure and stopping the search for an explanation or information, [and] reducing the impulse for redress by making them feel that they have been treated respectfully and fairly" [6]. Disclosing errors to patients is now widely seen as an ethical, professional and legal duty [3-5,7-8].

1.2. Support for staff
The phrase "second victims" was introduced in 2000 to highlight the significant emotional impact that staff involved in errors can experience [9], and has been defined as "a health care provider involved in an unanticipated adverse patient event, medical error and/or a patient related-injury who become victimized in the sense that the provider is traumatized by the event" [10]. Empirical evidence suggests that staff involved in major errors, without sufficient support, can experience burn-out, difficulty sleeping, depression, flashbacks and self-doubt; harming not only their health but also threatening their ability deliver safe, compassionate care [11-14]. It is estimated that between 10.4% to 43.3% are staff are left "second victims after an adverse event [15]. This has led to a number of organisational to develop and implement programs to support staff involved in adverse events [16]. Recent cost-benefit analysis of a well-known support program at Johns Hopkins Hospital in the United States, also found that the program has resulted in substantial cost savings (1.8 million dollars) to the hospital via reducing staff turnover and time off [17].

1.3. Interconnected support
Research also suggests that there may be a link between these two issues. Indeed, it appears that this link may go in both directions. Not only will the adequate support

of staff after an error likely assist with open disclosure, but also that positive open disclosure experiences for staff may also mitigate emotional distress associated with future errors [18].

2. What is known about this topic in the Swiss context?

There has been limited research conducted on this topic in Switzerland. While there is anecdotal evidence that a number of hospitals offer support for both types of victims, further research is needed to find out exactly what support is offered. The lack of research has provided challenges in preparing this short report. In addition to reviewing the literature, I have also contacted a number of individual quality and patient safety managers of Swiss hospitals regarding the support their hospital offers to victims and other key stakeholders in the Swiss health care system. However, the limitations and unrepresentativeness of this information need to be acknowledged.

2.1. Support for patients and families

In 2006, the Swiss Patient Safety Foundation translated the Massachusetts Coalition for the Prevention of Medical Errors' "When Things Go Wrong" into German ("Wenn etwas schief geht") [5], which has been widely distributed and has helped bring awareness to this issue in Switzerland. The Patient Safety Foundation has subsequently also developed a range of education materials and training courses regarding the communication of errors to patients [19].

However, previous research indicates that implementation of error disclosure policies by Swiss hospitals has been slow. In 2011, a cross-sectional survey of Swiss hospitals found that 46% of hospitals (94/205) had implemented a disclosure standard; 16% (33/205) were planning to implement one in the next 12 months; and 38% (78/205) had not implemented a disclosure standard and were not planning to do so [20]. However, the fact that open disclosure policies were implemented across cultures and languages in Switzerland, a country with an emphasis on decentralisation, is a promising sign and shows that moves towards more transparency and open communication with patients are being recognised as universally needed.

This survey, however, did not examine the contents of these policies, and I am not aware of any previous research examining the details of the practical and emotional support that Swiss hospitals currently provide patients and families after an adverse event. However, the policies I have reviewed and the feedback I have received suggests that:
1) While a number of Swiss hospitals now have policies acknowledging the importance of communicating with and supporting patients and families after an adverse event, most of these policies do not have the necessary detail and granularity to provide sufficient guidance about how to do this in practice;
2) Due to the possibility of a liability case, complaints management and legal departments are often the initial contact point for patients and families following an adverse event.

In 2012/2013, a cross-sectional survey was conducted with clinically active anaesthesiologists regarding communicating medical errors [21]. This study found, among other things, that only 12% of respondents had received any training on how to disclose errors to patients. Although, 93% were interested in receiving general

training on how to disclose errors to patients, and 95% were interested in receiving support from an expert on patient communication after a serious error [20]. Significant differences were also found between departments regarding error disclosure, likely reflecting leadership and the prevailing ethos of the individual department and hospital [21].

2.2. Support for staff
The Swiss Patient Safety Foundation was the first organization to systematically examine the issue of "second victims" in Europe, [22-23], It has also published a comprehensive document entitled "Täter als Opfer" (Offender as victim) in 2010, which provides a comprehensive overview of the topic and recommendations regarding what managers, colleagues and victims should know and do following an adverse event [24].

At present, there has been no research published regarding the exact support that Swiss hospitals provide to staff after an adverse event. However, there is currently a survey being conducted to assess this by PD Dr. Rene Schwendimann from the University Hospital Basel and Prof. David Schwappach from the Swiss Patient Safety Foundation. Nevertheless, the policies I have reviewed and feedback I have received suggests that while there are a few hospitals that have more developed support policies and procedures in place, most Swiss hospitals do not have formal support programs and support is provided inconsistently and on an ad hoc basis. Outside of hospitals, the Swiss Medical Association (FMH) also offers support to physicians via the ReMed support network [25]. ReMed provides support to physicians in crisis via its 24-hour hotline and team of experienced counsellors, and preventive services through workshops and training courses [25].

The cross-sectional survey conducted with Swiss anaesthesiologists in 2012/2013, also examined the emotional impact of medical errors [26]. The study found, among other things, that 1) 90% of participants disagreed that hospitals adequately support them in coping with the stress associated with medical errors (30% strongly), and 2) 92% reported that they were interested in psychological counselling after a serious error, but identified a number of barriers to seeking psychological counselling.

3. What are the barriers and challenges that exist in Swiss Healthcare regarding this topic?
There appears to be a number of interconnected barriers and challenges that exist in the Swiss health care system that can undermine the support of both types of victims.

3.1. Cultural Norms
The importance of creating a culture of safety in health care has been repeatedly noted in the quality and safety literature [27]. The most frequently cited dimensions of safety culture include: "leadership commitment to safety; open communication founded on trust; organisational learning; a non-punitive approach to adverse event reporting and analysis; teamwork; and shared belief in the importance of safety" [27]. Unfortunately, the medical profession has "traditionally relied upon that method found most unhelpful in reducing errors and improving quality—namely, shame and blame of individuals with accusations of incompetence, unprofessionalism, and unworthiness to treat patients…" [28]. This "blame culture" is at odds with the

contemporary "systems" conception of error causation, which holds that most errors have their roots in wider organisational factors [29], and is unlikely to foster an environment where staff feel they can safely discuss medical errors openly and seek help for themselves. While the importance of a good safety culture has been recognised in Switzerland, a number of stakeholders report that cultural norms towards medical error can still act as an important barrier to the support of victims. International research on general patient safety culture has found that organisational culture significantly varies between hospitals [30]. The limited research conducted in Switzerland also indicates that the cultural norms of individual hospitals and departments may be a key barrier or facilitator to the support of victims [20-21,26].

3.2. Policies and Training

The implementation of systematic policies and procedures may be an important indication of organisational culture concerning the support of victims. International research has also found that the implementation of systematic policies and procedures, along with the increase of specially trained staff, has been one of the driving forces behind the improved support of both types of victims [16,31]. Thus, the fact many Swiss hospitals do not appear to have such systematic policies and procedures regarding supporting victims, and that many staff have not received training of this issue, is potentially very concerning and an important barrier. Furthermore, in the absence of systematic policies and procedures there can also be a lack of clear responsibilities in relation to supporting victims, which some stakeholders report to be a current issue.

3.3 Legal

Legal fears of staff have been identified internationally as one of the most pervasive barriers in dealing with medical errors [32-33]. Although the focus on the law is often misguided [32-34], previous stakeholder interviews in Switzerland have highlighted some potentially important legal barriers to supporting victims [37-38]:

1) *Criminal liability:* Switzerland currently has the threshold for criminal liability set very low, with any negligent act that results in bodily injury a potential candidate for a criminal investigation [37]. While the current incidence of criminal cases regarding patient harm may be reasonably low, criminal prosecutions can have a significant negative impact on clinicians, often destroying their professional lives and reputations and having a significant impact on their personal lives and health, even though they do not result in a conviction. Fear around criminal liability, can, therefore, not only act as a barrier to supporting patients by making staff less willing to be open about medical errors, a criminal investigation can also further victimize the staff involved.

2) *Liability insurance:* Current practice of at least some liability insurance companies in Switzerland is currently inhibiting communication with harmed patients after an error [38]. Indeed, it appears that all communication with the patient is often stopped once a claim is made due to instructions given by insurance companies' lawyers, or hospitals and staff being overly cautious. Staff are particularly concerned about losing their liability insurance cover for apologising to harmed patients. This situation is likely to act as a barrier to providing support to patients and families after a medical error.

4. What are your recommendations for improvements in these areas?
This short report has highlighted how the support of patients, families and staff are not separate issues, but closely interconnected. As such, it would be preferable that the recommendations for improvements outlined below are implemented in a common, integrated, approach to supporting victims.

4.1. Support for patients and families
Disclosing and apologizing for an adverse event, is one of the most complex and difficult conversations that occur in healthcare [35]. It is recommended that enhancing the training and support of staff in relation to this process will likely make the biggest difference in the support of patients and families in Switzerland.

- **Recommendation 1: Training**

1) A broad-based educational initiative: Given the number of staff who at any time could become involved in an adverse event, it is important that all staff have a general understanding of open disclosure [39]. While the work of the Swiss Patient Safety Foundation has done much to address this issue, there is still a need to improve the general disclosure training of undergraduates and postgraduates, and for all staff to understand their organisation's approach to open disclosure.

2) Coaching expertise: It is, however, unrealistic that general education will enable all staff to be able to hold these discussions well and any moment [39]. Nevertheless, previous research has clearly established that patients want to be having these discussions with their physicians and not with risk managers or other institutional representatives [39]. It is therefore recommended that all Swiss health care organisations establish a core group of "just-in-time" disclosure coaches who are available to guide staff in how to have these discussions with patients and families well [39].

- **Recommendation 2: Guidance**

1) Harmonising guidance: There is currently significant unwarranted heterogeneity in open disclosure policies in Switzerland, which needs to be addressed. It is concerning that less than 50% of Swiss hospitals have implemented an open disclosure policy, and the policies that have been implemented often do not contain the necessary granularity to provide staff with specific guidance. Without sufficient guidance, it will be difficult for many staff to meet patients' expectations and needs. In many instances, health care policies should be context specific; the needs of a large university hospital will often be very different from a small rural hospital. However, in the context of open disclosure, there arguably should not be as much variation in the scope and contents of policies as currently seen and there is a need for greater harmonization across Swiss hospitals. It is recommended that key stakeholders come together to agree on a common approach to open disclosure guidance that not only provides sufficient detail and granularity for staff but also better meets the needs of consumers. A nation-wide open disclosure policy, similar to the Australian Open Disclosure Framework [40], may be a better approach, rather than requiring every hospital in Switzerland to reinvent the wheel, resulting in multiple individual policies with significant unwarranted variations. However, the experience of the United Kingdom in implementing a 2005 national policy highlights the importance of engaging and supporting staff to implement such a policy [41].

2) Making the open disclosure process more patient-centred: Whatever approach is used to harmonise open disclosure guidance, this guidance should take into consideration the findings of recent international research that has indicated how the open disclosure process could better support patients and families. This research suggests that there is a need to: 1) ask, and not assume, what patients and families need; and 2) provide injured patients with the opportunity to "be heard"; allowing their priorities to lead the conversation rather than just listening to the patient's answers to questions posed by staff [42-43].

4.2. Support for staff
There is a clear need for Swiss health care organisations to provide more consistent and timely support to staff involved medical errors. It is recommended that assisting health care organisations to develop systematic support programs and implementing multipronged educational initiatives will likely make the biggest difference in the support of staff in Switzerland.

Recommendation 1: Systematic support programs
1) Evidence-based tool kit: There is a need for Swiss health care organisations to implement more systematic support programs. It has been suggested, however, that "one of the reasons that health care organisations do not routinely offer emotional support might be that their leaders do not know how to develop and successfully implement a support system" [44]. Indeed, it has been found that in the absence of another structure to imitate, that it can take many years to develop and implement a support process [45]. While the Swiss Patient Safety Foundation has provided comprehensive recommendations regarding what health care managers should know and do following an adverse event [24], there is a need for more detailed guidance to assist Swiss health care organisations to practically develop and implement support programs. Consideration should be given to developing an evidence-based tool kit to assist Swiss healthcare organisations in developing and implementing a systematic support program, similar to tool kits developed in the United States [46]. Staff often "suffer in silence" following a medical error as they are not offered (nor seek out) the support that they need [47]. Given the post-event trajectory that has been identified, support programs could be developed to screen at-risk staff after an adverse event and proactively offer support to "expedite recovery and mitigate adverse career outcomes" [48]. Finally, support programs should reflect on the terminology used to describe the staff involved in adverse events and the services to support them. Although the term "second victim" is now widely used, there is some controversy over use of the term; with concerns that the term "victim" may stigmatize staff and offend patient advocates [49]. While the use of "second victims" may still be helpful in some contexts, it has been suggested that "[f]or support programs that appeal directly to health care workers, different language may attract more users [49].

2) Funding of programs: Although supporting staff after adverse events is clearly the right thing to do ethically, the cost-benefit analysis of Johns Hopkins Hospital's support program indicates that the implementation of such support programs is also in the financial interests of health care organisations [17]. Swiss health care organisations should, therefore, give serious consideration to investing in support programs due to both ethical and financial reasons.

Recommendation 2: Multipronged educational initiatives
One of the biggest challenges of support programs internationally has been getting staff who could benefit from them to actually use them [16]. Contact with quality and patient safety managers of Swiss hospitals suggests that this is also a challenge in Switzerland. Furthermore, a recent qualitative metasynthesis of the literature indicate that hospital safety culture plays a key role in the support of staff [50]. It is therefore recommended that the implementation of systematic support programs is combined with multipronged educational efforts to increase awareness of the problem, the availability of support programs, and that they are beneficial and safe to use.

References

1. Institute of Medicine. To err is human: building a safer health system. Washington, D.C.: The National Academies Press, 2000.
2. World Health Organization. WHO Patient Safety Research. World Health Organization, 2009.
3. National Patient Safety Agency. Being Open: Saying sorry when things go wrong. NHS: National Patient Safety Agency, 2009.
4. Australian Commission on Safety and Quality in Health Care. Open Disclosure Standard: A National Standard for Open Communication in Public and Private Hospitals, Following an Adverse Event in Health Care. Sydney: ACSQHC, 2008.
5. Massachusetts Coalition for the Prevention of Medical Errors. When Things go Wrong: Responding to Adverse Events. A Consensus Statement of the Harvard Hospitals. Massachusetts Coalition for the Prevention of Medical Errors, 2006.
6. Australian Commission on Safety and Quality in Health Care. 2012. Open disclosure standard review report. Sydney: ACSQHC.
7. Canadian Patient Safety Institute. Canadian Disclosure Guidelines. Ottawa: Canadian Patient Safety Institute; 2008.
8. New Zealand Ministry of Health. Health and Disability Services Standards NZS 8134. Wellington: Ministry of Health; 2008.
9. Wu A. Medical error: the second victim. The doctor who makes the mistake needs help too. BMJ 2000; 320: 726-727.
10. Scott SD, Hirschinger LE, Cox KR, McCoig M, Brandt J, Hall LW. The natural history of recovery for the healthcare provider "second victim" after adverse patient events. Qual. Saf. Health Care 2009; 18: 325-330.
11. Schwappach DLB, Boluarte TA: The emotional impact of medical error involvement on physicians: a call for leadership and organisational accountability. Swiss Med Wkly 2008; 138: 9–15.
12. Shanafelt TD, West C, Zhao X, Novotny P, Kolars J, Habermann T, Sloan J (2005) Relationship between increased personal well-being and enhanced empathy among internal medicine residents. J Gen Intern Med 2005; 20: 559-564.
13. West CP, Huschka MM, Novotny PJ, Sloan JA, Kolars JC, Habermann TM, Shanafelt TD. Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. JAMA 2006; 296: 1071-1078.
14. West CP, Tan AD, Habermann TM, Sloan JA, Shanafelt TD. Association of Resident Fatigue and Distress With Perceived Medical Errors. JAMA 2009; 302: 1294-1300.
15. Seys D, Wu AW, Van Gerven E, Vleugels A, Euwema M, Panella M, Scott SD, Conway J, Sermeus W, Vanhaecht K. Health care professionals as second victims after adverse events: a systematic review. Eval Health Prof. 2013;36(2):135-62.
16. Edrees H, Connors C, Paine L, Norvell M, Taylor H, Wu AW. Implementing the RISE second victim support programme at the Johns Hopkins Hospital: a case study. BMJ Open. 2016;6(9):e011708.
17. Moran D, Wu AW, Connors C, Chappidi MR, Sreedhara SK, Selter JH, Padula WV. Cost-Benefit Analysis of a Support Program for Nursing Staff. J Patient Saf. 2017 Apr 27. doi: 10.1097/PTS.0000000000000376. [Epub ahead of print]

18. McLennan SR, Engel-Glatter S, Meyer AH, Schwappach DLB, Scheidegger DH, Elger BS. The Impact of Medical Errors on Swiss Anaesthesiologists: A Cross-Sectional Survey. Acta Anaesthesiologica Scandinavica. 2015;59:990-8.

19. Stiftung für Patientensicherheit. Kommunikation nach einem Zwischenfall: https://www.patientensicherheit.ch/aktuell/kurse-und-tagungen/zwischenfall/ (accessed 07.12.2018).

20. McLennan S, Engel S, Ruhe K, Leu A, Schwappach S, Elger B. Implementation Status of Error Disclosure Standards Reported by Swiss Hospitals. Swiss Medical Weekly. 2013;143:w13820.

21. McLennan SR, Engel-Glatter S, Meyer AH, Schwappach DLB, Scheidegger DH, Elger BS. Disclosing and Reporting Medical Errors: Cross-sectional survey of Swiss Anaesthesiologists. European Journal of Anaesthesiology. 2015;2(7):471-476.

22. von Laue N, Schwappach DLB, Hochreutener MA. "Second victim" - error, crises and how to get out of it. Ther Umsch 2012; 69: 367-70.

23. von Laue N, Schwappach D, Hochreutener MA, Frank O. Täter als Opfer – „second victims" Konstruktiver Umgang mit BehandlungsFehlern in Gesundheitsorganisationen Autoren. Stiftung für Patientensicherheit, 2011.

24. Schwappach D, Hochreutener MA, von Laue N, Frank O. Schriftenreihe Nr. 3 – Täter als Opfer – Konstruktiver Umgang mit Fehlern in Gesundheitsorganisationen. Zürich: Stiftung für Patientensicherheit, 2010. https://www.patientensicherheit.ch/fileadmin/user_upload/3_Bildung/TaO/3_S R_3_Ta__ter_als_Opfer_D_160725.pdf

25. ReMed https://www.fmh.ch/en/rem/remed.html (accessed 07.12.2018)

26. McLennan SR, Engel-Glatter S, Meyer AH, Schwappach DLB, Scheidegger DH, Elger BS. The Impact of Medical Errors on Swiss Anaesthesiologists: A Cross-Sectional Survey. Acta Anaesthesiologica Scandinavica. 2015;59:990-8.

27. Halligan M, Zecevic A. Safety culture in healthcare: a review of concepts, dimensions, measures and progress. BMJ Qual Saf. 2011;20(4):338-43.

28. Liang BA. A system of medical error disclosure. Quality and Safety in Health Care. 2002; 11, 64-68.

29. Reason J. Human Error. Cambridge: Cambridge University Press, 1990.

30. Speroff T, Nwosu S, Greevy R, Weinger MB, Talbot TR, Wall RJ, Deshpande JK, France DJ, Ely EW, Burgess H, Englebright J, Williams MV, Dittus RS. Organisational culture: variation across hospitals and connection to patient safety climate. Qual Saf Health Care. 2010;19,592-596.

31. Iedema, R., Mallock, N., Sorensen, R. et al. Final Report. Evaluation of the National Open Disclosure Pilot Program. Sydney: Australian Commission on Safety and Quality in Health Care, 2008.

32. Iedema R, Allen S, Sorensen R, Gallagher TH. What Prevents Incident Disclosure, and What Can Be Done to Promote It? Joint Commission Journal on Quality and Patient Safety 2011; 37:409-417.

33. Hartnell N, MacKinnon N, Sketris I, Fleming M. Identifying, understanding and overcoming barriers to medication error reporting in hospitals: a focus group study. BMJ Quality and Safety 2012; 21:361-368.

34. McLennan S. The law as a barrier to error disclosure: a misguided focus? Trends in Anaesthesia and Critical Care. 2018; 19: 1-5.

35. McLennan S, Rich LE, Truog RD. Apologies in medicine: Legal protection is not enough. Canadian Medical Association Journal. 2015;187(5):E156-159.
36. McLennan SR, Truog RD. Apology Laws and Open Disclosure. Medical Journal of Australia. 2013;198(8):411-412.
37. McLennan S, Elger B. Criminal Liability and Medical Errors in Switzerland: An Unjust System? Revue Suisse de droit de la santé/Schweizerische Zeitschrift für Gesundheitsrecht [Swiss Journal of Health Law]. 2015; 135-142.
38. McLennan S, Shaw D, Leu A, Elger B. Professional Liability Insurance and Medical Error Disclosure. Swiss Medical Weekly. 2015;145:w14173.
39. Truog RD, Browning DM, Johnson JA, Gallagher TH, Leape LL. Talking with patients and families about medical error: A guide for education and practice. Baltimore: Johns Hopkins University Press, 2010.
40. Australian Commission on Safety and Quality in Health Care. Australlian Open Disclosure Framework. Sydney: Australian Commission on Safety and Quality in Health Care, 2013.
41. Wu AW, McCay L, Levinson W, Iedema R, Wallace G, Boyle DJ, McDonald TB, Bismark MM, Kraman SS, Forbes E, Conway JB, Gallagher TH. Disclosing Adverse Events to Patients: International Norms and Trends. J Patient Saf. 2017;13(1):43-49.
42. Moore J, Bismark M, Mello MM. Patients' Experiences With Communication-and-Resolution Programs After Medical Injury. JAMA Internal Medicine. 2017;177:1595-1603.
43. Moore J, Mello MM. Improving reconciliation following medical injury: a qualitative study of responses to patient safety incidents in New Zealand. BMJ Quality and Safety. 2017;26:788-798.
44. Pratt S, Kenney L, Scott SD, Wu AW. How to Develop a Second Victim Support Program: A Toolkit for Health Care Organizations. Jt Comm J Quality Safety 2012; 38: 235-240.
45. Scott SD, Hirschinger LE, Cox KR, McCoig M, Hahn-Cover K, Epperly KM, Phillips EC, Hall LW. Caring for Our Own: Deploying a Systemwide Second Victim Rapid Response Team. Jt Comm J Quality Safety 2010; 36: 233-240.
46. Pratt S, Kenney L, Scott SD, Wu AW. How to Develop a Second Victim Support Program: A Toolkit for Health Care Organizations. Jt Comm J Quality Safety 2012; 38: 235-240.
47. Ullström S, Andreen Sachs M, Hansson J, Ovretveit J, Brommels M. Suffering in silence: a qualitative study of second victims of adverse events. BMJ Qual Saf 2014; 23:325-31.
48. Scott SD, Hirschinger LE, Cox KR, McCoig M, Brandt J, Hall LW. The natural history of recovery for the healthcare provider "second victim" after adverse patient events. Qual. Saf. Health Care 2009; 18: 325-330.
49. Wu AW, Shapiro J, Harrison R, Scott SD, Connors C, Kenney L, Vanhaecht K. The Impact of Adverse Events on Clinicians: What's in a Name? J Patient Saf. 2017 Nov 4. doi: 10.1097/PTS.0000000000000256. [Epub ahead of print]
50. Schiess C, Schwappach D, Schwendimann R, Vanhaecht K, Burgstaller M, Senn B. A Transactional "Second-Victim" Model-Experiences of Affected Healthcare Professionals in Acute-Somatic Inpatient Settings: A Qualitative Metasynthesis. J Patient Saf. 2018 Jan 30. doi: 10.1097/PTS.0000000000000461. [Epub ahead of print]

REGULATION SYSTEM AND QUALITY / SAFETY

Contribution to the Swiss national report on quality and safety in the healthcare system

Professor Olivier Guillod
Director, Institute of Health Law

Rachel Christinat, Doctor of Law
Senior Lecturer, Institute of Health Law

University of Neuchâtel

January 2019

The authors confirm that they are not under any conflict of interest.

Abstract

National-level players in the healthcare field are not subject to any special regulations governing the safety and quality of the care that is provided. As far as we are aware, Valais is the only canton to have adopted specific provisions in its health legislation. Numerous federal and cantonal laws therefore contain articles that indirectly address patient safety and quality of care. The fragmented nature of the subject makes a legal analysis complicated, and implementation is left to various public bodies at national (Federal Council) and cantonal (cantonal public health authorities) level on the one hand, and private institutions (such as the Swiss Foundation for Patient Safety, patient advocacy organisations or even healthcare facilities) on the other. Furthermore, the medical liability system in place in Switzerland is poorly equipped to manage clinical risks, despite the case law of the Federal Supreme Court having resulted in various amendments to the relevant legal provisions. Moreover, with the exception of the Canton of Valais, healthcare providers are under no legal obligation to operate a Critical Incident Reporting System (CIRS) for adverse events that occur in the course of the treatment they provide. In our opinion, promoting safety and quality in healthcare would entail reforming the current liability system and introducing a legal obligation to report adverse events to an independent state organisation in such a way that both contribute to the establishment of a "learning from mistakes" culture among healthcare professionals.

Developments

1. What do we know about the subject in the Swiss context (brief summary)?

Baume recently carried out a particularly thorough survey of the subject[1]. As a result, this report is quite largely based on his report, and summarises its main findings.

At present, there is no national legal basis directly governing the safety of medical treatment and quality of care in themselves, nor, with the exception of general training requirements, are healthcare professionals and healthcare facilities subject to any universal system that aims to improve these two elements of medical delivery.

Ensuring patient safety and quality of care is essentially the task of the Cantons[2]. In this case, Valais is the only canton to have enacted legislation to set up a cantonal patient safety and care quality committee (*commission cantonale pour la sécurité des patients et la qualité des soins*, or CSPQS). This committee is tasked with developing and introducing both a strategy for and the tools needed to evaluate and manage patient safety and quality of care (Art. 42 LS/VS[3]). Moreover, the legislation requires everyone who works in a healthcare facility to report any incident. In return, reporters and staff members who were involved in the incident are granted immunity from disciplinary action (Art. 44 LS/VS). The database containing these reports is used solely for incident-prevention and training purposes. It sets out proposed or actual measures to prevent a repetition of the incidents (Art. 47 LS/VS). Finally, the law gives the Health Department[4] authority to extend the system to outpatient care providers if the CSPQS proposes doing so, and after consultation with the healthcare professions concerned (Art. 48 LS/VS).

The majority of the other Cantons make provision for patient safety or quality of care in the context of granting or withdrawing licences to practice a medical profession or operate a healthcare facility[5], granting relief[6], assigning public functions or even ordering emergency measures[7]. Some Cantons' health legislation does not directly mention safety[8], but all have adopted provisions governing patient rights, something that guarantees a certain safety threshold in clinical care delivery.[9] Moreover, safety is linked to quality of care, and all Cantons impose conditions intended to guarantee a certain quality level on facilities, such as implementing a quality assurance system[10].

Under the "SwissDRG" system of financing hospital care by mandatory health insurance (Federal Health Insurance Act, HIA), the Cantons designate public or private hospitals that are

---

[1] Baume Cédric, *Gestion des risques cliniques et responsabilité médico-hospitalière* [Management of clinical risks and hospitals' medical responsibility], Neuchâtel 2015, 573 pages.
[2] Baume, note 1, N 255 ff.
[3] *Loi valaisanne sur la santé* [Valais health act] of 14 February 2008 (classified compilation [hereafter: RS]/VS 800.1).
[4] In full the Department of Health, Social Affairs and Culture.
[5] For examples see Art. 79 para. 2 of the Neuchâtel health act of 6 February 1995 (RS/NE 800.1) and Art. 24 para. 1 of the Jura act on hospitals of 28 June 2011 (RS/JU 810.11).
[6] In particular see para. 15 of Basel's ordinance on healthcare professionals and facilities of 6 December 1978 (RS/BS 310.120).
[7] For an example, refer to Art. 23 para. 1 of the Vaud act on the planning and financing of public health facilities of 5 December 1978 (RS/VD 810.01).
[8] Baume, note 1, N 261.
[9] Baume, note 1, N 259.
[10] Baume, note 1, N 259 and 296.

permitted to provide services that are reimbursed by basic health insurance cover and cantonal funding. This list of hospitals is based primarily on quality criteria[11]. Under Article 39 para. 2b HIA, the Cantons are also required to work together on nationwide planning for highly specialised services (hereafter HSS). In the light of this, the Cantons have adopted the inter-cantonal convention on HSS, one of the primary goals of which is to safeguard the quality of these complex and expensive treatments, for which extensive technical knowledge and high levels of staff and equipment resources are required[12].

Quality of care is an integral part of the quality system, and managing clinical risk is an important constituent. Baume states that "*this notion stems from the conviction ... that the search for errors should not end with individual blame, but extend to organisational dysfunction and the system in which care is provided*".[13]

The main area in which federal law has an effect on evaluations of the quality of medical care is mandatory health insurance, where Article 58 HIA prescribes a quality assurance system[14]. Under this provision, the quality of the services provided by mandatory health insurers can be inspected for the purpose of ensuring that the best care is delivered at the lowest possible cost. The health insurers also verify quality in two ways. Firstly, the tariff agreements they sign with listed hospitals (Art. 46 HIA) frequently describe the precise measures that service providers have to implement to guarantee quality of care. Secondly, they verify that service providers comply with the measures set in place to assure quality of care.

Federal laws on other specific subjects also contain provisions governing quality of care, either by defining the criteria that people authorised to administer certain treatments have to fulfil or to guarantee the quality of analytical tests, products or procedures[15].

By harmonising the training and eligibility conditions for a number of healthcare professions, the federal government was also endeavouring to ensure that practitioners possess a high level of skills and are thus able to administer high-quality care[16].

Quality indicators for Swiss acute-care hospitals (hereafter CH-IQI[17]) have been in place since 2008 to evaluate inpatient care. They give the public a summary of the services provided by the hospitals, which are funded mainly by social insurance premiums and taxes. The indicators thus facilitate comparisons of healthcare facilities and feed into discussions of quality[18].

---

[11] Baume, note 1, N 269 ff.
[12] Baume, note 1, N 299 ff.
[13] Baume, note 1, N 266.
[14] Federal Act of 18 March 1994 on Health Insurance (HIA; RS 832.10).
[15] In particular, see Articles 9 and 10 of the Federal Act of 18 December 1998 on Medically Assisted Reproduction (RS 810.11); 8 and 13 of the Federal Act of 8 October 2004 on Human Genetic Testing (RS 810.12); 6 of the Radiological Protection Act of 22 March 1991 (RS 814.50); and 10 of the Federal Act of 30 September 2011 on Research involving Human Beings (RS 810.30).
[16] Applies to doctors, dentists, pharmacists, vets and chiropractors (see the Federal Act of 23 June 2006 on University Courses for Medical Professions [RS 811.11]), the psychology professions (see the Federal Act of 18 March 2011 on the Psychology Professions 2011 [RS 935.81]), and nurses, physiotherapists,occupational therapists, midwives, dieticians, optometrists and osteopaths (see the Federal Act of 30 September 2016 on Healthcare Occupations [this Act is scheduled to come into force in 2020; Federal Gazette 2016, p. 7383 ff]).
[17] Abbreviation of Swiss Inpatient Quality Indicators.
[18] https://www.bag.admin.ch/bag/fr/home/zahlen-und-statistiken/zahlen-fakten-zu-spitaelern/qualitaet sindikatoren-der-schweizer-akutspitaeler.html (viewed on 28 December 2018).

However, it must be emphasised that the CH-IQI "*are not indicative of structural or process quality, nor of other aspects of results quality, such as infection or patient satisfaction levels*"[19].

2. What significant and pertinent changes have occurred in the Swiss healthcare system?

Legal experts have been working on the issue of quality and safety of care for nearly forty years now, but they have focused mainly on professional liability[20]. The issue has grown in importance since the start of the 21st century in particular[21]. Even though a number of authors have put forward suggestions, no significant changes have been made to federal law. However, the mandatory health insurance scheme operated under the HIA has progressively paid greater attention to quality of care and patient safety, particularly in connection with the new financing system for hospital care.

A professional liability system based on individual blame is not conducive to the evolution of a culture of learning from mistakes. The Federal Supreme Court (FSC) has made two liability law rulings that benefit patients who have suffered damage as a result of medical treatment. First the FSC has distanced itself from the normal principle that liability is based on a breach of the duty to exercise due care such that healthcare professionals bear a greater portion of the risk inherent in any medical treatment[22]. Accordingly, it has decided that "*the risk involved in any medical action, which is normally borne by the patient, passes to the practitioner if he proceeds without obtaining the informed consent that he could or should have obtained* "[23]. Since then, the FSC has produced a body of case law concerning the amount of risk-related information to be given to patients, which is dependent on the seriousness and frequency of the risk in question[24]. In a 1994 ruling, the FSC lightened the burden of proof on patients to demonstrate that the rules of medical practice had been breached when it made doctor error a presumed fact in a case where a patient had developed an infection at the site of an injection of a medicinal product[25]. Secondly, the FSC recognised that healthcare institutions have a responsibility if no other organisation is in place[26]. Under this case law, facilities are obliged by the hospitalisation contract to take the measures needed to guarantee patients' safety while they are in hospital[27].

3. What obstacles and challenges have to be faced?

From a legal perspective, the first difficulty is the lack of harmonised national regulations on the management of clinical risk and quality in the healthcare sector[28]. With the exception of

---

[19] Baume, note 1, N 277.

[20] Guillod Olivier, *Sécurité, qualité des soins et responsabilité des soignants* [Safety, quality of care and healthcare professionals' responsibility¨] in *Accessibilité aux soins et nouvelles technologies* [Access to care and new technologies] (eds. Rigaud-Bully/Auray), Paris 2002, p. 123, notes 43 and 44.

[21] Guillod, note 200, p. 113.

[22] Guillod, note 210, p. 117.

[23] DTF 108 II 59 c. 3.

[24] Baume, note 1, N 228 ff.

[25] DTF 120 II 248 c. 2.

[26] DTF 130 I 337 ; 123 III 204 ; 120 Ib 411 ; 112 Ib 322.

[27] See also Landolt Hardy/Herzog-Zwitter Iris, *Haftung für Pflegefehler* [Liability for iatrogenic injury], in *Responsabilité et assurances 2018* [Liability and insurance 2018], p. 115 ff.

[28] Baume, note 1, N 243 ff.

the legislation in force in the Canton of Valais, therefore, regulation exists only in fragmented form in various federal and cantonal laws. This has resulted in a partial blurring of the extent of healthcare professionals' obligations, notably the obligation to inform patients of any mistakes that may have been made, and the obligation to report to an independent body adverse events during medical treatment.

Patient safety and quality of care are not the responsibility of a single independent organisation tasked not only with overseeing but also collecting data that can subsequently be used to issue directives to care providers as a way of improving patient care. This is a second hurdle. The sheer diversity of the applicable legislation splits jurisdiction between the national and cantonal authorities. Thus, for example, the Federal Council is responsible for assuring the quality of care funded by mandatory health insurance (Art. 58 HIA), whereas the cantonal health authorities review the quality of care provided by healthcare professionals and hospitals. Finally, certain Cantons require healthcare institutions themselves to set up quality assurance systems. The large number of stakeholders complicates analysis and makes it hard to compile a global view of the situation.

A third complicating factor stems from the existence of numerous "soft law"[29] provisions with no direct force. This factor affects not only private healthcare organisations and healthcare institutions, but also public authorities[30].

The final obstacle is the inadequacy of the Swiss medical liability system. Liability governs the conditions under which someone who suffers injury as a result of a medical act can obtain financial compensation from the healthcare professional responsible for the injury. Here, three conditions must be met: the professional must have failed to exercise due care by breaching the rules of medical practice or the obligation to inform patients; the patient must have suffered physical or moral injury; and the injury must be causally linked to the professional's breach of care. While liability law exists primarily to make reparation (to restore the patient to a financial situation that he would have enjoyed had the injury not occurred), it also has a preventive function (to make the responsible party feel the cost of negligent behaviour and by so doing prevent a repetition)[31]. However, three factors largely diminish the preventive function of civil liability (and its contribution to patient safety)[32]. Firstly, healthcare facilities and doctors who practice under their own professional responsibility generally have liability insurance that covers them for the financial cost of liability. Secondly, the process of determining liability provides no systematic guarantee of identifying cases where a healthcare professional has actually breached his duty to exercise due care and caused a patient injury. Finally, the liability system has the perverse side effect of encouraging the healthcare professionals who may potentially be responsible to conceal any behaviour that might be construed as wrongful.

In the light of these findings, one of the authors of this report wrote as long ago as 2002 that "*applied to medical care, a liability system based on personal blame – attributable either to the responsible person himself or to one of his assistants – has largely become inadequate if there is a genuine intention to encourage high-quality care and respond to concerns about fairness*"[33].

---

[29] These are rules that do not have legal force but influence the behaviour of a group of people. The people affected sometimes construe them as being "as good as binding".
[30] For further details, refer to Baume, note 1, N 357 ff.
[31] Guillod, note 21, p. 114.
[32] Guillod note 21, p. 115 ff.
[33] Guillod, note 21, p. 114.

Finally, it must be stated that the current liability system does not recognise therapeutic risks that arise independently of any error by a healthcare professional (for example nosocomial infections or patients presenting with complications).

4. What action do you recommend?

Our proposal consists in essence of two modifications. Firstly, healthcare professionals should be under a legal obligation to spontaneously communicate any adverse event that occurs during medical care (the nature of the procedure – diagnostic, therapeutic, aesthetic or palliative – is of little relevance). This would make it possible to systematise and standardise adverse event reporting independently of error by a healthcare professional. Reports should be sent to an ad hoc centralised body, which would count and analyse them for the purpose of issuing directives to prevent risky or inappropriate acts. Given the current medical liability system, adverse event reporting should be subject to total immunity to prevent lawyers using reports in proceedings against healthcare professionals or healthcare facilities.

The second proposal involves changing the medical liability system by shifting its basis from personal blame to objective responsibility – say risk-based or, better still, compensation-based, as in Belgium, France or New Zealand. This change would remove any legal incentive to conceal errors. Professional malpractice could possibly be retained as a prior condition of legal action.

Harm to patients in Switzerland – an overview

Contribution to the Swiss National Report on Quality and Safety in Healthcare

Author: Dr. sc. nat. Stephanie Züllig

Thanks to Julia Boysen and Prof. Dr. David Schwappach for commenting on the manuscript.

Swiss Patient Safety Foundation, January 2019

Inhalt

1. Introduction

According to the World Health Organization (WHO) a patient's chance of being harmed whilst receiving healthcare is 1 in 300. Harm can be caused by a range of incidents or adverse events (AE), with nearly 50% of them being preventable. AEs include adverse drug events (ADEs), health care associated infections (HAI), venous thromboembolisms (VTEs), falls and pressure ulcers. But harm is also caused by diagnostic errors, surgical complications and administrative errors, such as lost to follow up (1).

Harm to patients occurs in the hospital as well as in the primary and ambulatory care setting. The OECD report 2017 'The economics of patient safety' states patient harm as the 14th leading cause of global disease burden, comparable to tuberculosis, malaria and some types of cancer. The OECD further reports on its website that on average, 1 in 10 hospitalizations results in safety failure or AEs and that as many as 4 out of 10 patients experience safety issues in primary and ambulatory care settings. In addition to the social burden of patient harm, AEs cause considerable financial costs. Available evidence shows that up to 15% of total hospital activity and expenditure is a direct result of AEs in OECD countries (2,3).

Since the publication of the national report 'To err is human: building a safer healthcare system' of the Institute of Medicine in 2000 national health services, governments and researchers worldwide have begun to take action in respect of measuring the extent of harm in their healthcare systems (4). The methods used include incident reporting, medical record review, observational and ethnographic studies, patient experience surveys, routine collection of safety metrics and automated data extraction from electronic medical records (5).

In Switzerland, a systematic data collection on patient harms is lacking. Since there is no national obligation to report on harm to patients the exact size of the problem is currently unknown. Data are collected in various places such as hospitals, liability insurers, cantonal physicians or patient protection organisations. However, the reason data are collected for varies and a standard list of harms is often missing. Due to the specific objective of the data collection some cases might be accounted twice whereas others are not reported at all. To make matters worse, the data are not openly accessible and are hardly ever published.

According to the lack of systematically collected data the extent of patient harm in the Swiss healthcare system is usually extrapolated. Applying the OECD figures from 2017 to the Swiss context in 2016 a median of 10% of patients is affected by at least one adverse event during hospitalisation, resulting in more than 100 000 patients annually experiencing at least one unintended injury or complication associated with hospital care (2,6).

A few organisations – which provide their own contribution to the Swiss National Report on Quality and Safety in Healthcare – do systematically collect data on patient harm. As a general rule the data collection is restricted to certain clinical topics. For example, a standardized nationwide data collection on falls, decubitus, surgical site infections as well as potentially avoidable rehospitalisations and reoperation is provided by the Swiss Association for Quality Development in Hospitals and Clinics (ANQ). The ANQ analyses the data collected by hospitals and clinics from acute care, rehabilitation and psychiatry in a nationwide comparable manner and publishes it annually. Healthcare associated infections (HAI) – commonly considered preventable adverse events – are reported by Swissnoso, the national association of leading professionals in the fields of infectious diseases and infection prevention. In 2017, Swissnoso and the University Hospital of Geneva lead a point prevalence survey on HAIs and the use of antimicrobials in almost hundred acute care hospitals (7). This was the second survey on HAI in Switzerland after 2004. Although the two surveys differ in methodology they draw a picture on the burden of patient harm caused by nosocomial infections in Switzerland and allow benchmarking with other countries in Europe. Yet another

example provides the collection of claims data in anaesthesia by the Swiss Society of Anaesthesiology and Resuscitation (SSAR) (see also section 3.2 of this report).

In contrast, reporting and learning systems such as the Critical Incident Reporting System (CIRS) are often erroneously believed to provide information on patient harm. As described in the "Incident reporting and safety learning" report – another contribution from the Swiss Patient Safety Foundation to the Swiss National Report on Quality and Safety in Healthcare – CIRS are not the right tool for collecting data on patient harm and should not be (mis)used as such.

To address the topic of patient harm in Switzerland we decided to choose an approach by methodology relying on data published in peer-reviewed journals between 2000/01/01 and 2018/10/30, focusing on preventable adverse events as a surrogate marker for patient harm.

2. Methodologies applied in Switzerland

2.1 *Chart reviews*

Retrospective chart reviews, also known as medical record reviews, are commonly used to measure the prevalence of AEs (8). The most frequently used review methods are the "Harvard Method" and the Institute of Healthcare Improvement's Global Trigger Tool (see also Global Trigger Tool, section 3.1 of this report) (9,10). Although numerous studies have been published worldwide, data for Switzerland are rare. To our knowledge the study by Halfon and colleagues published in 2017 is the only retrospective chart review determining the incidence of AEs carried out in Switzerland (11). By performing a two steps retrospective chart review in one acute care hospital the authors found an overall hospital incidence rate of AEs of 14.1%. The proportion of hospitalizations with at least one AE was 12.3%. Almost half of all AEs were judged preventable. Whereas 60% of AEs lead to no or minor disability, 23% of AEs resulted in severe impairment. Interestingly, none of the AEs resulted in death. This result contrasts international findings that estimate around 7% of AEs being lethal. However, the main limitations are that the study was conducted in only one medium size community hospital and data are from medical records dating from one single year (2008).

2.2 *Surveys*

Survey studies that involve healthcare professionals or patients are another useful source to assess information on the frequency and severity of patient harm in healthcare. In contrast to medical chart reviews which rely on complete and correct patient documentation survey studies provide a methodology to assess the entire range of safety events occurring during patient care. In the last few years, a couple of surveys have been published for Switzerland. Some of them took place in primary care, aiming at gaining additional insights into the hot spots of patient safety. Gehring and colleagues assessed the frequency and harm associated with primary care safety incidents by surveying primary care physicians and nurses about the occurrence of safety problems in their offices (12). Out of 316 physicians almost one third reported that at least one of the described incidents occurred daily or weekly in their offices. In the group of nurses it was one in six. Over the course of one year, each responder counted on average a total of 92 incidents. The incidents most frequently reported occurred in the following areas 1) documentation, 2) information from external provider and 3) medication. In general, the frequency of reported incidents was considerably higher for physicians than for nurses. Some events, however, nurses noticed more often than physicians supporting the involvement of both, physicians and nurses, into patient safety activities. The authors also found differences in the reporting frequencies between the different types of medical office organisation. In medical centres physicians and nurses reported higher frequencies of incidents than in single-handed and joint offices. This finding most likely reflects the higher case load and number of staff employed in such medical centres.

Survey studies of self-reported patients' safety events and perceptions of safety provide another method to gain information on preventable adverse events that are not reported in the medical record. For example in the survey study of Schwappach and colleagues 21.4% of patients reported to have experienced at least one definite event, and 29.1% reported at least one definite or possible event (13). The results of the patient survey were reported back to the hospitals which allowed them to initiate a discussion of safety issues within their organisation. Another study addressed patients' experiences of drug administration safety in the oncology setting and investigated the relationship between perceptions of risk and potential harm, staff safety practices, and patients' engagement in error prevention strategies (14). The authors found that 16% of patients reported having experienced an error in their cancer care, and 11% were currently very concerned about errors. Surprisingly, patients rated the potential harm for drug overdosing rather low. This finding is rather unexpected and points out the necessity to improve communication about safety issues between care provider and patient. Patient safety surveys of the experience of medical errors have also been conducted in a multinational setting (15). For Switzerland the frequency of self-reported errors was 11.9%.

Taken together, survey studies have been shown to report AEs in hospitals and in the outpatient setting. The frequency of self-reported AEs is in line with the above noted ratio of 1 out of 10 patients being harmed during medical care. In addition, survey studies offer the possibility to tackle patient safety issues from a different perspective thereby helping risk managers and healthcare providers to guide their quality improvement activities.

2.3 *Autopsies*

Autopsies have long been considered the gold standard for detecting diagnostic errors. Diagnostic errors are usually more common than expected and remain often undetected while the patient is alive. Major diagnostic errors have an impact on patients' survival in that knowledge of the correct diagnosis would have changed treatment. Diagnostic performance can be monitored by comparing medical reports with autopsy reports. Several retrospective analyses have been published showing that the diagnostic error rate in Swiss hospitals is rather low. For a primary referral hospital Thurnheer and colleagues found cardiovascular diseases being misdiagnosed in 18.7%, followed by infectious diseases in 12.9%, oncological diseases in 3.6% and neurological diseases in 1.8% (16). Diagnostic sensitivity and specificity improved from 67% in 1997 to 87% in 2009 and from 94% to 99% in 2009, respectively. As the authors noted, diagnostic accuracy went along with the availability of highly sensitive laboratory markers and rapid imaging techniques. A reduction in major diagnostic errors over time was also seen at a large tertiary teaching hospital resulting in 7% in 2002 (17). Diagnostic accuracy, sensitivity and specificity rose for all studied diseases (cardiovascular, infectious and neoplastic diseases). Another study, analysing the rate of diagnostic errors in neonates and paediatric intensive care patients from 2004 to 2013 found 6% major diagnostic errors (18).

Despite the relatively low numbers of diagnostic errors found in Swiss hospitals, the problem of missing, wrong or delayed diagnosis does nevertheless exist and might cause major harm to patients. The extent of the problem might be even higher as autopsy rates are steadily declining and alternative methods to detect and measure diagnostic errors are not established yet.

3. Methodologies underused in Switzerland

Further methodologies such as the global trigger tool, claims data and patient safety indicators from routine data are important sources of finding information on AEs. However, published data for Switzerland hardly exist. We found the following information:

3.1 *Global trigger tool*

The global trigger tool (GTT) has been established in 2003 by the Institute of Healthcare Improvement (IHI) to detect AEs through a two-stage retrospective medical record review. To collect data in review stage 1 two independent reviewers (e.g. nurse, physician) screen the medical record for the presence of triggers indicating patient harm. In stage 2 the findings are discussed within the team. The review is performed regularly on a random small sample of medical charts and provides data on the frequency and types of AEs. The method has been demonstrated to be effective and has become widely used to monitor AE rates at the hospital level. However, as to our knowledge, while the GTT has been applied in Switzerland, no data on the frequency of AEs in Swiss hospitals measured by the GTT have been published so far. The Department of Public Health by the University of Basel is currently performing a multicentre study with the aim to measure AEs in adult care settings by using the GTT (https://nursing.unibas.ch/de/forschungsprojekte/forschung/forschung/gttkaim/; retrieved January 2019).

3.2 *Claims data*

Claims data might be another valuable source of information on harm to patients. However, they are rarely accessible as they are often associated with legal proceedings. Healthcare providers themselves, patient protection organisations and the Swiss Medical Association possess information on claims data.

To our knowledge, the Swiss Society of Anaesthesiology and Reanimation (SSAR) is the only medical organisation that analyses and publishes claims data in order to learn from it and to formulate recommendations to their members. In the late 1990, the SSAR initiated a commission to systematically analyse closed malpractice claims. Records of closed claims are provided by currently three out of four professional medical liability insurance companies in Switzerland and the Office for Extrajudicial Expert Review of the Swiss Medical Association. In a retrospective study covering the period 1987-2008 the commission found 171 events leading to anaesthesia-related injuries (19). More than half of the claims were related to regional anaesthesia whereas 28% of injuries were allocated to general anaesthesia. Other anaesthesia related-procedures accounted for 18% of reported injuries. The injuries were lethal in 12% of cases and lead to permanent harm in 63% of patients. The commission also judged the quality of care and found it in 55% of cases to be substandard. Liability was accepted in almost 46% of all claims. Until spring 2017 more than 220 claims were analysed (information from www.sgar-ssar.ch; retrieved December 2018).

When analysing closed malpractice claims one has to be aware that they can only provide relative data on error rates. Claims data are best used for learning from the event and improving patient safety but not for measuring the level of harm.

3.3 *Patient safety indicators from routine data*

The patient safety indicators (PSI) have been developed by the Agency for Healthcare Research and Quality (AHRQ) in 2003 in order to provide information on complications and AEs following surgeries, medical procedures and child birth in acute care hospitals. The PSI are compiled from routine data normally found in the discharge record and can be used by hospitals to improve their patient safety. However, PSI are not used as such in Switzerland. Instead, individual indicators, such as the pressure ulcer rate or the surgical site infection rate, are collected by hospitals to obtain information on the quality of care. Foreign bodies left in a body cavity or surgical wound at the end of a procedure – a so called never event – are also counted. In the OECD Health Statistic 2017 Switzerland leads the rankings of 13 OECD countries with 12.3 foreign bodies left per 100 000 surgical discharges in 2015 (20). At first glance, these findings are disturbing. A closer look,

however, reveals differences in data collection as the OECD report states that «variations in how countries record diagnoses and procedures and define hospital admissions can affect calculation of rates». Most likely, Switzerland stands out due to an exact coding practice that is performed uniformly by professional coders and not by clinicians. In addition, Swiss samples are small, thus calculations may result in an artefact which may distort the picture. The differences between Switzerland and other OECD countries may be therefore rather explained by different documentation quality than true differences in patient safety.

4. Summary

In Switzerland, no exact quantitative statement on harm to patients is possible today. So far, a mix of methodologies is being used to collect information on patient harm that occurs in hospitals and primary care. Each of the methodologies mentioned in this report represents a detail, but taken together the existing knowledge still does not make up the overall picture. For certain areas, such as long term care or home care no data on harm to patients are available, either because they are not collected or because they are not published. Furthermore, due to the different methodologies the existing data are not comparable and do not allow a national benchmarking.

There is no reason to believe that patient harm is more or less frequent in Switzerland than in other developed countries. It is estimated that every 10th patient is experiencing at least one adverse event during hospitalisation in Switzerland, resulting in more than 100 000 harmed patients yearly. The published data are in line with internationally published figures despite methodological differences. Diagnostic errors for example are judged to be a significant and common challenge in healthcare (21). The report even states that most people will experience at least one diagnostic error in their lifetime. But measuring diagnostic errors is challenging. Autopsies are a limited data source to determine the incidence of diagnostic errors since they are only conducted on people who have died, meaning all errors that did not involve death are not captured by this method. Furthermore, autopsies are only conducted upon request and autopsy rates are continually declining in the last decades. Other methods to measure the incidence and nature of diagnostic errors such as medical records reviews or malpractice claims have limitations too, why it is necessary to work further on new approaches to monitor the diagnostic process in order to identify, learn from and reduce diagnostic errors.

Other harm is measured more easily. But as stated in section 3 of this report, Switzerland is not even using the existing methodologies sufficiently. We are missing a national monitoring of patient harm. Data on the incidence of preventable AEs, the kind of injury and the severity of harm have to be known in order to improve patient safety. These data are necessary to identify the need of corrective measures within the system and to regulate them. Without a systematic data collection accurate information on the extent of patient harm in the Swiss healthcare system will not be available and the opportunity of learning from mistakes and improving the healthcare system passes unused.

We are aware that Switzerland has still a long way to go to establish a healthcare system that knows about its frequency of harm and streaks with all its efforts to prevent them. We are convinced there is no need to be afraid of transparency. Measuring harm might lead to higher harm rates which does not necessarily mean a worse performance. On the contrary, higher harm rates may reflect more developed patient safety monitoring systems and a stronger patient safety culture.

5. Recommendations

Regarding patient safety the Swiss healthcare system has significant potential for improvement. We recommend to

- systematically collect data on AEs
  - ➢ The Swiss healthcare system is asked to establish a standardized reporting and learning system in order to know the incidence of AEs, to learn from them and to take measures to prevent them.
- register never events
  - ➢ The Swiss healthcare system is asked to establish a national registry for never events in order to capture the dimensions and size of the problem and to allow learning on a systems level by analysing the collected data.
- capture data on healthcare related injuries form routine data
  - ➢ The Swiss healthcare system is asked to timely adopt and implement the new ICD-11 with a completely revised section on documentation related to patient safety that is planned to be adopted by the WHO in 2019.
- make patient safety a higher priority in education and training of all healthcare professionals
  - ➢ The Swiss healthcare system is asked to establish a curriculum in patient safety and quality improvement for all educational stages e.g. pre-graduate, post-graduate and continuing education.

6. About us

Swiss Patient Safety Foundation

The Swiss Patient Safety Foundation is the national competence centre for developing and promoting patient safety. It has been founded in 2003 by the Federal Office of Public Health (FOPH) and the Federal Social Insurance Office, the Swiss Academy of Medical Sciences and numerous professional associations. The foundation works for a constructive and consequent safety culture in the Swiss healthcare system. All its activities rely on cooperation with institutions and a large network of experts from Switzerland and abroad.

The foundation's activities focus on projects and programmes, research, training, further education and continued development as well as advice and expertise.

The foundation's national programmes, called progress! aim to improve significant systemic safety deficiencies by means of a methodical, evidence-based and practice-oriented approach. The programmes always include elements for implementation, evaluation and monitoring and are accompanied by an awareness campaign. The programmes have been initiated in 2012 as part of the federal government's quality strategy. Since then, the foundation has been conducting five programmes, of which progress! Medication safety in nursing homes and progress! CoM Check – safe surgery are still ongoing. The programmes are developed in cooperation with leading experts and receive substantial financial support from the FOPH.

The research projects of the foundation such as speak up and double checking in oncology, generate new knowledge that is transferred into practice through recommendations for healthcare professionals. The foundation publishes its research findings in peer-reviewed journals and thus helps to spread the knowledge to the broader scientific community.

The foundation also maintains the national platform CIRRNET, the Critical Incident Reporting & Reacting Network. CIRRNET has been established in 2006 in order to bring together the local error reporting systems to allow learning from others. Today, Patient Safety Switzerland manages the network, identifies nationally relevant problem areas in patient safety, works together with experts to develop recommended actions and publishes them as "Quick-Alerts® ".

In line with the increasing efforts of the healthcare system to make healthcare safer, the Swiss Patient Safety Foundation will continue to develop solutions for enhancing patient safety and the necessary principles and tools to disseminate them. Wherever people work, mistakes will happen. It is our duty to support service providers and healthcare organisations to prevent the mistakes of tomorrow.

7. References

1.   WHO. 10 facts on patient safety. [cited 2019 Mar 7].
     Available from: https://www.who.int/features/factfiles/patient_safety/en/
2.   Slawomirski L, Auraaen A, Klazinga N. The economics of patient safety - Strengthening a value-based approach to reducing patient harm at national level. OECD Heal Work Pap. 2017;(96):67. Available from: https://doi.org/10.1787/5a9858cd-en.
3.   Auraaeni A, Slawomirskii L, Klazingai N. The economics of patient safety in primary and ambulatory care. 2018; Available from: https://www.oecd-ilibrary.org/social-issues-migration-health/the-economics-of-patient-safety-in-primary-and-ambulatory-care_baf425ad-en
4.   Kohn LT, Corrigan JM, Donaldson MS (Eds). Institute of Medicine (U.S.) Committee on Quality of Health Care in America. National Academy of Sciences; 2000.To err is human: building a safer health system.
5.   Molloy CJ, Braithwaite J, Lachman P, Hibbert PD, Hooper TD, Runciman WB, et al. The application of the Global Trigger Tool: a systematic review. Int J Qual Heal Care. 2016;28(September):640–9.
6.   Schwendimann R, Blatter C, Dhaini S, Simon M, Ausserhofer D. The occurrence, types, consequences and preventability of in-hospital adverse events - a scoping review. BMC Health Serv Res. 2018 Jul;18(1):521.
7.   Hôpitaux Universitaires de Genève and Swissnoso. Point Prevalence Survey 2017 of healthcare-associated infections and antimicrobial use in Swiss acute care hospitals. Hôpitaux Universitaires de Genève; Swissnoso (2018).
8.   Hanskamp-Sebregts M, Zegers M, Vincent C, van Gurp PJ, de Vet HCW, Wollersheim H. Measurement of patient safety: a systematic review of the reliability and validity of adverse event detection with record review. BMJ Open. 2016 Aug;6(8):e011078.
9.   Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. 1991. Qual Saf Health Care. 2004 Apr;13(2):142–5.
10. Griffin FA, Resar RK. IHI global trigger tool for measuring adverse events (second edition). IHI Innov Ser white Pap. 2009.
11. Halfon P, Staines A, Burnand B. Adverse events related to hospital care: a retrospective medical records review in a Swiss hospital. Int J Qual Heal care J Int Soc Qual Heal Care. 2017 Aug;29(4):527–33.
12. Gehring K, Schwappach DLB, Battaglia M, Buff R, Huber F, Sauter P, et al. Frequency of and harm associated with primary care safety incidents. Am J Manag Care. 2012 Sep;18(9):e323-37.
13. Schwappach DLB, Frank O, Hochreutener M-A. "New perspectives on well-known issues": patients' experiences and perceptions of safety in Swiss hospitals. Z Evid Fortbild Qual Gesundhwes. 2011;105(7):542–8.
14. Schwappach DLB, Wernli M. Chemotherapy patients' perceptions of drug administration safety. J Clin Oncol. 2010;28(17):2896–901.
15. Schwappach DLB. Risk factors for patient-reported medical errors in eleven countries. Heal Expect an Int J public Particip Heal care Heal policy. 2014 Jun;17(3):321–31.
16. Thurnheer R, Hoess C, Doenecke C, Moll C, Muntwyler J, Krause M. Diagnostic performance in a primary referral hospital assessed by autopsy: evolution over a ten-year period. Eur J Intern Med. 2009 Dec;20(8):784–7.
17. Schwanda-Burger S, Moch H, Muntwyler J, Salomon F. Diagnostic errors in the new millennium: a follow-up autopsy study. Mod Pathol an Off J United States Can Acad Pathol Inc. 2012 Jun;25(6):777–83.
18. Widmann R, Caduff R, Giudici L, Zhong Q, Vogetseder A, Arlettaz R, et al. Value of postmortem studies in deceased neonatal and pediatric intensive care unit patients.

Virchows Arch. 2017 Feb;470(2):217–23.

19. Staender S, Schaer H, Clergue F, Gerber H, Pasch T, Skarvan K, et al. A Swiss anaesthesiology closed claims analysis: report of events in the years 1987-2008. Eur J Anaesthesiol. 2011 Feb;28(2):85–91.

20. OECD Publishing Paris. "Surgical Complications" in Health at a Glance 2017: OECD Indicators. 2017. Available from: https://doi.org/10.1787/health_glance-2017-37-en

21. Balogh EP, Miller BT, Ball JR. Improving Diagnosis in Health Care. Vol. 181, Military Medicine. 2016. 183-185.

Safe communication between staff and with patients

Annegret F. Hannawa, Ph.D.
Associate Professor and Director,
Center for the Advancement of Healthcare Quality and Patient Safety (CAHQS),
Faculty of Communication Sciences,
Università della Svizzera italiana (USI)

This is a contribution to the Swiss National Report on Quality and Safety in Healthcare.

Abstract

Inadequate communication among healthcare professionals and with patients and care companions is consistently identified as a core contributing factor to adverse events and as a key determinant of poor quality care. Numerous communication improvement tools have been implemented in healthcare to resolve this problem. While they have attained some effects, the problem remains large: Too many patients are still harmed every day because care participants fail to establish a shared understanding with each other. This report summarizes the communication improvement tools that have been implemented to date to address this cause and briefly discusses their measured effects. It also introduces a new framework that conceptualizes safe communication as a fundamental resilience-enhancing interpersonal process that affects quality and safety across all contexts and stages of care. This "SACCIA" framework pursues a systematic improvement of *all* care participants' (i.e. providers, patients and care companions) communication skills over time, accompanied by scientific measurement of the impact of these improvements on the quality and safety of care. In other words, it pursues a first evidence base for the formulation of context-independent "safe communication" guidelines, and it provides a blueprint that care institutions as well as educators, students and practitioners of medicine and nursing across Switzerland may use to enhance the quality and safety of their practice in sustainable ways.

Safe communication between staff and with patients

Quality and safety are a central concern in healthcare across the globe.[1,2] Every 10th patient is harmed instead of cured during hospital care. At a rate of 0,1%,[3] the estimated mortality that results from such harm appears small at first glance. But the felt impact of this fragment on patients is tremendous: The Swiss Federal Office for Statistics counts about 1.5 million hospitalizations across Switzerland every year.[4] This means that over 160 patients are harmed and 4 patients die at Swiss hospitals *every day* as a result of a medical error.

Up to 80% of these events are triggered by unsafe communication,[5] such as insufficient or inaccurate information exchange, poor documentation, the failure to read patient records, unclear discharge instructions, and miscommunication due to linguistic discrepancies.[6] **Thus, inadequate communication frequently stands in the way to successful care provision and causes severe patient harm.** Politicians have recognized this problem as well: the Swiss, German and Austrian health ministries jointly dedicated the International Patient Safety Day 2017 to the topic "communication."[7]

Communication interventions in healthcare

The fact that interpersonal communication constitutes a severe safety challenge in healthcare has been widely known for some time now. Several communication frameworks, tools and techniques have been developed and implemented across the globe to standardize message content in healthcare interactions – both for the purpose of *preventing harm*, and for optimizing communication *in response to harmful events*.

Communication frameworks for preventing harm

Probably the most well-known framework for a team-based approach to harm prevention is TeamSTEPPS[8] (Team Strategies and Tools to Enhance Performance and Patient Safety). The U.S. Department of Defense (DoD) and AHRQ jointly developed this outcomes-based framework, which promotes four teachable skills to optimize team performance: Leadership, situation monitoring, mutual support, and communication. The "communication" domain within this framework encompasses several (mostly mnemonic) techniques, including:
- IPASS[9] (Introduction, Patient, Assessment, Situation, Safety), which aims to enhance information exchange during care transitions ("handoffs"),
- SBAR[10] (Situation, Background, Assessment, Recommendation and Request) for communicating critical information that require immediate response and/or action,
- "Check-back" (i.e. closed-loop) communication for validating message receipt, and
- "Call-outs" for communicating important or critical information to other team members.

Other communication tools have been developed to address more context-specific communication challenges. For example, SPIKES[11] constitutes a six-step protocol for disclosing bad news to cancer patients about their illness (Setting up the interview, assessing the patient's Perception, obtaining the patient's Invitation, giving

Knowledge and information to the patient, addressing the patient's **E**motions with empathic response, and **S**trategy and Summary).

Very few experimental (i.e. before-after) designs, controlled trials or meta-analyses have been conducted to date to measure and summarize the impact of these harm-preventing communication improvement tools on healthcare quality and patient safety. In particular, high-quality studies are lacking. There is *some* evidence on the effectiveness of SBAR implementations on patient outcomes, but this evidence is limited to specific circumstances (e.g. communication over the phone).[12] Similarly, only few experimental studies have tested the effects of IPASS on objective outcomes. The most successful study in this context evidenced a 30% decrease in the rate of preventable adverse events, but only at two-thirds of the investigated sites.[13] No studies to date have been conducted *in Switzerland* to systematically measure pre-post effects of the abovementioned *preventive* communication techniques on healthcare quality and patient safety (i.e. to prevent patient safety events).

Framed within the focal theme of the International Patient Safety Day 2017, the Swiss health ministry launched a national "Speak-up" program with the premise that care participants' willingness to speak up when they perceive a patient safety risk could reduce communication errors and/or adverse events. However, to date, evidence supporting that premise is sparse and limited to mostly qualitative inquiries. Objective pre-post effects of speak-up interventions on quality and safety outcomes have not been measured with consistent findings.[14] In fact, one study reports that speak-up-induced "collective vigilance" (e.g. the process by which health care professionals pick up on potential errors made by another clinician) may actually *create risk* because reliance on others to catch and correct errors may erode individuals' professional accountability.[15] Thus, also with respect to the speak-up program, empirical evidence remains sparse and inconsistent.

Frameworks for optimizing communication in response to harm

Communication between staff and with patients and care companions *after* harm has occurred (which is commonly summarized under the term "medical error disclosure") may be as relevant to healthcare quality and patient safety as communication for the *prevention* of harm. Toolkits like CANDOR[16] (**C**ommunication and **O**ptimal **R**esolution) prescribe the organizational processes that facilitate a timely, thorough, and just response to unexpected patient harm. The MEDC[17-19] (Medical Error Disclosure Competence) model focuses on the *interpersonal* processes that constitute *safe disclosures* of adverse events (i.e. disclosures that cause beneficial rather than harmful outcomes at all levels of the healthcare system). Several systematic outcomes-based studies with representative national samples have been conducted under a SNF grant in Switzerland to generate and validate evidence-based "safe disclosure" guidelines (see Appendix), purely based on Swiss data.[18,19] These studies have evidenced significant effects of MEDC-guidelines-adherent disclosures on patients' symptoms and coping tactics on personal, relational, institutional and societal levels.

Barriers to safe communication for the *prevention* of harm

As shown above, none of the *preventive* communication interventions to date have been successful in "solving" the communication problem. Studies have reported some results, but the problem remains large. One reason for this may be that healthcare is situated in a *communication-hostile* environment: many people from different professional and sociodemographic backgrounds with variable linguistic and cognitive processing skills must quickly and many times a day achieve a shared understanding with each other in a setting that is compromised by distracting noises, limited privacy, immense time pressures and questions concerning what matters most of us: life and death. Another reason may be that the medical field still understands communication as a synonym for "information": A conduit metaphor that is commonly found in the medical literature is that communication "fails" or "breaks down" in the same way like an engine or a telephone fails to operate.[20-24] This misconception is further reinforced by manifold care innovations that now *delegate* interpersonal sense-making processes to digitized pathways. But communication transpires *between* people. It encompasses complex encoding, decoding and transactional sense-making processes that cannot be delegated. Thus, communication "problems" are not a symptom that can be "fixed" like a knee by a prosthesis. Communication is not a *problem*, it is our human nature. We were born to communicate, but not with the competency to communicate well: A sizeable percentage of the average population lacks fundamental communication skills and experiences difficulties negotiating the necessities of everyday life through their interactions with others.[25-28] As a result, we commonly encounter disruptive experiences in our interpersonal encounters.[28] At the same time, *competent* communication can have positive health effects that are as substantial as almost anything that modern medicine can offer in terms of extending people's lifespans.[29-32] Communication interventions to date have not considered these processes sufficiently to inform urgently needed core competencies and "safe practice" guidelines that apply across all stages and contexts of care.

That said, the path forward is clear: beyond standardizing message contents with the help of mnemonics and digitized communication channels in the healthcare setting, **we must make our fundamental interpersonal sense-making processes more resilient to failure**.[33,34] Our case analyses have shown that by doing so, we can affect that patients no longer receive wrong-site surgery, come out of anaesthesia with a foreign object in their body, get the wrong kind or dose of medication, carry away the consequences of wrong or delayed diagnoses, or go home with discharge instructions they do not understand.[20-24] By doing so, we could prevent a majority of the 60'000 patient injuries and 1'500 deaths that are incurred at Swiss hospitals every year,[1,4] and we could save a majority of the annual healthcare spending that currently flows into the correction of adverse events.[1] If we do not invest the necessary labour for attaining consistent mutual understanding at the frontline of care, miscommunication will continue to penetrate everyday healthcare encounters and cause substantial harm. Thus, "safe communication" must become recognized as a **core competency for safe, high-quality care.**

What does "safe communication" look like?

Based on our scientific analyses of hundreds of patient safety events (the results of which we have published in four books), we conceptualize "safe communication" as an interpersonal sense-making practice that adheres to five *core competencies* summarized under the acronym "SACCIA".[20-24] These competencies encompass "all verbal and nonverbal behaviours that, through adequate quantity (i.e. Sufficiency) and quality (i.e. Accuracy, Clarity, Contextualization, Interpersonal Adaptation), optimize the likelihood of achieving most appropriate and effective care outcomes."[20] Each of these five "safe communication" practices entails participants' encoding, decoding, and transactional (i.e., mutually negotiated) sense-making processes.[35] In other words, all participants involved in a healthcare episode (1) abstract (i.e., encode) complex thoughts, intentions, meanings or feelings they have in mind into written, oral, and nonverbal messages; (2) reassemble (i.e., decode) the written, oral, and nonverbal messages they "received" to match the sender's originally intended thoughts, intentions, meaning or feelings; and (3) engage in mutual negotiation (i.e., transactional communication) of these expressed thoughts, intentions, meaning or feelings to co-create a shared understanding. These three sense-making processes are inherent in all five "safe communication" practices that are summarized by the "SACCIA" framework:[20-24]

o **Sufficiency -** the extent to which care participants convey, extract, and exchange a sufficient amount of information in order to arrive at a shared understanding.
o **Accuracy -** the extent to which care participants convey correct information, interpret information correctly, and utilize their communication with each other to validate the accuracy of their communicated message contents.
o **Clarity -** the extent to which care participants express and interpret verbal and nonverbal messages clearly (i.e., unambiguously), in order to reduce uncertainties.
o **Contextualization -** the extent to which care participants frame their interaction within local interactional circumstances (such as hierarchies, time pressure, or discrepant goals) that either facilitate or create barriers to shared understanding.
o **Interpersonal Adaptation** - the extent to which participants implicitly (nonverbally) and explicitly (verbally) express needs and expectations that maximize the likelihood of shared understanding.

In sum, directly filling the abovementioned void in the current literature, these five SACCIA core competencies operationalize **"safe communication" as a fundamental resilience-enhancing interpersonal process for improving the quality and safety of healthcare.** In contrast to existing communication improvement tools that have mostly resorted to mnemonics and simple communication techniques to address specific acute communication challenges (e.g. handoffs, bad news, critical situations) in healthcare, the SACCIA framework is grounded in extensive communication science analyses of (all kinds of) actual patient safety events. While existing tools have primarily focused on enhancing clinicians' information transfer and standardizing the quantity of sent and received message content, the SACCIA framework focuses on the *interpersonal sense-making process between all care participants* and advances evidence-based *core competencies* that make this process

more resilient to failure. In other words, it addresses *all* safety communication rather than a specific context or tool, and it involves staff, patients and care companions as equivalent partners for the establishment of a "shared understanding".

Our most recent study[36] has shown that both patients and providers in the Ticino healthcare system also perceive SACCIA-safe interpersonal communication as a core element of "quality care", evidencing that the SACCIA framework reaches beyond *patient safety*. Both clinicians and patients referenced the full spectrum of SACCIA-safe communication when talking about "good" and "poor" quality care episodes. This first Switzerland-based "SACCIA" study evidenced that "quality care" is characterized by a consistent SACCIA-safe communication practice that ensures effective interpersonal sense-making between staff and with patients and care companions across all care contexts. The study further underlines that **health outcomes can be enhanced when clinicians communicate well with each other and with patients, and compromised when they interact poorly.** These findings are consistent with many studies that have shown that **poor communication is a core determinant of "quality care"[37,38] and a leading root cause of a majority of preventable adverse events**.[5]

What needs to be done to improve "safe communication" at the frontline of healthcare in Switzerland?

There are two necessary steps to affect practice improvements at the frontline of Swiss care. First, we need to identify the problematic behaviours that needs to be changed, i.e. the concrete communication practices that cause these prevalent cases of patient harm. With the research we have accomplished to date, we have identified that the five interpersonal "SACCIA"-processes consistently cause harm at the frontline of care. The second step is to *change* these communication practices at the frontline of care to avoid that these cases of harm continue to happen in the future. Thus, as a next step, we need to examine the extent to which an interpersonal "SACCIA-safe communication" practice at the frontline of care will improve the frequency with which care participants (i.e. clinicians, patients and care companions) establish a shared understanding and, consequentially, improve the quality and safety of care in measurable ways. In other words, **we must establish a scientific evidence base for a new (yet non-existing) communication-based "safe practice" standard for all health professions.** This objective requires that science and government walk hand-in-hand: In science, we are now in the process of developing and validating a blended-learning "SACCIA" intervention for current and future practitioners of medicine and nursing, which will be implementable by medical schools and quality managers to enhance the safety and quality of everyday care in flexible, sustainable ways. We need the government to pave the pathway for these implementations to reach and affect the frontline of care nationwide.

What are the barriers and challenges for improving "safe communication" in the Swiss healthcare system?

The key barrier, in my view, lies in our traditional healthcare culture. Medical schools and healthcare institutions have their own established routines and

procedures. Many do not see the need to change, either because they perceive no problem (i.e. lack of awareness) or because they are already doing something they perceive as sufficient for addressing the problem (i.e. "Wobegon effect"[39,40]). In other words, the potential of safe communication interventions to improve the safety and quality of care is, just like with any other intervention, compromised by a dominant healthcare culture that is generally resistant to change. Cultural change must grow from the inside out, but this growth must be accompanied by clear rules and formal standards (i.e. guidelines) that are evidence-based in the current state of science and recognized as such at the frontline of care. In terms of the "safe communication" topic, we must rescue *communication* from its exile as a nice-to-have *soft skill*. We must formally recognize "safe communication" as a core "safe practice" criterion for harm prevention, just like it is recognized as a core contributing factor in *causing* severe patient harm. We must enforce this recognition with clear formalized practice guidelines that reflect the current "state of science" (i.e. evidence-based care provision), and we must ensure that these guidelines reach the frontline of care across Switzerland.

What are the strengths of Swiss healthcare in applying/implementing/developing this theme?

The Swiss health ministry has already recognized the importance of safe communication for improving the safety and quality of care in Switzerland.[7] It has also acknowledged the importance of the SACCIA model in particular for affecting the required change.[23] Thus, the fundament for a nationwide "safe communication" implementation is established. A close collaboration between government and science from this point forward can affect the needed practice improvements, pending further scientific evidence (as discussed above).

Summary

A widespread (i.e. nationwide) "safe communication" intervention that blankets the Swiss healthcare system has the potential to affect lasting improvements in the safety and quality of care with considerable impact. The expected innovations and improvements that will be advanced by such an intervention are threefold: First, we could provide a strong evidence base for the advancement, implementation and assessment of first context-independent "safe communication" guidelines that focus on optimizing the quality and safety across all stages and contexts of care, thereby addressing an urgent void in the patient safety discipline. Second, the teaching materials and assessment tools we are developing for medical and nursing education and practice are usable by all stakeholders, following the exact procedures we lay out in our scientific "blueprint", to lastingly improve the safety and quality of care. Last but not least, a nationwide "safe communication" intervention could help us prevent a large amount of the 60'000 patient injuries and 1'500 patient deaths that are incurred in Swiss hospital care every year, and it may save a majority of our annual healthcare spending that currently flows into the correction of preventable adverse events – not because of modernized medicine, but by **strengthening clinicians, patients and care companions as core resources for enhancing resilience at the frontline of care.**

References

[1]   Slawomirski N, Auraaen A, Klazinga N. The economics of patient safety: Strengthening a value-based approach to reducing patient harm at national level. OECD; 2017. Content last reviewed September 2018. https://www.oecd.org/els/health-systems/The-economics-of-patient-safety-March-2017.pdf

[2]   Slawomirski N, Auraaen A, Klazinga N. The economics of patient safety in primary and ambulatory care: Flying blind; 2018. Content last reviewed September 2018. https://www.oecd.org/health/health-systems/The-Economics-of-Patient-Safety-in-Primary-and-Ambulatory-Care-April2018.pdf

[3]   Aktionsbündnis Patientensicherheit (APS). Systematischer Review zu Häufigkeiten von unerwünschten Ereignissen, Fehlerns, Schäden, Behandlungsschäden und Beinaheschäden in der Medizin. In: Aktionsbündnis Patientensicherheit (Hrsg.), *Agenda Patientensicherheit 2006.* Berlin: APS.

[4]   Bundesamt für Statistik: Hospitalisierungen 2016. Content last reviewed September 2018. https://www.bfs.admin.ch/bfs/de/home/statistiken/gesundheit/gesundheitswesen/spitaeler/patienten-hospitalisierungen.html

[5]   Leonard M, Graham S, Bonacum D. The human factor: the critical importance of effective teamwork and communication in providing safe care. *BMJ Quality & Safety.* 2004;13(Suppl. 1):i85–i90.

[6]   CRICO Strategies. *Malpractice risks in communication failures.* Boston, MA: Harvard Medical Institutions; 2016.

[7]   Internationaler Tag der Patientensicherheit 2017: Wenn Schweigen gefährlich ist. Content last reviewed September 2018. https://www.tag-der-patientensicherheit.de/archiv-2017.html

[8]   TeamSTEPPS® 2.0. Content last reviewed September 2018. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/teamstepps/instructor/index.html

[9]   Starmer AJ*,* Spector ND*,* Srivastava R*,* Allen AD*,* Landrigan CP*,* Sectish TC. I-pass – A mnemonic *to* standardize verbal handoffs*. Pediatrics* 2012*;*129*(2):201-4*.

[10] Leonard M, Graham S, Bonacum D. The human factor: The critical importance of effective teamwork and communication in providing safe care. *Quality and Safety in Health Care*. 2004;13(Suppl 1):i85–i90.

[11] Baile WF, Buckman R, Lenzi R, Glober G, Beale EA, Kudelka AP. SPIKES – A Six-Step Protocol for Delivering Bad News: Application to the Patient with Cancer. *Oncologist.* 2000;5:302-11.

[12] Müller M, Jürgens J, Redaèlli M, Klingberg K, Hautz WE, Stock S. Impact of the communication and patient hand-off tool SBAR on patient safety: a systematic review. BMJ Open. 2018 Aug 23;8(8):e022202.

[13] Starmer AJ, Spector ND, Srivastava R, West DC, Rosenbluth G, Allen AD, Noble EL, T et al. Changes in medical errors after implementation of a handoff program. N Engl J Med. 2014 Nov 6;371(19):1803-12.

[14] Okuyama A, Wagner C, Bijnen B. Speaking up for patient safety by hospital-based health care professionals: a literature review. BMC Health Serv Res. 2014 Feb 8;14:61.

[15] Jeffs LP, Lingard L, Berta W, Baker GR. Catching and correcting near misses: the collective vigilance and individual accountability trade-off. J Interprof Care 2012, 26(2):121-126.

[16] Communication and Optimal Resolution (CANDOR) Toolkit. Content last reviewed September 2018. Agency for Healthcare Research and Quality, Rockville, MD. http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/candor/introduction.html

[17] Hannawa AF. What constitutes "competent error disclosure"? Insights from a national focus group study in Switzerland. Swiss Med Wkly. 2017 May 2;147:w14427.

[18] Hannawa AF, Frankel RM. "It Matters What I Think, Not What You Say": Scientific Evidence for a Medical Error Disclosure Competence (MEDC) Model. J Patient Saf. 2018 Jul 20.

[19] Hannawa AF. When facing our fallibility constitutes "safe practice": Further evidence for the MEDC guidelines. *Manuscript in preparation for submission;* 2018.

[20] Hannawa AF, Wu Q, Juhasz R. *New horizons for patient safety: Understanding communication – case studies for physicians.* Berlin: Walter de Gruyter;2017.

[21] Hannawa AF, Wendt A, Day L. *New horizons for patient safety: Safe communication – evidence-based core competencies with case studies from nursing practice.* Berlin: Walter de Gruyter; 2017.

[22] Hannawa AF, Jonitz G. *Neue Wege für die Patientensicherheit: Sichere Kommunikation – evidenzbasierte Kernkompetenzen mit Fallbeispielen aus der medizinische Praxis.* Berlin: Walter de Gruyter; 2017.

[23] Hannawa AF, Postel S. *SACCIA-Sichere Kommunikation.* Berlin: Walter de Gruyter;2018.

[24] Hannawa AF. SACCIA safe communication: Five core competencies for safe and high-quality care. *Journal of Patient Safety and Risk Management.* 2018;23(3):99-107.

[25] Bassett RE, Whittington N, Staton-Spicer A. The basics in speaking and listening for high school graduates: what should be assessed? Communication Education 1978;27:293-303.

[26] Ilott I. Incompetence: an unspoken consensus. In: Raven J, Stephenson J (Eds.), Competence in the learning society (pp. 57–66). New York: Peter Lang Publishing; 2001.

[27] National Center for Education Statistics. National Assessment of Adult Literacy (NAAL): A first look at the literacy of America's adults in the 21st century. Washington DC: U.S. Department of Education (NCES 206-470); 2003.

[28] Spitzberg BH, Cupach WR. The dark side of interpersonal communication (2nd ed.). Mahwah, NJ: Lawrence Erlbaum Associates; 2007.

[29] Holt-Lunstad J, Smith TB, Baker M, Harris T, Stephenson D. Loneliness and social isolation as risk factors for mortality: A meta-analytic review. Persp on Psych Sci. 2015;10(2):227-237.

[30] Nyqvist F, Pape B, Pellfolk T, Forsman AK, & Wahlbeck K. Structural and cognitive aspects of social capital and all-cause mortality: a meta-analysis of cohort studies. Social Indicators Res. 2014;116(2):545-566.

[31] Pinquart M, Duberstein PR. Associations of social networks with cancer mortality: a meta-analysis. Critical Rev in Oncology/Hematology. 2010;75(2):122-137.

[32] Shor E, Roelfs DJ, Yogev T. The strength of family ties: a meta-analysis and meta-regression of self-reported social support and mortality. Social Networks. 2013;35(4):626-638.

[33] The Joint Commission. National patient safety goals effective January 2018. Content last reviewed September 2018. file:///C:/Users/Admin/Downloads/NPSG_Chapter_HAP_Jan2018.pdf

[34] World Health Organization. Communication during patient handovers. Patient Safety Solutions; 2007(1). Content last reviewed September 2018. http://www.who.int/patientsafety/solutions/patientsafety/PS-Solution3.pdf?ua=1

[35] Barnlund DC. A transactional model of communication. In. C. D. Mortensen (Eds.), *Communication theory* (2nd ed., pp. 47-57). New Brunswick, New Jersey: Transaction; 2008.

[36] Hannawa, AF et al. "SACCIA", "Hippocratic Pride" and "Rapid Reactivity": New Indicators of Good and Poor Quality Care. *Manuscript in preparation for submission;* 2018.

[37] Amati R, Kaissi AA, Hannawa AF. Determinants of good and poor quality as perceived by U.S. health care managers: A grounded taxonomy based on evidence from narratives of care. *J Health Org Management; 2018.*

[38] Amati R, Brook RH, Kaissi AA, Hannawa AF. Evolving dimensions of quality care: Comparing physicians and managerial perspectives. In A. A. McDermott, M. Kitchener & M. Exworthy: *Managing improvement in healthcare: attaining, sustaining and spreading quality.* Palgrave Macmillan; 2017.

[39] Alicke MD, Govorun O. The better-than-average effect. In: Alicke MD, Dunning D, Krueger J (Eds.), The self in social judgment. New York: Psychology Press; 2005.

[40] Sedikides C, Gaertner L, Toguchi Y. Pancultural self-enhancement. J Personality Soc Psychol. 2003;84:60-79.

APPENDIX: Final *Medical Error Disclosure Competence (MEDC) Guidelines* for Safe Disclosure[19]

In preparation for the disclosure, take into account the following *contextual* considerations:

(1) Decide whether the disclosure is beneficial to the patient's health condition; if not, consider disclosing the error to a family member instead or disclose it later when the patient is stable.
(2) If possible, the patient should bring a care companion to the disclosure.
(3) Invite a neutral (external) third party to the disclosure (as a person of trust for the patient).
(4) Be prepared to send the patient a written account after the disclosure so the patient can revisit and better understand the communicated information (if desired by the patient).
(5) Make sure you schedule plenty of time for the disclosure (no time limit would be ideal).
(6) Recognize the disclosure as a gradual, sequential conversation (there will be more than one meeting with the patient, the patient will need time to process and revisit the information).

DO NOT invite too many care participants to the disclosure – the number of clinicians should *not* outnumber the patients' side.
DO NOT disclose an error over the phone.

Enter the disclosure with the *motivation* to…

(1) establish a close, trusting relationship with the patient (as a foundation for mutual empathy).
(2) maintain a relationship with the patient (opening the door for the patient to return in the future).
(3) invest into the relationship with the patient ("paying for" the error in relational terms).
(4) demonstrate relational sincerity (take the patient seriously, convey genuine respect).
(5) straighten things out for the patient (e.g., in light of the error's impact on the patient's life).
(6) alleviate the implications of the error for the patient's personal and professional life.

DO NOT appear avoidant, distant, or defensive.

Enter the disclosure with informed *knowledge* about the patient's…

(1) informational preferences (i.e., participatory or authoritarian care style).
(2) medical history/records.
(3) personal preferences (e.g., what type of person the patient is, what the patient [doesn't] want).

DO NOT enter the disclosure unprepared.

During the disclosure, demonstrate the following *communication skills*:

(1) Attentiveness (i.e. sit in front or next to the patient; directly face the patient; occasionally lean toward the patient; make appropriate eye contact with the patient; look at the patient while s/he talks; show the patient that you are listening to him/her; show the patient that you have made it a priority to be here with him/her; seek personal contact with the patient and take his/her comments seriously; demonstrate a certain devotion to the patient's needs; show the patient that you truly care for his health and well-being).
(2) Composure (i.e. humbly try to calm down the situation; use a calm voice; calmly explain what happened; talk with calm confidence).
(3) Coordination (i.e. pause occasionally/appropriately to give the patient an opportunity to react).
(4) Expressiveness (i.e. display a small smile when you enter the room; use a kind tone of voice; talk to the patient very clearly; try to talk in simple terms; be empathic but do not get too emotional – remain informative and clear).

(5)   Interpersonal adaptability (i.e. embrace any cognitive, linguistic, informational and/or emotional needs/expectations that the patient expresses, verbally *or* nonverbally, during the disclosure conversation; feel out the patient and see how s/he reacts; for example, be sensitive to the patient's needs to decide something on his/her own; adapt to the patient's language, check whether the patient understands what you are saying; try to get inside the patient's head and skin; get a feel of how much information the patient needs so s/he does not get overwhelmed; see whether the patient needs a hand on the shoulder).

DO NOT introduce physical barriers to the conversation (e.g. a desk in between you and the patient, stacked-up charts, a ringing phone or beeper).

DO NOT use technical language or medical terms that the patient cannot understand.

During the disclosure, make sure to explicitly state the following *contents*:

(1)   Be as open, honest, transparent, and authentic in your communication as possible.

(2)   Admit and assume *responsibility* for the error (if applicable, a statement of responsibility should also be conveyed by your supervisor).

(3)   Make sure to express *remorse*.

(4)   Provide an *explanation* of (a) what happened to this point in time (chronologically), (b) why the patient is there, (c) why and how this could happen, (d) what should have been done, and (e) if applicable, what the patient needs to do now as a consequence of the error (e.g., adjusted behaviors/medication intake etc.). Succinctly and clearly discuss the (a) consequences of the error and (7) corrective steps that will be taken.

(5)   Discuss what you will do / suggest do to next to correct the situation and/or repair the consequences of the error.

(6)   Discuss how you intend to repair the patient's *health* (so that the patient feels better).

(7)   Offer the patient *psychological* support.

(8)   If applicable, offer the patient *financial* reparation (that any extra costs will be covered).

(9)   If applicable, discuss how you intend to repair the patient's *professional life* (e.g., inform the patient's employer).

(10)   Ensure *future forbearance* by stating that you will actively engage in an investigation to reflect and draw consequences from this experience to prevent such errors in the future (conveying that the error didn't happen for nothing, but that it led to improve things).

DO NOT ramble around.

DO NOT ignore or deny the error.

DO NOT downplay the situation / make seem everything half as bad.

DO NOT display any arrogance whatsoever.

Maintain your communication skills! Give the patient opportunities to ask questions; keep your calm voice; stay attuned and adapt your informational contents to the patients' needs and expectations; pay close attention to the patient while you explain things; keep your own nonverbal displays in mind and be careful not to overwhelm.

Safety culture in the context of Swiss healthcare: a contribution to the Swiss National Report on Quality and Safety in Healthcare

Prof. Dr. Tanja Manser
Fachhochschule Nordwestschweiz
Hochschule für Angewandte Psychologie FHNW
Riggenbachstrasse 16
CH-4600 Olten

Date of submission: 13.01.2019

Abstract

Safety culture assessment and development is a key area of patient safety research and improvement. From a national perspective, the uptake of safety culture assessment in Swiss healthcare seems to have been very limited. Given that safety culture assessment instruments for a range of Swiss healthcare contexts have been adapted and psychometrically validated, the availability of suitable instruments is certainly not the limiting factor.

This report identifies challenges and barriers concerning safety culture assessment and improvement at the project, organisational and policy level highlighting the importance of leadership engagement and collaboration across healthcare organisations. To overcome these challenges this report recommends to:

1. Establish an infrastructure ensuring access and support to increase the use of validated safety culture assessment instruments,

2. Develop approaches for safety culture assessment that incorporate the patient perspective,

3. Make it a requirement for healthcare organisations to engage in safety culture assessment and development while maintaining openness concerning the specific approach,

4. Prioritise trans-organisational learning over benchmarking and

5. Develop a systematic approach for linking safety culture assessment and improvement.

In conclusion, there is an apparent lack of overview and coordination of ongoing efforts to measure and improve safety culture that hinders transorganisational learning and local improvement. Nevertheless, there are many promising initiatives by individual healthcare organisations that could inform national programmes in this area.

1. The current state of safety culture in the context of Swiss healthcare

This report provides an overview of the current state of safety culture in Swiss healthcare[1] regarding two key issues o: safety culture assessment and safety culture improvement. Naturally, these issues are rather closely linked since it is unlikely that improvements will be achieved without a prior assessment of safety culture,[1, 2] identification of areas that may require improvement and then by measuring to ascertain whether any improvement can be observed.

1.1 What is safety culture?

Safety culture is an aspect of organisational culture that refers to how safety is viewed and treated in organizations.[1] Generally, organisational culture is a relatively stable, multi-dimensional construct that is based on shared values and norms in the work environment that affect the attitudes, perceptions and behaviour of all members of an organisation.[3] Consequently, safety culture is comprised of employees' shared values and norms that orient the attitudes, perceptions and behaviour related to safety.

Throughout high-risk industries, safety culture has been recognized as an essential foundation for any safety program to take its maximum effect. A culture that prioritises safety, facilitates safety-oriented management decisions and worker behaviour, supports learning from error and increases organisation's capability to effectively respond to known and emerging risks.[1]

In healthcare the call for a culture of safety has become louder in recent years. This has mainly two reasons: First, the experience from a range of patient safety improvement efforts in various healthcare settings and different countries has shown that the success of these improvement projects has frequently been challenged by the prevailing culture. This has limited the sustainability of patient safety improvements in particular.[4, 5] Second, a growing number of studies highlights the relationship between a culture of safety and patient outcomes.[6-9]

1.2 Safety culture assessment[2]

Whilst qualitative measures help to understand the underlying values and basic assumptions,[1] the actual "measurement" of safety culture is usually based on a quantitative research approach. Internationally, a range of quantitatively oriented safety culture instruments have been developed and used extensively across safety-critical industries.[2, 10] While many of the theoretical constructs underpinning safety culture are similar across industries, healthcare-specific assessment instruments have been developed due to differences in the regulatory environment and in the organisational structures and processes related to safety management.

Swiss validations of internationally established instruments. Several internationally established instruments for safety culture assessment in healthcare have been adapted and psychometrically validated for the Swiss context.[11-16] Table 1 provides an overview of the available quantitative safety culture assessment instruments detailing; whether it was specifically developed for healthcare or based on another instrument, for which healthcare setting it is intended, in which of the Swiss

---

[1] While the focus of this report is Swiss healthcare, some of the statements also apply to other healthcare contexts and are reported in the international patient safety literature as many of the challenges are not unique to a specific national or health system context.

[2] In this report safety culture assessment comprises all qualitative or quantitative approaches to capturing facets of safety culture in a group of healthcare professionals.

national languages it is available and how it has been evaluated in terms of basic psychometric properties.

Behaviourally focused developments. While most instruments in table 1 cover a set of safety culture dimensions that are quite similar across instruments, there are some new developments available that address specific aspects of healthcare culture that may further or hinder specific safety-related behaviours of healthcare professionals.[17] On the one hand such thematically focused developments are a reflection of the need to conceptually expand safety culture to areas of safety relevant behaviours on which evidence has become available only recently. On the other hand these new developments point at some of the insufficiencies of previous instruments when aiming for and evaluating improvements with a specific behavioural focus.

1.3 Uses of assessment instruments and empirical findings on safety culture in Swiss healthcare[3]

While there is no complete picture of the level of implementation of safety culture surveys in Swiss healthcare or their findings, the literature provides some insights into the uses of assessment instruments and many (validation) studies report descriptive results such as mean values or percentages of positive/problematic responses.[12, 13, 18-23]

In the year 2000, Sexton and colleagues[32] published a comparison between pilots and healthcare staff using a set of 23 items on safety culture from the operating room management attitudes questionnaire[33] and the intensive care unit management attitudes questionnaire.[32] Unfortunately, it is unclear from the publication exactly when data at the 12 hospitals in Italy, Germany, Switzerland, Israel, and the USA were collected and the analysis does not allow for identifying the characteristics and data of the Swiss sample. However, some of the research included was conducted in the early 1980s. The Swiss data may originate from a project at the University Hospital Basel in the early 1990s.[33] This marks the likely date of the first safety culture assessment in Switzerland.

Other surveys published in the literature were:

- A report on the way in which the survey was used at the University Hospital Zurich in 2006.[34]
- A study assessing the effects of a crew resource management training on safety culture (see 1.4).[35]
- A study assessing patient safety culture among healthcare professionals in the emergency department of the University Hospital Bern and testing the impact of an intervention (see 1.4).[36]

---

[3] It has to be noted that this section of the report is prone to publication bias because some healthcare organisations prefer using their safety culture data for internal purposes, without publish their findings.

Table 1: Safety culture assessment instruments validated for a Swiss healthcare context

Instrument name	Patient Safety Climate Inventory (PaSKI)[11]	French version of the Hospital Survey on Patient Safety Culture[12]	Nursing Home Survey on Patient Safety Culture (NHSPSC-CH)[13]	Safety attitudes questionnaire (SAQ-Swiss version)[14]	Safety climate Survey (SCS)[15]	Safety Organizing Scale (SOS-Swiss-version)[16]	Speak up-related climate (SUPS-Q)[20]	SafeQuest[18]
Language region	German speaking	French speaking	German speaking	German speaking	German speaking	German speaking	German speaking	German speaking
Care setting	Hospital	Hospital	Nursing home	Hospital	Hospital	Hospital	Hospital	Primary care / diagnostic service
Target group	All hospital staff	All hospital staff	Nurses	Nurses and physicians	Hospital staff in clinical settings	Nurses	Nurses and physicians	All staff
Based on	Hospital Survey on Patient Safety Culture (HSOPS)(24)	French language version(25) of the HSOPS(24)	Nursing Home Survey on Patient Safety Culture(26)	Safety attitudes questionnaire (SAQ)(27) (Short version)	Safety climate survey (SCS)(28)	Safety Organizing Scale (SOS)(29)	Speak up climate safety scale(30) and own item development	SafeQuest(31)
Dimensions incl. number of items and Cronbach's Alpha (α)	Teamwork within units (4; α=.73)	Teamwork within units (4; α=.80)	Teamwork (4; α=.79)	Teamwork climate (6; α=.65)	Safety climate (19; α=.86)	Safety organizing scale (9; α=.90)	Psychological safety for speaking up (5; α=.84)	30 items; overall α=.97 (range .96-.98)
	Supervisor expectations/ actions promoting patient safety (4; α=.78)	Supervisor expectations/ actions promoting patient safety (4; α=.75)	Supervisor expectations and promoting of safety (3; α=.77)	Safety climate (7; α=.75)			Encouraging environment for speaking up (3; α=.74)	
	Organizational learning, continuous improvement (3; α=.68)	Organizational learning, continuous improvement (3; α=.57)	Organizational learning (4; α=.74)	Job satisfaction (5; α=.79)			Resignation (5; α=.73)	
	Hospital management support for patient safety (3; α=.83)	Hospital management support for patient safety (3; α=.79)	Management support for resident safety (3; α=.79)	Stress recognition (4; α=.79)				

	Feedback & communication about error (3; α=.79)	Feedback & communication about error (3; α=.77)	Feedback & communication about incidents (4; α=.77)	Perceptions of management (4; α=.44)				
	Staffing (3; α=.61)	Staffing (3; α=.61)	Staffing (4; α=.60)	Working conditions (4; α=.65)				
	Communication openness (3; α=.64)	Communication openness (3; α=.67)	Communication openness (3; α=.70)					
	Teamwork across hospital units (4; α=.76)	Teamwork across hospital units (4; α=.71)	Training & Skills (3; α=.64)					
	Hospital handoffs & transitions (2; α=.71)	Hospital handoffs & transitions (2; α=.78)	Handoffs (4; α=.67)					
	Nonpunitive response to error (3; α=.71)	Nonpunitive response to error (3; α=.60)	Nonpunitive response to errors (4; α=.75)					
	Unit management support for patient safety (4; α=NR)		Compliance with procedures (3; α=.70)					
	Unit handoffs and transitions (4; α=NR)							
Outcome dimensions	Overall perceptions of safety (4; α=.75)	Overall perceptions of safety (4; α=.68)	Overall perceptions of safety (3; α=.83)					
	Frequency of event reporting (3; α=.88)	Frequency of event reporting (3; α=.86)						
All dimensions	14	12	12	6	1	1	3	NR
Items	47	42	42	34	19	9	13	30

Note: NR= not reported

There are further studies that made use of safety culture surveys, or at least certain scales, as part of studies in Swiss healthcare with a different focus such as organisational factors associated with burnout or workforce issues.[37-42] However, these studies do not provide sufficient details on findings related to safety culture to inform this report.

Through her professional network, the author of this report is aware of a current safety culture assessment at the University Hospital Zurich in 2017 and 2020 and that other hospitals are considering conducting similar surveys (e.g. University Hospital Bern).

It was exactly this lack of coordination and overview of ongoing efforts to measure and improve safety culture that led the Conference of Medical Directors[4] to launch a large collaborative safety culture survey of all public hospitals in the French- and Italian-speaking regions of Switzerland in order to share the results and to use the experience in this field to define common actions for improvement. The survey was conducted over a three-year period from 2015-2017 targeting medical, nursing and paramedical staff working with patients, as well as the senior hospital managers. With 32'000 staff receiving the survey the overall participation rate was 41% (ranging from 19%-74%). This is probably the most comprehensive dataset on safety culture in Swiss healthcare.

1.4 Safety culture improvement[5]

The evidence supporting the link between safety culture and patient outcomes or patient safety indicators is growing and strengthens the role of safety culture as a leading indicator.[6-9] Thus, one focus of patient safety programmes is frequently the development of a positive safety culture.

Changes in safety culture related to patient safety interventions. In Switzerland, for example, Haller and colleagues[35] found positive changes in team and safety climate and improved stress recognition after a training intervention in obstetrics. Recently, Ricklin and colleagues[36] tested the impact of an information campaign about patient safety on safety culture, finding no statistically significant effects. However, the intervention strength has to be considered as rather limited. Besides these examples of unit-based experiences at single institutions, safety culture assessment was also part of the evaluation strategy of a national quality improvement program.[23] Results showed no substantial change but small significant differences in the level of safety climate for some subgroups.

Framing safety culture development. Most conceptual models of culture development frame it as a cyclical process of organisational learning and thus safety culture is viewed as an input into what can be achieved in the next cycle rather than as an outcome.[5, 43]

---

[4] The Conference of Medical Directors was created in 2009 bringing together the medical directors (i.e. physicians serving as members of the management board) of public hospitals in the French- and Italian-speaking regions of Switzerland: the Geneva University Hospitals, the Federation of Waldensian Hospitals, the Neuchâtel Hospital, the Fribourg Hospital, the Jura Hospital, the French-speaking Valais Hospital, the Ente Ospedalerio Cantonale and more recently, the Biel hospital centre.

[5] In this report safety culture improvement refers to targeted interventions/programs aiming to positively influence culture within a healthcare unit/organisation.

Based on this understanding of safety culture development it is not surprising that most studies which aim to improve safety culture through an intervention that is very limited in time, intensity and organisational spread can only achieve a very limited change that is also extremely difficult to sustain.[5] Even resource intensive long-term intervention projects often struggle with the fact that the prevailing culture may undermine the effects of the intervention.[4] Also, as highlighted in the Swiss study by Mascherek and colleagues,[23] other measures such as culture strengths should be considered when assessing safety culture development.

Specifically targeting safety culture development. Since safety culture improvement is not a by-product of interventions such as team training or the introduction of new protocols, specific tools or practices are needed to facilitate safety culture improvement. These practices (e.g. safety walk-rounds, peer-reviews, recurrent team training) will have to become part of the way the organisation operates on a routine basis before they can be expected to achieve the long-term effects expected of them.

In the following, an example will be given of one such tool that has recently made its way from other industries to healthcare: "safety culture dialogues". Safety culture dialogues are conducted in teams that discuss predefined themes such as "walkthroughs and audits", "supervisor behaviour after incidents" or "reporting and learning from harm" (see figure 1 for an example).

The aim of the discussion is to first describe typical behaviour regarding each theme to identify behavioural anchors for the five stages of safety culture maturity by Dianne Parker[44] building on her work on employee perceptions of these levels of maturity.[45] This discussion helps the team to conduct a thematically focused safety culture assessment of their unit or organisation and to understand that different maturity levels are present within one organisation at any given time. The second step is to develop a vision of which behaviours the team would like to see more of because these behaviours would help them to achieve the next level or at least function at that level more often.
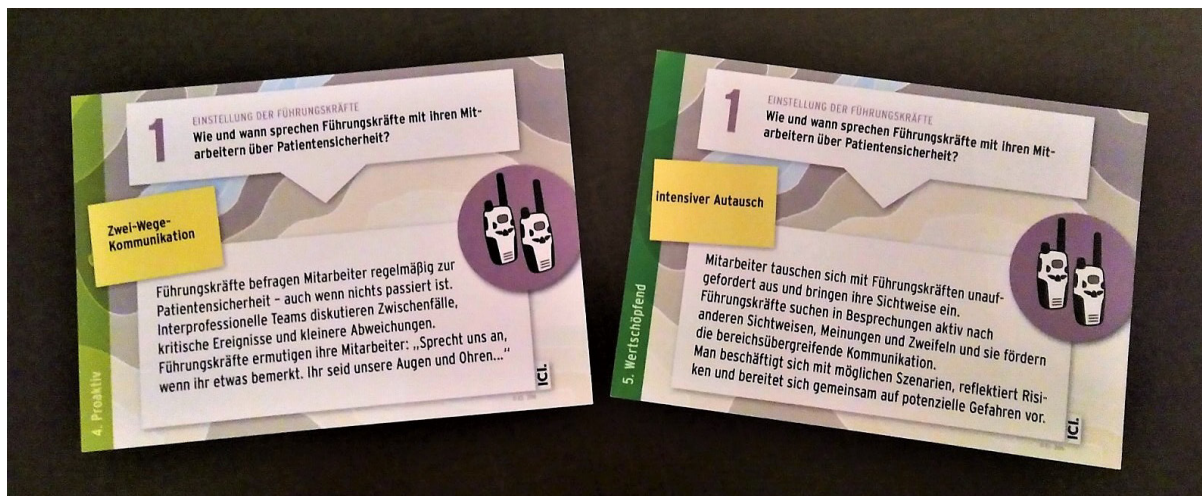
Figure 1: Cards for maturity level 4 and 5 on the theme "supervisor attitudes".

The unit for quality management and patient safety at the University Hospital Zurich was involved in the adaptation to healthcare and is currently gaining experience with various forms of conducting these dialogues to promote culture change (see http://icl-net.de/de/casespages/culture-dialogues-for-patient-safety).

2. Challenges and barriers concerning safety culture assessment and improvement

Project level. With one exception,[34] published studies did not include a detailed description of the approach taken or the challenges faced when assessing safety culture in a Swiss healthcare organization. However, such reports would be extremely valuable to quality and safety practitioners thinking about similar projects in their organization.

Organisational level. The main focus should be on raising the awareness of safety issues within the organisation and instilling a dialogue around the values underpinning the safe provision of healthcare. Thus, not simply the survey but particularly the discussion of results within the organisation should be encouraged. It is possible that healthcare organisations might benefit from expert support on how best to conduct safety culture assessment, taking their organisational specifics into consideration, how to interpret the results and how best to link the discussion around assessment results with ongoing improvement efforts. However, the most important component of such a process is leadership involvement. Currently, leadership competencies in Swiss healthcare seem mainly oriented towards management and clinical leadership.

Policy level. So far, safety culture assessment has not been made mandatory in Swiss healthcare. This approach is very much aligned with the decentralised approach to healthcare regulation and management in Switzerland that has many positives. However, looking at other countries that have mandated safety culture assessment for all healthcare sectors at regular intervals, there seems to be something to be gained from this approach; especially when not linking the assessment results to the accreditation of healthcare organisations but seeing them as an input into ongoing safety culture development.

3. Summary of the significant and relevant changes and improvements that have taken place in Swiss Healthcare

In recent years, there has been a stark increase in the availability of safety culture assessment instruments suitable for various Swiss healthcare settings. Much like other countries, safety culture assessment remains focused on acute care but has recently also gained attention in Swiss primary and long-term care settings.

This very positive development provides the foundation for large-scale studies on the state of safety culture, on the impact of safety culture on relevant healthcare outcomes but also on factors influencing safety culture. However, such studies are still missing.

Safety culture assessment is mostly limited to single institutions, sometimes even single units, and only a few established collaboratives have started to look at safety culture from a cross-organisational perspective. However, their experiences could be used by others

in making this a national undertaking and connecting measurement with improvement more closely.

4. Recommendations concerning safety culture assessment and improvement

Given the already existing body of safety culture assessment instruments validated for a Swiss healthcare context it is rather surprising that the uptake seems to have been very limited.[6] As demonstrated in this report, the availability of suitable instruments is certainly not the limiting factor and existing instruments could easily be adapted for additional healthcare settings or national languages; especially since a number of researchers with the relevant conceptual and methodological expertise are based in Switzerland.

Infrastructure ensuring access and support. It may be that interested healthcare institutions without a research-oriented quality and safety unit find it challenging to a) identify the best instrument for their purposes (e.g. evaluation of unit-based team training interventions, baseline assessment across departments at the planning stages of a hospital-wide safety initiative), b) access and use the instruments in a way that allows for valid conclusions, and c) make their findings publicly available in the form of scientific publications.

Recommendation 1: A repository of validated safety culture assessment instruments including user manuals and contacts for support should be established to promote open access to and correct use of existing instruments. This repository should be hosted and regularly updated by a national non-profit organisation in the field of patient safety.

Incorporating the patient perspective. One area of future development in safety culture assessment internationally, but also in Switzerland, might be to explicitly consider patients' perspectives on patient safety culture. So far, there have been mostly qualitative studies eliciting patients' perspectives on safety relevant behaviours by themselves or by healthcare professionals.[47-51] Recently a new scale to quantitatively measure patients' perceptions of patient safety culture has been developed.[52] While these are only initial steps to appreciate the many ways in which patients perceive the safety culture of a healthcare organisation, their views provide a valuable addition since they are not prone to organisational blindness.

Recommendation 2: The patient perspective should be considered as one area for expanding the scope of safety culture assessment throughout Swiss healthcare. To

---

[6] Since there is no current data available on the implementation of systematic safety culture assessment in Swiss healthcare, this statement is based on the authors subjective experience working with Swiss healthcare organizations on issues related to safety culture and her knowledge of the safety culture literature. In a national survey on Clinical Risk Management practices in Swiss hospitals, it was highlighted that the development of safety culture was one of the strategic risk management priorities for many hospitals and they acknowledged the key role of active leadership engagement in achieving this goal.[46]

account for the potential cultural differences between language regions, research on the development of instruments for capturing the patient perspective should be prioritised at a national level.

Openness concerning the approach to safety culture assessment. Conducting a safety culture survey may be a good and seemingly simple first step. However, there are other forms of safety culture assessment that might be more suitable to a given healthcare organisation depending on its size, structure (e.g. organisations with very diverse, largely self-regulated service units), safety concerns, the level of leadership involvement in patient safety management, etc. For example, the safety culture dialogue mentioned above can be used as a tool to assess the current safety culture as well as to develop a shared vision of safety culture and define measure to shift the organisational safety culture in the intended direction. Such an approach offers a more dynamic, self-regulated way to continuously develop safety culture and frame this as a critical process rather than a key performance indicator.

Recommendation 3: While there may be a general expectation for healthcare organisations to take a systematic approach to assessing and developing their safety culture, healthcare organisations should be allowed to choose their approach to safety culture assessment depending on their maturity level concerning patient safety management. Thus, when considering a mandatory approach to safety culture assessment at the national level, no restrictions to the methodological approach or a specific instrument should be applied. Each healthcare organisation should be able to decide between scientifically established approaches based on the specifics of their organisation.

Trans-organisational learning vs benchmarking. Following the example from the French- and Italian-speaking parts of Switzerland,[53] collaboration on safety culture assessment and development certainly provides an opportunity for trans-organisational learning. However, safety culture should be taken seriously as a leading indicator rather than a performance measure of healthcare organisations. As healthcare is only just beginning to understand the impact of this cultural foundation for any kind of improvement programme, collaboration is likely to be the best way to establish best practices linking safety culture measurement and improvement.

Recommendation 4: Healthcare organisations should be encouraged to collaborate when assessing and developing safety culture and to prioritise leadership involvement in promoting safety. This could lead to a pooling of resources and identification of best practices. In contrast, simple benchmarking approaches should be explicitly discouraged in light of the empirical evidence on regionally different response patterns in Switzerland and the impact of organisational as well as sample characteristics on healthcare professionals' responses to safety culture assessment.[23, 54, 55] If one still wishes to establish any kind of benchmarking report, this task should be delegated to an established research group in the field of safety culture research with the necessary scientific expertise.

Linking safety culture assessment and improvement. The call for a culture change in healthcare has become louder in recent years, especially as the success of patient safety improvement efforts has frequently been challenged or compromised by the prevailing safety culture; especially when it comes to sustainability.[4, 5] Safety culture assessment can provide valuable information to support successful implementation. However, the interpretation of safety culture data is quite different from the classical medical paradigm. For example, in clinical studies, overlapping confidence intervals indicate that there was no effect of an intervention. In the context of safety culture assessment these overlaps can be interpreted as a sign of culture strength. Depending on the initial assessment, one aim of an intervention might be to reduce differences in perception across units and to increase culture strength. Further, a sustained change in safety culture may reflect a shift in safety-related attitudes and values within an organisation, making safety-oriented behaviours a shared norm and thus more likely to occur.

Recommendation 5: Not only the overall level of safety culture but also the patterns of safety culture data need to be considered carefully when planning and evaluation interventions for safety culture improvement. Additionally, safety culture assessment should thus be linked to behavioural indicators of shifting attitudes, norms and values related to patient safety. Therefore, research linking safety culture assessment and improvement should be the focus of a national research programme.

References

1.	Manser T, Brösterhaus M, Hammer A. You can't improve what you don't measure: Safety climate measures available in the German-speaking countries to support safety culture development in healthcare. Z Evid Fortbild Qual Gesundhwes. 2016;114:58-71.
2.	Waterson P, editor. Patient Safety Culture: Theory, Methods and Application. Aldershot: Ashgate; 2014.
3.	Pfaff H, Hammer A, Ernstmann N, Kowalski C, Ommen O. Sicherheitskultur: Definition, Modelle und Gestaltung. Zeitschrift für Ärztliche Fortbildung und Qualität im Gesundheitswesen. 2009;103(8):493–7.
4.	McCulloch P, Mishra A, Handa A, Dale T, Hirst G, Catchpole K. The effects of aviation-style non-technical skills training on technical performance and outcome in the operating theatre. Qual Saf Health Care. 2009;18(2):109-15.
5.	Singer SJ, Vogus TJ. Reducing hospital errors: interventions that build safety culture. Annual Review of Public Health. 2013;34:373–96.
6.	Huang DT, Clermont G, Kong L, Weissfeld LA, Sexton JB, Rowan KM, et al. Intensive care unit safety culture and outcomes: a US multicenter study. Int J Qual Health Care. 2010;22(3):151-61.
7.	Mardon RE, Khanna K, Sorra J, Dyer N, Famolaro T. Exploring relationships between hospital patient safety culture and adverse events. J Patient Saf. 2010;6(4):226-32.
8.	Hansen LO, Williams MV, Singer SJ. Perceptions of hospital safety climate and incidence of readmission. Health Serv Res. 2011;46(2):596-616.

9.   The Health Foundation. Evidence scan: Does improving safety culture affect patient outcomes? London: The Health Foundation; 2011.

10.   Flin R, Burns C, Mearns K, Yule S, Robertson EM. Measuring safety climate in health care. Quality and Safety in Healthcare. 2006;15:109-15.

11.   Pfeiffer Y, Manser T. Development of the German version of the Hospital Survey on Patient Safety Culture: Dimensionality and psychometric properties. Safety Science. 2010;48(10):1452-62.

12.   Perneger TV, Staines A, Kundig F. Internal consistency, factor structure and construct validity of the French version of the Hospital Survey on Patient Safety Culture. BMJ quality & safety. 2014;23(5):389-97.

13.   Zuniga F, Schwappach D, De Geest S, Schwendimann R. Psychometric properties of the Swiss version of the Nursing Home Survey on Patient Safety Culture. Safety Science. 2013;55:88–118.

14.   Zimmermann N, Kung K, Sereika SM, Engberg S, Sexton B, Schwendimann R. Assessing the Safety Attitudes Questionnaire (SAQ), German language version in Swiss university hospitals--a validation study. BMC health services research. 2013;13:347.

15.   Gehring K, Mascherek AC, Bezzola P, Schwappach DL. Safety climate in Swiss hospital units: Swiss version of the Safety Climate Survey. J Eval Clin Pract. 2015;21(2):332-8.

16.   Ausserhofer D, Schubert M, Blegen M, De geest S, Schwendimann R. Validity and reliability on three european language versions of the safety organizing scale. International Journal for Quality in Health Care. 2013;25(2):157-66.

17.   Schwappach D, Richard A. Speak up-related climate and its association with healthcare workers' speaking up and withholding voice behaviours: a cross-sectional survey in Switzerland. BMJ quality & safety. 2018;27(10):827-35.

18.   Jossen M, Valeri F, Heilmaier C, Schwappach D. Assessment of the safety climate in outpatient diagnostic services: Development and psychometric evaluation of a questionnaire. Eur Radiol. 2018

19.   Zimmermann N, Kung K, Sereika SM, Engberg S, Sexton B, Schwendimann R. Assessing the Safety Attitudes Questionnaire (SAQ), German language version in Swiss university hospitals--a validation study. BMC health services research. 2013;13:347. eng.

20.   Richard A, Pfeiffer Y, Schwappach DDL. Development and Psychometric Evaluation of the Speaking Up About Patient Safety Questionnaire. J Patient Saf. 2017.

21.   Gehring K, Schwappach DLB, Battaglia M, Buff R, Huber F, Sauter P, et al. Safety climate and its association with office type and team involvement in primary care. International Journal for Quality in Health Care. 2013;25(4):394-402.

22.   Gehring K, Mascherek AC, Bezzola P, Schwappach DLB. Safety climate in Swiss hospital units: Swiss version of the Safety Climate Survey. Journal of evaluation in clinical practice. 2015;21(2):332–8.

23.   Mascherek AC, Schwappach DLB. Patient safety climate profiles across time: Strength and level of safety climate associated with a quality improvement program in Switzerland-A cross-sectional survey study. PLoS One. 2017;12(7):e0181410.

24.   Sorra J, Nieva V, Quality AfHRa. Hospital survey on patient safety culture. AHRQ Publication. Rockville, MD. 2004.

25.   Vlayen A, Hellings J, Claes N, Peleman H, Schrooten W. A nationwide hospital survey on patient safety culture in Belgian hospitals: setting priorities at the launch of a 5-year patient safety plan. BMJ quality & safety. 2012;21(9):760-7.

26.   Sorra J, Franklin M, Streagle S. Survey user's guide: Nursing home survey on patient safety culture. Rockville: Agency for Healthcare Research and Quality U.S. Department of Health and Human Services; 2008.

27.   Sexton J, Helmreich R, Neilands T, Rowan K, Vella K, Boyden J, et al. The Safety Attitudes Questionnaire: psychometric properties, benchmarking data, and emerging research. BMC Health Services Research. 2006;6(1):44-53.

28.   Sexton JB, Thomas EJ. The Safety Climate Survey: Psychometric and Benchmarking Properties. Technical Report 03-03; 2003.

29.   Vogus TJ, Sutcliffe KM. The Safety Organizing Scale: development and validation of a behavioral measure of safety culture in hospital nursing units. Med Care. 2007;45(1):46-54.

30.   Martinez W, Etchegaray JM, Thomas EJ, Hickson GB, Lehmann LS, Schleyer AM, et al. 'Speaking up' about patient safety concerns and unprofessional behaviour among residents: validation of two scales. BMJ quality & safety. 2015;24(11):671-80.

31.   de Wet C, Spence W, Mash R, Johnson P, Bowie P. The development and psychometric evaluation of a safety climate measure for primary care. Qual Saf Health Care. 2010;19(6):578-84.

32.   Sexton JB, Thomas EJ, Helmreich RL. Error, stress, and teamwork in medicine and aviation: cross sectional surveys. British Medical Journal. 2000;320(7237):745-9.

33.   Helmreich RL, Schaefer HG. Team performance in the operating room. In: Bogner MS, editor. Human Error in Medicine. Hillsdale, NJ: Lawrence Erlbaum Associates; 1994. p. 225-53.

34.   Van Vegten A, Pfeiffer Y, Giuliani F, Manser T. Patient safety culture in hospitals: Experiences in planning, organising and conducting a survey among hospital staff. Zeitschrift fur Evidenz, Fortbildung und Qualitat im Gesundheitswesen. 2011;105(10):734-42.

35.   Haller G, Garnerin P, Morales MA, Pfister R, Berner M, Irion O, et al. Effect of crew resource management training in a multidisciplinary obstetrical setting. International Journal for Quality in Health Care. 2008;20(4):254-63.

36.   Ricklin ME, Hess F, Hautz WE. Patient safety culture in a university hospital emergency department in Switzerland – a survey study. GMS Journal for Medical Education. in press.

37.   Aiken LH, Sloane D, Griffiths P, Rafferty AM, Bruyneel L, McHugh M, et al. Nursing skill mix in European hospitals: Cross-sectional study of the association with mortality, patient ratings, and quality of care. BMJ Qual Saf. 2017;26(7):559-68.

38.   Auer C, Schwendimann R, Koch R, De Geest S, Ausserhofer D. How hospital leaders contribute to patient safety through the development of trust. J Nurs Adm. 2014;44(1):23-9.

39.   Ausserhofer D, Schubert M, Desmedt M, Blegen MA, De Geest S, Schwendimann R. The association of patient safety climate and nurse-related organizational factors with selected patient outcomes: a cross-sectional survey. Int J Nurs Stud. 2013;50(2):240-52.

40.   Zuniga F, Ausserhofer D, Hamers JPH, Engberg S, Simon M, Schwendimann R. Are Staffing, Work Environment, Work Stressors, and Rationing of Care Related to Care Workers' Perception of Quality of Care? A Cross-Sectional Study. J Am Med Dir Assoc. 2015;16(10):860-6.

41.   Welp A, Meier LL, Manser T. Emotional exhaustion and workload predict clinician-rated and objective patient safety. Front Psychol. 2015;5:1573.

42.   Welp A, Meier LL, Manser T. The interplay between teamwork, clinicians' emotional exhaustion, and clinician-rated patient safety: a longitudinal study. Critical care 2016;20(1):110.

43.   Vogus TJ, Sutcliffe KM, Weick KE. Doing No Harm: Enabling, Enacting, and Elaborating a Culture of Safety in Health Care. The Academy of Management Perspectives. 2010, 2010;24(4):60-77.

44. Parker D, Lawrie M, Hudson P. A framework for understanding the development of organisational safety culture. Safety Science. 2006;44(6):551.

45. Lawrie M, Parker D, Hudson P. Investigating employee perceptions of a framework of safety culture maturity. Safety Science. 2006;44(3):259-76.

46. Briner M, Kessler O, Pfeiffer Y, Wehner T, Manser T. Erste Schweizer Erhebung zum klinischen Risikomanagement im Spital: Zusammenfassung der Ergebnisse. Schweiz Arzteztg. 2009;90(15/16):635-8.

47. Schwappach DLB, Frank O, Buschmann U, Babst R. Effects of an educational patient safety campaign on patients' safety behaviours and adverse events. Journal of Evaluation in Clinical Practice. 2013;19(2):285-91.

48. Schwappach DLB, Frank O, Koppenberg J, Müller B, Wasserfallen JB. Patients' and healthcare workers' perceptions of a patient safety advisory. International Journal for Quality in Health Care. 2011;23(6):713-20.

49. Schwappach DLB, Wernli M. Am I (un)safe here? Chemotherapy patients' perspectives towards engaging in their safety. Qual Saf Health Care. 2010;19(5):6.

50. Schwappach DLB, Wernli M. Predictors of chemotherapy patients' intentions to engage in medical error prevention. Oncologist. 2010;15(8):903-12. English.

51. Schwappach DLB, Wernli M. Barriers and facilitators to chemotherapy patients' engagement in medical error prevention. Ann Oncol. 2011;22(2):424-30.

52. Monaca C, Bestmann B, Kattein M, Langner D, Muller H, Manser T. Assessing Patients' Perceptions of Safety Culture in the Hospital Setting: Development and Initial Evaluation of the Patients' Perceptions of Safety Culture Scale. J Patient Saf. 2017 21.

53. Mercier Y. Enquête sur la culture de la sécurité des patients auprès des hôpitaux de Suisse latine (2015-2016-2017). 2017.

54. Singer SJ, Gaba DM, Geppert JJ, Sinaiko AD, Howard SK, Park KC. The culture of safety: results of an organization-wide survey in 15 California hospitals. Qual Saf Health Care. 2003;12(2):112-8.

55. Gambashidze N, Hammer A, Wagner A, Rieger MA, Brösterhaus M, Van Vegten A, et al. Influence of gender, profession and managerial function on clinicians' perceptions of patient safety culture. A cross-national cross-sectional study. Journal of Patient Sefty, 2019, doi: 10.1097/PTS.0000000000000585 (published ahead of print).

” The safety and quality of healthcare in Switzerland: Indicators and evaluation of quality and safety”

Literature Review “1” for the «Swiss National Report on Quality and Safety in Healthcare»

Authors

- Bernard Burnand, MD, MPH, Emeritus Prof. [1, 2]
- Muaamar Al-Gobari, BSc Pharm, MPH, PhD [2]

Other contributors

- Marie-Annick Le Pogam, MD, MSc, Cheffe de Clinique [1]
- Thomas Brauchli, Literature search specialist [1]

Affiliations

1. Center for Primary Care and Public Health (Unisanté), University of Lausanne
2. Association Point Information Santé, Lausanne

Potential conflicts of interest

The authors declare no conflict of interest beyond their scientific research interests in the domain of the review.

Text statistics

Text: 7'622 words

Abstract: 261 words

Table of contents

Summary

Assessing the performance of the healthcare system is mandatory, which includes assessing the quality and safety of healthcare procedures. Using appropriate indicators allows both to indicate areas needing improvement and to evaluate the effectiveness and impact of interventions aimed at improving quality and safety. We conducted a rapid literature review to assess the current state of quality and patient safety in the healthcare system, mainly by means of indicators.

Globally, this review of indicators of quality and safety available in Switzerland over the last decade confirm that quality of care and patient safety are reasonably good in Switzerland. However, the results observed in presence of international comparisons or with acknowledged or evidence-based standards indicate first that the performance is usually not better in Switzerland than in other developed countries, and second that in many areas there is room for further improvement. The review indicated that only a few indicators are routinely established by the federal office of public health (FOPH) and other national organisations (e.g., Swiss National Association for Quality Development in Hospitals and Clinics (ANQ)). However, the many publications we found, about 150 between 2008 and 2018, indicate a patchy coverage by domain and geographic areas. A national effort is needed to allow the development, and evaluation, of valid indicators that could be implemented and evaluated nationwide at a reasonable cost. The indicators should inform the healthcare professionals to help them improve their practice and the healthcare managers and decision makers to adapt the system, the structures and the conditions to allow providing high quality healthcare, with optimal patient safety.

Introduction

According to the world health organisation (WHO),"Poor-quality health care around the globe causes ongoing damage to human health. In low- and middle-income countries (LMICs), between 5.7 and 8.4 million deaths occur each year from poor quality of care, which means that quality defects cause 10 to 15 percent of the total deaths in these countries. The resulting costs of lost productivity alone amount to between $1.4 and $1.6 trillion each year."[1] Actually, patient safety and quality of care are also major issues in developed countries. The median overall incidence of in-hospital adverse events was 9.2% (8 studies, about 75'000 patient records) (1). The median percentage of preventability was 43.5% (1). The OECD[2] Health Care Quality and Outcomes programme (formerly known as Health Care Quality Indicators Project) was initiated in 2001[3]. The aim of this project was to develop and report indicators for international comparisons of health care quality. Over the past twenty years, series of data collection and analyses have been carried out. The coverage of the dimensions expanded progressively, within the framework proposed by OECD. These developments were brought up by contributions from a representative group of experts from OECD and non-OECD countries, international organisations including the WHO,the European Commission and other relevant collaborating institutions, including universities, subject matter experts and research organisations (OECD[3]).

The 2011 WHO – OECD report on the performance of the Swiss healthcare system indicates that the information system should be improved, also to allow better assessment of quality and safety. The Swiss law on medical insurance indicates that mandatory health insurance should cover the interventions that are effective, appropriate and economical (Art 32). Quality of care is indicated in another article (Art 58), which allow the Federal government to organise scientific and systematic quality controls. These activities can be delegated to professional associations or other appropriate stakeholders. Following several initiatives, the Federal office of public health (FOPH) has introduced some quality measures, and the Swiss National Association for Quality Development in Hospitals and Clinics (ANQ) has developed a series of measures that are mandatory in hospitals. Therefore, assessing the performance of the healthcare system, including the quality and safety of healthcare procedures, is also compulsory.

Using appropriate quality and safety indicators allows both to indicate areas needing improvement and to evaluate the effectiveness and impact of interventions aimed at improving quality and safety.

The purpose of this literature review was to provide an authoritative overview of what is currently known about the safety and quality of healthcare in Switzerland. A comprehensive coverage of every aspect of Swiss healthcare was not feasible or desirable. Instead, this review focused on a limited number of core areas that included indicators of healthcare quality, indicators of patient safety, initiatives and projects to assess quality and safety, and evaluations and reviews of quality and patient safety.

---

[1] WHO; Crossing the Global Quality Chasm: Improving Health Care Worldwide.
http://nationalacademies.org/hmd/Reports/2018/crossing-global-quality-chasm-improving-health-care-worldwide.aspx
[2] Organisation for Economic Co-operation and Development
[3] OECD - http://www.oecd.org/health/health-care-quality-framework.htm

Methods

Literature and information search

We searched the Medline database via PubMed from 2008 up to 25 November 2018. The search strategy was limited to studies involving human subjects and Swiss data. There were no language restrictions or study design limitation. We used a combination of MeSH[4] terms (e.g., "Quality Indicators, Health Care"[MeSH]; "Patient Safety"[MeSH]), free text words (e.g., healthcare associated injury), Boolean terms (e.g., AND, OR) and truncations (e.g., medical error*) where possible. The search strategy was originally developed for a study protocol (2) and was adapted for our work. The search strategy for this review is presented in appendix 1. Moreover, additional studies were added due to authors' expertise in the domain of study. In addition to the electronic literature search and hand search, we searched additional sources of information, such as the websites of the Federal government, organisations, foundations and associations involved in quality and safety assessment, programmes, etc. On December 11, 2018 we searched the websites of FOPH (www.bag.admin.ch/bag/fr), the Swiss health Observatory (Obsan: www.obsan.admin.ch), and the Swiss National Association for Quality in Hospitals (ANQ, www.anq.ch), for publications or reports.

Eligibility of studies

Limited by time of publication (2008 and upwards), studies were eligible for inclusion if they covered any of the following topics:

- Indicators of healthcare quality
- Indicators of patient safety
- Initiatives and projects to assess quality and safety
- Evaluations and reviews of quality and patient safety
- Adverse events and medication errors
- Appropriateness of healthcare interventions and adherence to guidelines
- Satisfaction and opinion surveys and patient-reported outcomes

The included studies should have included data collected in Switzerland, but could also contain data from other countries, i.e. in international studies with separate results for Switzerland.

Data abstraction and analysis

We abstracted the following data: study identification information, study main characteristics, patients' characteristics, and relevant outcomes. Two reviewers (BB & MA) were independently involved in the search, selection and abstraction of data. We used www.covidence.org for the process of study selection. Discrepancies were solved upon discussions and consensus. We intended to provide a descriptive and qualitative synthesis of results due to our study design. Therefore, it was not feasible to estimate the potential risks of bias of the included studies.

Synthesis of information

There are various ways to describe and present healthcare quality and safety indicators. We used a mix of several approaches, including the classical presentation according to Donabedian categories (structure, process, outcomes), We also used other classification approaches, such as healthcare location (in- vs outpatient care), according to the study scope (local or regional, national, international), to the type of information (use of routinely vs ad hoc collected data or survey). Some data were issued from quality and safety monitoring initiatives, other from health services research projects. The scope of indicators may also be narrow, such as the appropriateness of a specialized intervention for a specific disease or

---

[4] Medical Subject Heading

wider, such as the general opinion and satisfaction about hospital care. Moreover, the indicators were related to different clinical fields, such as general or family medicine, specialised care (e.g., surgery, anaesthesiology), or care for chronic or complex diseases that requires the collaboration of multiple healthcare professionals.

Eventually, to facilitate their appraisal for the reader, we classified the results in an ordered stratified description, by:

- geographic coverage (nationwide vs regional or local)
  - frequency of assessment (routine vs occasional)
    - type of care: in- vs outpatient (general or specialized))
      - several subcategories:
        - mortality
        - infection (healthcare related, hospital acquired)
        - other adverse events
        - appropriateness of care
        - opinion and satisfaction

We have thus grouped indicators of quality and safety together; one may actually consider that safety is included in a broader assessment of quality. Our stratified and hierarchic classification ended in a potential maximum of 60 categories; however, what we found clustered in 15 groups only.

Results

Study selection and characteristics

The search strategy resulted into the inclusion of 142 studies after removal of duplicates and screening of titles and abstracts followed by full-text articles. Figure 1 shows the results of the search strategy (Appendix 2). The included studies fulfilled our eligibility criteria and they had addressed at least one of the research topics cited in the methods above. The studies covered a wide variety of interventions (such as primary care, in hospital care or inpatient care) and some focused on particular diseases (such as colorectal cancer, diabetes, acute coronary syndrome, or chronic obstructive pulmonary disease (COPD)). Most studies were conducted in Switzerland while some were international studies with separated data for Switzerland were also included. Table 1 shows all included studies with some characteristics (Appendix 3).

Nationwide assessments

Routinely collected data

In-patient care

Mortality

Since 2006, FOPH has developed and improved a series of inpatient quality indicators (CH-IQI) to allow monitoring the quality of inpatient care in acute care hospitals. These indicators were developed initially in a pilot project, since 2009, and then adapted in a collaborative framework with Germany and Austria. They are calculated from the hospital discharge summaries annually submitted by Swiss hospitals to the Federal Office of statistics. The data include discharge diagnoses according to the International Classification of Diseases (ICD-10, evolving versions) and to the CHOP procedure classification (Swiss classification of surgical interventions). The main indicators are inpatient standardised mortality ratios for a series of diagnoses (e.g., myocardial infarction, pneumonia) and interventions (e.g., surgery for colorectal cancer), and the number of cases for some special situations or interventions (e,g., caesarean section). For each Swiss acute care hospital, the results are presented for the index year and the average of the five years preceding the index year, by hospital (3).

Infection

In addition to the evaluation of patient satisfaction, several other, classical, safety indicators are assessed nationwide in the framework of the ANQ measures in hospitals. Surgical site infection is monitored in collaboration with the Swissnoso network, by ad hoc surveys.

The assessment of hospital acquired infections was developed relatively early; in 1994 FOPH ask the specialists in infectious diseases and hospital hygiene to develop programmes to reduce the occurrence of hospital acquired infections and antibiotic resistance. The Swissnoso network organises the data collection to monitoring surgical site infection and hand hygiene guidance observance, in the framework of the ANQ (www.swissnoso.ch).

A report presented the results of the Swiss national surgical site infection (SSI) surveillance program, over a 4-year period (2011-15) in 164 Swiss public and private hospitals with surgical activities. A total of 187,501 operations performed in this setting were included. Cumulative SSI rates varied from 1% for knee arthroplasty to 14% for colon surgery. Post discharge follow-up was completed in >90% of patients at one month for surgeries without an implant and in >80% of patients at 12 months for surgeries with an implant. High rates of SSIs were detected post discharge, from 21% in colon surgery to 93.3% in knee arthroplasty (4). Previous analyses indicated that individual surgical practices constituted a risk for surgical site infection (5). Previous reports of the surgical site infections rates have been

conducted over longer periods, however, restricted to participating hospitals (6,7). The prevalence of healthcare-associated infections in two tertiary and one secondary care hospital was close to 6% (153 infections in 136 of 2'421 patients) was close to the rates reported in other European countries (8). A report of viral hospital-associated infection frequencies in one infectious disease ward and three general paediatric wards in Finland and Switzerland indicated a frequency of 12%, with 2% of the patients developing an infection in the hospital, most often a gastroenteritis, and 10% within 72 h of discharge. Sharing room was a risk factor for hospital-acquired infection (9). Although relatively rare in hospitals clostridium difficile infections, an incidence of 2.3/10,000 patient days was measured in one tertiary care hospital. In the majority of cases, the transmission was from another patient, where age and comorbidity being risk factors (10).

Other adverse events

Among the other ANQ measures, the rate of potentially avoidable rehospitalisation is measured on the basis of the hospital discharge data statistics, these data are collected by the Federal office of statistics. In addition, the occurrence rates of falls in hospitals as well as the occurrence of decubitus ulcers are also measured on an annual basis. Finally, a register of surgical implants, SIRIS, allows overseeing the safety and effectiveness of the various implanted knee and hip arthroplasties and to detect potential problems related to inferior implant performance (www.anq.ch).

Using routinely collected hospital discharge data from five countries including Switzerland, the occurrence of in-hospital venous thromboembolism in patients undergoing hip replacement indicated comparatively low rates in Switzerland (<0.5%) that were close to an evidence-based benchmark (11). This an example of the Patient Safety Indicators that can be derived from routinely collected hospital discharge data.

Several studies have evaluated patient safety in specialised care. The Swiss society of anaesthesia and reanimation introduced Anaesthesia Databank Switzerland (ADS), a voluntary data registry introduced in 1996 and conducted until 2015 (replaced by the A-QUA-CH programme). The ADS registry analysed routinely recorded adverse events and provided benchmark comparisons between anaesthesia departments. Up to 2010, the database included 2,158,735 anaesthetic procedures. Between 1996 and 2010, 125,579 adverse events were recorded, of which 34% were cardiovascular, 7% respiratory, 39% technical and 20% non-specific. The most severe events were resuscitation (50%), oliguria (22%), myocardial ischaemia (17%) and haemorrhage (10%) (12).

Appropriateness of care

In a prospective cohort of 1260 patients hospitalized for acute coronary syndrome in four tertiary centres, the prescription of recommended preventive drugs was very high (mostly above 90%), although suboptimal for some drugs, allowing thus room for further improvements (13). Among over 45,000 patients with an acute coronary syndrome in the Swiss AMIS (Acute Myocardial Infarction in Switzerland) registry, a small percentage (<5%) received only palliative care, not taking advantage of the available effective strategies, in absence of obvious rationale (14).

A further analysis of the same AMIS registry data about of treatment of an acute coronary syndrome in older adults (13,662 ≥70 years) indicated increased adherence to recommendations between 2001 and 2012 and simultaneous improvement in outcomes, suggesting that increasing use of guideline-recommended therapies was appropriate (15).

Opinion and satisfaction

Patients' opinion and satisfaction surveys were introduced relatively early in Switzerland comparatively to other quality indicators. Patient satisfaction in hospitals is now included, for about ten years in acute care, in the ANQ set of indicators with, usually, short questionnaires (acute care, psychiatry, rehabilitation and for paediatric care) (www.anq.ch). These results are available on the ANQ website and allow comparisons across hospitals. Many hospitals combine ANQ measures with additional questionnaires.

In the framework of an international study that included a cross-sectional survey of nurses (RN4CAST), 1,593 nurses participated in 34 Swiss hospitals; 20% of them reported their ward to have poor or fair quality of care (i.e., close to the international median value of 23%), whereas 4% gave a poor or failing ward safety grade (i.e., lower than the international median value of 6%), and 15% indicated that patient safety was not a priority of hospital management (16,17). Patients were highly satisfied in comparison. In the Swiss report of a substudy of this survey, in only 33/120 eligible units did at least 60% of nurses reported a positive patient safety climate. A majority of nurses reported that they were "consistently engaged" in only three of the nine proposed patient safety behaviours (18). A survey of 4,311 nurses and nurses' aides in nursing homes indicated that 7% of them rated the quality of care provided as rather low or very low. Important factors related to better quality of care were higher teamwork and safety climate, better staffing and resources adequacy, and low levels of stress due to workload (19).

Ambulatory care, general medicine

We found only data presented in the following category in ambulatory care.

Appropriateness of care

The 'Smarter Medicine' campaign began in 2014 with the aim of reducing the prescription of unnecessary care. The "top five list" of unnecessary tests and treatments in primary care, such as imaging for acute low-back pain and long-term prescribing of proton pump inhibitors, was released. Responding to an online survey of 277 general practitioners of the 'Swiss primary care active monitoring' (SPAM) network, 104 (62%) knew of 'Smarter Medicine'. Agreement with the five recommendations was high, with scores around nine out of 10. Over two thirds indicated that they follow each recommendation, except not continuing long-term proton pump inhibitors prescriptions without attempting dose reduction that followed by only one third (20).

In a study based on routinely collected data of two million insured individuals followed over one or two years, there were 23,129 hospitalisations for ambulatory care sensitive conditions (i.e., conditions or diseases that could and should be usually treated in ambulatory care – e.g., asthma, congestive heart failure, chronic obstructive pulmonary diseases) during the follow-up period. After excluding 2,829 cases with severe comorbidity justifying the hospitalisation and 2,701 involving a therapeutic operation requiring an inpatient stay, and 550 for both conditions, there were 17,049 potentially avoidable hospitalisations during the follow-up period, corresponding to 6.3 per 1,000 insured, per year. There was an important variation of potentially avoidable hospitalisation rates per canton (from 1.4 to 9.6 per 1,000 insured, per year) (21,22).

The prevalence and determinants of potentially inappropriate medication use, and related hospitalization was measured in a sample of managed care patients aged 65 and older using health care claims data of four health insurers. The estimated prevalence of potentially inappropriate medication use was above 22% and associated with higher hospitalisation (23). A similar study in over 50,000 patients indicated a slightly higher rate of potentially inappropriate medication delivered by physicians compared to pharmacists (24).

The analysis of potential drug-drug interactions (DDI) in ambulatory care, based on claims data from three large health insurers in 2010, indicated that 1.3% and 1.2% of 1'607'233 female and 1'525'307 male patients, respectively, were exposed to potential drug-drug interaction for 12 months. A small proportion of physicians caused potential DDI in a frequency that is very unlikely to be explained by chance when compared to their peers (25).

Occasional inquiries

In-patient care

Other adverse events

Postpartum haemorrhage is a relatively common and potentially dangerous obstetric complication. Using data of all patients with deliveries between 1993 and 2014 from the national Swiss Hospital in-patient database for obstetric and gynaecological hospital admissions, an increasing incidence was observed during these two decades (26). On the same topic, a recent analysis in one large hospital indicated a similar trend using hospital discharge data, whereas, including measured blood losses from electronic medical records indicated a decreased secular incidence trend (27).

Ambulatory care, general medicine

Other adverse events

A large international survey (28) in primary care in 11 countries, conducted in 2013, included over 20'000 patients aged 18 and over, assessing various aspects of primary care (e.g., access, coordination of care, communication) and potential problems occurring during encounters. Countries differed regarding the proportion of the population experiencing problems with primary care. The mean of self-reported primary care problems was 1.8 in Switzerland, lower than the average of 2.1, but in the mid-range of countries (28).

In a representative population sample of 1306 Swiss citizens, 11% reported at least one error in their care in the previous two years, including 5% of medication errors (29).

The representative "Sentinella" network of primary healthcare physicians evaluated the occurrence of any *erroneous* event related to the medication process and interfering with normal treatment course, as judged by their physician. The 180 participating physicians detected two medication incidents per general practitioner per year (46.5 per 1 00 000 contacts). Higher patient age and morbidity, care by community nurse or by an institution, chronic conditions were risk factors. Most cases were linked to an incorrect dosage for a given patient, while prescription of an erroneous medication was the second most common error (30).

Appropriateness of care

Based on the survey of health, ageing and retirement in Europe (SHARE), polypharmacy, a common condition among the elderly, was assessed in adults aged 65 or more years across 18 countries. The results showed a prevalence of polypharmacy ranging from 26 to 40%. Switzerland was among the countries with the lowest prevalence (26%). Globally, age, gender, number of limitations with activities of daily living, number of chronic diseases, quality of life, depression, physical inactivity, network satisfaction, difficulty in taking medications, years of education and shortage of money were significant variables associated with polypharmacy (31).

Local or regional assessments

Routinely collected data

We found no studies in this category.

Occasional inquiries

In-patient care

Infection

In one academic centre, the baseline figure of an intervention aimed at improving hand hygiene compliance was an observation rate of 66% among 1430 opportunities (32).

Among 5825 urologists surveyed in Austria, Germany and Switzerland, 364 (92%) of 374 respondents, 74% reported non-adherence to guidelines on antimicrobial prophylaxis for low-risk patients undergoing transurethral resection of the prostate, corresponding to overuses of pre- and postoperative antibiotics. The performance of Swiss urologists was comparable to the practice of their foreign colleagues (33).

Other adverse events

Several retrospective medical records reviews have been conducted in several countries to assess patient safety (1). These studies have shown substantial rates of adverse events (AE) among hospitalized patients. A similar study was conducted in Switzerland and reported recently. The estimated rate of AE in one acute care hospital indicated that there was at least one AE in 12%, corresponding to one or more preventable AE in 6.4% of hospitalisations (34).

In a study on medication errors in one cardiovascular surgery department, 119 nurses used a self-reporting tool during one-month. Out of 987 reports, 288 (29%) indicated that there had been a medication error. Nurses reported preventing 49 (5%) of them, and, overall, eight (3%) had patient consequences (35).

Unintentional paracetamol overdosing is a common medication error in hospitals. All patients who received paracetamol in a tertiary care hospital were analysed to detect cases of paracetamol overdosing using a pharmaco-epidemiological database. From 2011 to 2013, relevant overdosing occurred in 11 patients (5–8 g/day for 3 to 5 days), corresponding to less than 1% of all patients exposed to any paracetamol overdosing (mean n = 988 per year) (36).

Ten regional acute care hospitals monitored the discrepancies between drugs prescribed and those prepared for administration, as well as the occurrence of adverse events. The baseline rates in 2010 indicated that pillbox discrepancies were present in 6% of doses; about 1 adverse event per 1000 doses was recorded (37).

In one academic hospital neurology department, drug-related problems were assessed in 1,263 consecutive inpatient cases over 12 months. In 29% of cases one or more drug related problem was present (38).

A survey of pharmacy heads indicated that communication barriers with people of foreign origin are considered a risk for drug related events (39).

A survey of nurses working in oncology departments of three hospitals indicated that medication double checking was applied by two thirds of respondents and considered very appropriate to avoid medication errors (40,41).

In another survey of nurses and physicians in oncology, a majority of responders reported at least some episodes of withholding concerns about patient safety. Thirty-seven per cent said

they remained silent at least once when they had information that might have helped prevent an incident (42).

Furthermore, the same research team implemented patients' surveys to assess safety; 21% reported at least one definite safety event, and the mean number of 'definite' incidents per patient was 0.31 (29,43). However, oncology patients seem to underestimate the occurrence and risk of chemotherapy (44). In addition, the direct participation of patients, to prevent safety adverse events, was considered positive by a majority of the 1141 hospital healthcare professionals who responded to a vignette survey (45).

Between 1972 and 2010, 5,277 consecutive thyroid gland surgeries with 7,383 nerves at risk were performed in one teaching institution. The incidence of permanent recurrent laryngeal nerve palsy in primary operations was significantly higher in the first period (4%) compared to the second period (1%). Permanent hypoparathyroidism decreased from 3% in the first period to 1% in the second period, and the incidence of recurrent goiter surgery decreased from 11% in the first period to 8 % in the second period, indicating improvement in techniques and processes (46).

In 143 surgical esophagectomies performed between 2004 and 2013, mostly by two surgeons, postoperative morbidity was 43% that was linked with a five day increase in length of stay (47).

Appropriateness of care

Number of days spent in acute hospitals at the end of life is regarded as an important care quality indicator for cancer patients. Insurance claims data identified 2086 patients as dying of cancer, that indicated a high number of days spent in the hospital in four Swiss cantons compared to most other countries palliative care (48). Moreover, anticancer drug therapy was given in 22.2% and radiotherapy in 11.7% of these palliative care episodes, which questions the appropriateness of these interventions (49).

Ambulatory care, general medicine

Other adverse events

A survey conducted amongst 630 physicians and nurses working in Swiss German primary care offices to determine safety risks and safety climate in their offices indicated that 30 % of the physicians and 17 % of the nurses observed at least one of the 23 survey incidents in their offices on a daily or weekly basis. Errors in documentation were reported most frequently. The study indicated also that telephone triage was a relevant area of patient safety in primary care (50). Among the 630 primary care physicians and nurses, 391 (31%) described 936 threats to patient safety. Errors in diagnosis, drug interactions and compliance of patients were more likely to be cited by physicians, whereas X-rays, confusion of patients or records, hygiene, safety of office rooms and confidentiality were more likely to be described by nurses (39).

Appropriateness of care

A vignette-based survey investigated the management of outpatients presenting with acute chest pain by 471 general practitioners and 36 cardiologists in private practice. The vast majority responded appropriately to directly refer cases to a close catheter service (88%), or for other selected cases, to an inpatient ward (94%) with no difference between the specialties. Adherence to international guideline was high, although some improvements could be made (51).

A study conducted among all adult patients hospitalized for more than 24 hours in a tertiary care centre and discharged either to their home or to a nursing facility for one month indicated that about two thirds had pain, considered as severe in about half of them.

Whereas three quarters indicated that treatment definitively relieved pain, less than 5% indicated that it did not (52).

In another study conducted among 532 community dwelling adults aged ≥65 years, the prevalence of potentially inappropriate prescribing was 17% in Switzerland compared to 13% in the Netherlands and 9% in Ireland, whereas potential prescribing omissions was close to 25% in Switzerland and the Netherlands and lower in Ireland (14%). Multimorbidity and polypharmacy were more frequently determinants of inappropriate prescription in Switzerland (53).

A Swiss pilot survey of 53 general internal medicine practitioners examined the practice of use of the new direct oral anticoagulants showed that only about two-thirds of GPs adhere to recommendations on clinical and blood test follow-ups (54). Quality of preventive healthcare services in primary care was assessed by means of analysing the database of the Swiss «Family Medicine ICPC Research using Electronic Medical Records» (FIRE) project. In 2,807 patients with coronary heart disease treated for at least 15 months between 2009 and 2014, the proportion of patients per year meeting four quality indicators (blood pressure and cholesterol targets and prescription of anti-platelet therapy, and recommended drugs for patients with previous myocardial infarction) were above 80% for blood pressure control and in presence of a prior myocardial infarction and above 70% for the two other conditions (55).

However, one should not only evaluate the rate of cardiovascular risks factors control (hypertension, dyslipidemia, diabetes mellitus), but also the related physicians' appropriate response as well as markers of potential overtreatment (21). In four university primary care settings, 20% of patients with hypertension, 41% with dyslipidemia and 36% with diabetes mellitus were in control. When appropriate clinical action in response to poor control was integrated into measuring quality of care, 52 to 55% had appropriate quality of care (21).

A survey of 250 primary care physicians with high prescription rates allowed assessing the quality of antibiotic prescribing among 9961 medical records. Overall, antibiotics were prescribed to 32% of patients. For tonsillitis/pharyngitis, acute otitis media, acute rhinosinusitis and acute bronchitis the acceptable maximum of antibiotic prescriptions was exceeded by 24%, 50%, 27% and 12%, respectively. The proportion of non-recommended antibiotics was above the recommended maximum of 20% for all diagnoses (32%–89%). Antibiotic prescribing quality of Swiss primary care physicians with high prescription rates was low, begging for corrective measures (56).

Another set of projects investigated quality of care for chronic diseases, mostly in primary care practice, in coordination with respective specialists. Analyses of recommended processes-of-care performed among patients living with diabetes included in a representative cohort study in one canton indicated that, whereas routine tests were performed in over 90% of patients (blood pressure, lipid HbA1C check during the previous year), influenza immunisation, physical activity and dietary recommendations were less often reported, i.e., in less than two-thirds of patients (57). Of eleven quality-of-care indicators measured in the same patients, three were significantly lower in individuals with lower education achievement, indicating needs for special attention to these patients (58). Similarly, two of seven indicators were lower in those patients with low health literacy (59). In addition, 323 patients of the aforementioned cohort completed a self-administered questionnaire assessing prevalence, awareness and practices regarding eye diseases. Only 70% of participants underwent an eye examination by an ophthalmologist during the previous year, whereas awareness that diabetes could damage the eyes was reported by almost all participants (60). Another study retrieved information of electronic medical records used by general practitioners (46 practices, 1,781 diabetes patients). Similar results were obtained with very high observance for blood pressure measurement and lower for influenza vaccination diabetes (61).

In 604 patients with diabetes included in another cohort study, authors found that the 2013 Swiss Society of Endocrinology and Diabetology targets on good disease management in diabetes were achieved in the majority of participants. However, results also highlight areas where disease management can be improved, particularly the role of nutrition counselling followed for only about half of the patients (62).

Among 295 patients hospitalized for an exacerbation of chronic obstructive pulmonary disease (COPD) in 19 hospitals in 2011, an overall high standard of adherence to the European the GOLD[5] 2010 recommendations was observed. Nevertheless, only 79% of the patients received a short-acting bronchodilator at admission, and seven recommendations to improve and standardize the management of acute exacerbation episodes were consecutively proposed (63). A previous study was conducted among 454 COPD treated by 139 general practitioners in 2007 indicated lower adherence to GOLD guidelines (64).

The quality of preventive care was also studied. In 2009, 281 randomly selected physicians provided data on five consecutive hypertensive patients attending their practices for blood pressure follow-up. Data from 1376 patients were available; overall, blood pressure was controlled in about half patients with uncomplicated hypertension, but in patients with uncontrolled hypertension a change in drug therapy was made in one third of them only (65).

In a random sample of 1,002 patients aged 50–80 years followed for 2 years from all Swiss university primary care settings, 69% received recommended preventive care. However, if 83% of patients received recommended care for cardiovascular risk factors, only 35% received recommended care for the early diagnosis of colon cancer. Prevention indicator rates were lower for women and the elderly, and for cancer screening, thus targeting further quality improvement initiatives (66). Moreover, despite universal healthcare coverage, forced migrants receive less preventive care than Swiss patients in university primary care settings (67).

Ambulatory care, specialty medicine
Appropriateness of care

A survey of quality of surveillance after curative surgery for colon cancer among a cohort of 129 stage I–III colon cancer patients compared actual surveillance practice with guidelines recommendations. The recommendations were followed in less than one third of patients pointing on an inadequate surveillance and needs for enhanced practice and monitoring (68).

About 200,000 breasts screens were performed between 1999 and 2006 in three long standing Swiss cantonal programmes. Swiss programmes met most European standards of performance with a substantial, favourable cancer stage shift, but indicated desirable adaptation of screening processes (69).

A study involving 23 cardiologists and 622 ambulatory patients with atrial fibrillation in private practice in one canton indicated one of the highest appropriate anticoagulant prescription rates reported at the time of the study (70).

The Swiss inflammatory bowel diseases study allowed to conduct several analyses of appropriateness of care. In this cohort, 9 out of 10 indications for infliximab therapy in Crohn's disease patients were clinically generally acceptable (appropriate or uncertain) (71). Appropriateness of the first-line biological treatment was determined in 186 patients with ulcerative colitis, for 64% of them, this treatment was considered appropriate (72). In addition, more than three-quarters of the patients with fistulising Crohn's disease, therapy was globally appropriate (71).

---

[5] Global Initiative for Chronic Obstructive Lung Disease

The adherence to recommendations for management of early breast cancer was assessed in 3499 women aged 25–79 years diagnosed with invasive breast cancer in 2003–2005. In one-third of the patients, management met guidelines in all items, whereas in about one-fifth, three or more items did not comply. Treatment by a surgeon with higher caseload was an independent predictor of a high compliance score (73). A previous study included all 1404 breast cancer patients operated in the public unit or the private network and recorded at the Geneva Cancer Registry between 2000 and 2005 showed high quality indicators of breast cancer care with both networks (74).

Two studies were achieved using data of cancer registry in canton Ticino. Among 474 colorectal cancers adherence to recommendations was generally positive and encouraging, sometimes more favourable in comparison with other international studies, except the very low proportion of patients with a diagnosis based on opportunistic screening (9%) (75). Adherence to evidence-based quality indicators for prostate cancer in 700 patients with prostate cancer indicated that guidelines were followed in about two thirds of cases, but active surveillance was performed is less than half of patients (76).

Initiatives and projects to assess quality and safety

National initiatives and programmes should allow or promote the regular, annual in general, production of nationwide indicators of healthcare quality and patient safety. FOPH has developed a series of inpatient quality indicators, targeting cute somatic care in Swiss hospitals. These indicators are based on the "medical hospital statistics" acute care hospital discharge data and published annually. ANQ measures the aforementioned measured indicators that are also publicly available on its website (www.anq.ch).

The monitoring of hospital-acquired infections by the Swissnoso initiative started early, with rates of surgical site infections now included in the mandatory ANQ reporting (www.anq.ch / www.swissnoso.ch / (4). A recent assessment of the structure and quality of surveillance activities of the surgical site infection surveillance program in 147 hospitals showed that, irrespective of a well-defined surveillance methodology, there was a wide variation of surveillance quality, and that the quality of chart review and the accuracy of data collection were main areas for improvement (77).

The Swiss participation to the nurses' RN4CAST survey (16) led to several publications, including methodological papers about the relation between nurses rationing and patient safety (78,79), and contributed to the awareness of the importance of patient safety in hospitals (80–82).

The Swiss participation to the OECD initiative to assess and compare quality and safety indicators (cf. http://www.oecd.org/els/health-systems/health-care-quality-and-outcomes) indicated the expected methodological difficulties (83) but allowed useful contacts for FOPH. Actually, several international projects allowed the assessment and comparison of quality and safety figures, such as projects coordinated and co-funded by the Commonwealth Fund that analysed quality and coordination of care for elderly patients and patients with complex situations (84–86) or a project in primary care aimed at describing variability in process quality in family medicine among 31 mostly European countries (87–89). These studies indicated relatively good results for Switzerland, allowing possibilities for improvement in primary care and care for individuals living with chronic conditions.

Other specialty societies than infectious diseases have also developed initiatives to foster quality and patient safety. For instance, several projects have been conducted in anaesthesia such as the former Anaesthesia Data Bank Project (12) and the ongoing A-QUA-CH programme.

In addition the Swiss Society for Anaesthesiology and Reanimation has been maintaining a national critical incident reporting system since 1998, with the participation of a minority of Swiss hospitals and a selected reporting of incidents (90) (www.cirsmedical.ch).

Safety climate instruments were developed and adapted to conduct surveys in Switzerland (91) and safety climate was assessed in several studies. A survey conducted in 10 hospitals indicated a mean of 3.8 for safety climate. i.e. in the mid-range of the scale (92). However, an in-depth study in two hospitals indicated that taking several measures into account and describing safety climate from different perspectives is necessary in order to fully understand differences and trends within groups and to develop interventions addressing the needs of different groups more precisely (93)

Evaluations and reviews of quality and patient safety

Several evaluations were based on epidemiological approaches, such as cohorts. For instance the evaluation of trends of neonatal survival rates in very preterm infants (<32 weeks), that showed improvement between 2000 and 2004, but not after (Ref Berger TM). Late preterm deliveries were also observed during 11 years in one large academic hospital that indicated no changes over time, and the persistence of complications in non-evidence-based indications (94). The assessment of the impact of perinatal predictors and medical centre on the outcome of 6892 very low-gestational-age neonates (<32 weeks), from 2002 to 2011, indicated that 85% of the live-born infants survived and 84% of the survivors did not have severe neonatal complications. After adjusting for perinatal factors, the survival of neonates without severe neonatal morbidity was strongly influenced by the medical centre that treated them (95).

A series of projects allowed the development and implementation of assessment of safety culture in different settings. A prospective observational study in 57 intensive care units in Austria, Germany, and Switzerland with self-reporting of medical errors by staff and concurrent assessment of safety climate indicated that for 795 observed patients, a total of 641 errors affecting 269 patients were reported. Enhanced safety climate apparently contributed to a reduction of medical errors during typical routine processes in intensive care (96,97).

A recently published national survey in acute care hospitals indicated that mortality & morbidity weekly reports have been introduced and are used in the majority of settings, although their structure, format, and procedures should be improved (98).

Surveys have been conducted to monitor safety initiatives such as the introduction of the surgery checklist (99), motivation to report incidents by nurses and physicians (98,100). Another survey examined how Swiss healthcare risk and quality managers reacts to safety alerts about possibly risky procedures indicated that they were ready or used to disseminate such information but less so to implement institutional changes (101). A study conducted in 350 dialysed patients from 27 centres, representing 14% of the dialysis population in Switzerland, indicated that, using moderately high epoetin doses, 85% of the patients achieved a mean haemoglobin level ≥11 g/dL. In comparison to European studies of reference, this survey shows a remarkable and continuous control of anaemia in Swiss dialysis centres (102).

In mental healthcare, the projects and evaluation of quality and safety have started later and are still less developed. The opinion and satisfaction of patient is ,however, now included in the ANQ reports (www.anq.ch), and other assessments are being proposed and discussed (103).

Comments

The development of quality and safety indicators has occurred relatively late in Switzerland, comparatively to other developed countries. This review indicated the indicators routinely established by FOPH and other national organisations, nationwide, on the one hand, and multiple developments and studies of various quality, coverage and size, most often conducted locally or regionally, by various stakeholders and researchers, on the other hand.

We have summarised key findings in the following Tables, first related to the monitoring of quality and patients safety, second to the assessment of quality and safety, and third, briefly, about qualify and safety culture.

• **Assessment of quality and safety**
○ Limited number of routine assessments of quality and safety nationwide
▪ Essentially targeting inpatient care
▪ Relatively crude assessments (e.g., inpatient quality indicators, patient satisfaction), to be used for surveillance
• Should lead to further more in depth analyses if considered insufficient
○ Insufficient use of - validated – indicators based on existing routinely collected data (e.g., discharge summary statistics, insurance statistics)
○ Assessment of quality and safety insufficient in ambulatory care
▪ No regular, nationwide, assessment
▪ Patchy series of unrelated, uncoordinated surveys
○ No one source of information easily accessible
▪ Where all stakeholders could find assessments of quality and safety in the Swiss healthcare system

We have found a sizable number of studies reported in close to 150 publications that examined quality and safety, however most studies are limited in their coverage and impact, because they have been conducted in one or a few settings, are restrained to one specific intervention, or corresponds at one assessment at a given time. Thus, beyond the few indicators of quality and safety that are currently measured repeatedly at the national level, by FOPH and ANQ, there is a need for additional assessment in key areas. For instance, for the highly prevalent chronic diseases. Several studies have monitored quality of treatment of diabetes and COPD, but a wider coverage is needed and other domains need to be covered. Also, many invasive interventions are associated with risks of adverse events and complications that request monitoring. Many initiatives are local in hospitals, or in cantons; quite a few analyses have been conducted in the framework of health services research initiatives and development groups and projects. For instance, several research projects are currently conducted in the framework of the ongoing national SNF research project NFP 74. They are designed to implement and test novel approaches to assessing quality and safety, in order to improve indicators and measurements.

Globally, this review of indicators of quality and safety available in Switzerland over the last decade confirm that quality of care and patient safety are reasonably good in Switzerland. However, the results observed in presence of international comparisons or with acknowledged or evidence-based standards indicate first that the performance is usually not better in Switzerland than in other developed countries, and second that in many areas there is room for further improvement.

• **Status of quality and safety in the Swiss healthcare system**
o Inpatient care
▪ Good monitoring of infection occurrence
▪ Control of infection appropriate, although perfectible, especially when risk is high as in surgery control of infections in hospital settings
• High risk of infection for some types of interventions (e.g., colon surgery)
▪ Occurrence rate of adverse events in hospitals not lower than in most other developed countries
▪ Drug related errors, and events, may be comparatively high
• Most often drug related errors (prescription, delivery) not followed by adverse events
o However susceptible to increase if number and qualification of healthcare professionals decrease
o Ambulatory care
▪ Relatively numerous evaluation of appropriateness of care, when compared to guidelines or standards
• Relatively good results for prescription of laboratory tests and treatments in presence of chronic diseases e.g., (hypertension, diabetes)
• Indications of relatively high figure of inappropriate medications
• Indications of relatively high figure of inappropriate hospitalisation
▪ Occurrence of adverse events also in ambulatory care
• Drug prescription errors
• Several reports indicate potential high rates

• **Culture of quality and safety**
o Insufficiently assessed
o Awareness of quality and safety risks probably low
▪ In many inpatient settings
▪ Also in ambulatory care

This review has several limitations. The restriction of the search strategy to PubMed and the date of publication starting from 2008 may have induced a selection of retrieved articles. Moreover, our search strategy may have missed several published articles. These limitations could be explained by the limited time and resources available to conduct this rapid review, which should actually be considered as a kind of scoping review from which we extracted information for this report. In addition, many assessments of quality and safety are not conducted as research projects and are thus not published in the healthcare literature. Moreover, we did not asses the quality of the assessments of quality and safety, nor of the studies themselves.

Future development should include the increase in coverage of the assessment of quality and safety in the Swiss healthcare system. The national indicators are essentially targeting

hospital care. In addition to primary care ad usual specialty care, more and more interventions, many invasive, are conducted in ambulatory settings. Although national initiatives are ongoing to better cover this crucial field of healthcare, further developments are needed.

Further research axes include the development and evaluation of quality and safety indicators derived from routinely collected data (e.g., hospital discharge summary statistics, insurance statistics, electronic medical records). For instance, the proposed 11th version of the international classification of diseases (ICD-11) has been developed to better capture quality and safety (104). The electronic medical record (EMR) may be an interesting source of information. However, implementing techniques such as data and text mining are not easy actually, begging for further developments and testing. Furthermore, the large number of types and brands of EMR do not ease the approach. If ones want to increase the number and coverage of the assessment of quality and safety, this should be done in a parsimonious way, attempting to minimize the time and efforts required from healthcare professionals to transfer the information. This is a formidable challenge indeed.

Conclusions

Although the quality and safety of the Swiss healthcare system appears good, there are many areas for which we do not have information and many others where we have only patchy data. Only few indicators are available nationally, and we have almost no national coverage of the ambulatory and primary care sectors. However, we do have information that indicate that in several areas efforts need to be done to improve quality and safety.

The national efforts should be reinforced to allow the development, and evaluation, of valid indicators that could be implemented and evaluated nationwide at a reasonable cost. The indicators should inform the healthcare professionals to help them improve their practice and the healthcare managers and decision makers to adapt the system, the structures and the conditions to allow providing high quality healthcare, with optimal patient safety. This information should also be easily available for the public and the patients.

Appendixes

Appendix 1

Search strategy for MEDLINE via PubMed

((patient safety indicator*[tiab] OR ACOVE[tiab]) OR (("Outcome and Process Assessment (Health Care)"[MeSH] OR "Quality Indicators, Health Care"[MeSH] OR "Patient Safety"[MeSH] OR "Patient Harm"[MeSH] OR "Iatrogenic Disease"[MeSH] OR "Intraoperative Complications"[MeSH] OR "Long Term Adverse Effects"[MeSH] OR "Medical Errors"[MeSH] OR "Postoperative Complications"[MeSH] OR patient safety measure*[tiab] OR patient safety metric*[tiab] OR quality indicator*[tiab] OR quality metric*[tiab] or adverse drug event*[tiab] OR adverse drug reaction*[tiab] OR adverse event*[tiab] OR adverse outcome*[tiab] OR clinical incident*[tiab] OR complication*[tiab] OR diagnostic error*[tiab] OR "healthcare associated injury"[tiab] OR "healthcare associated injuries"[tiab] OR "health care associated injury"[tiab] OR "health care associated injuries"[tiab] OR iatrogenic disease*[tiab] OR medical error*[tiab] OR medication error*[tiab] OR safety event*[tiab] OR sentinel event*[tiab]) AND ("Insurance Claim Review"[MeSH] OR "administrative claims"[tiab] OR "administrative data"[tiab] OR "administrative healthcare data"[tiab] OR "administrative health care data"[tiab] OR "administrative health data"[tiab] OR "claims-based data"[tiab] OR "claims data"[tiab] OR "discharge data"[tiab] OR "hospital billing data"[tiab] OR "hospital data"[tiab] OR "hospitalisation data"[tiab] OR "hospitalization data"[tiab] OR insurance claim*[tiab] OR "insurance data"[tiab] OR "linked data"[tiab] OR "physician billing data"[tiab] OR clinical database*[tiab] OR cohort[tiab] OR electronic health record*[tiab] OR electronic medical record*[tiab] OR "observational data"[tiab] OR register*[tiab] OR registries[tiab] OR registry[tiab] OR survey*[tiab]))) AND (Switzerland[MeSH] OR swiss[tiab] OR Switzerland[tiab]) AND (hasabstract[text]) AND (("2008/01/01"[PDat] : "2018/12/31"[PDat])

Figure 1. Flow-chart of the literature search strategy
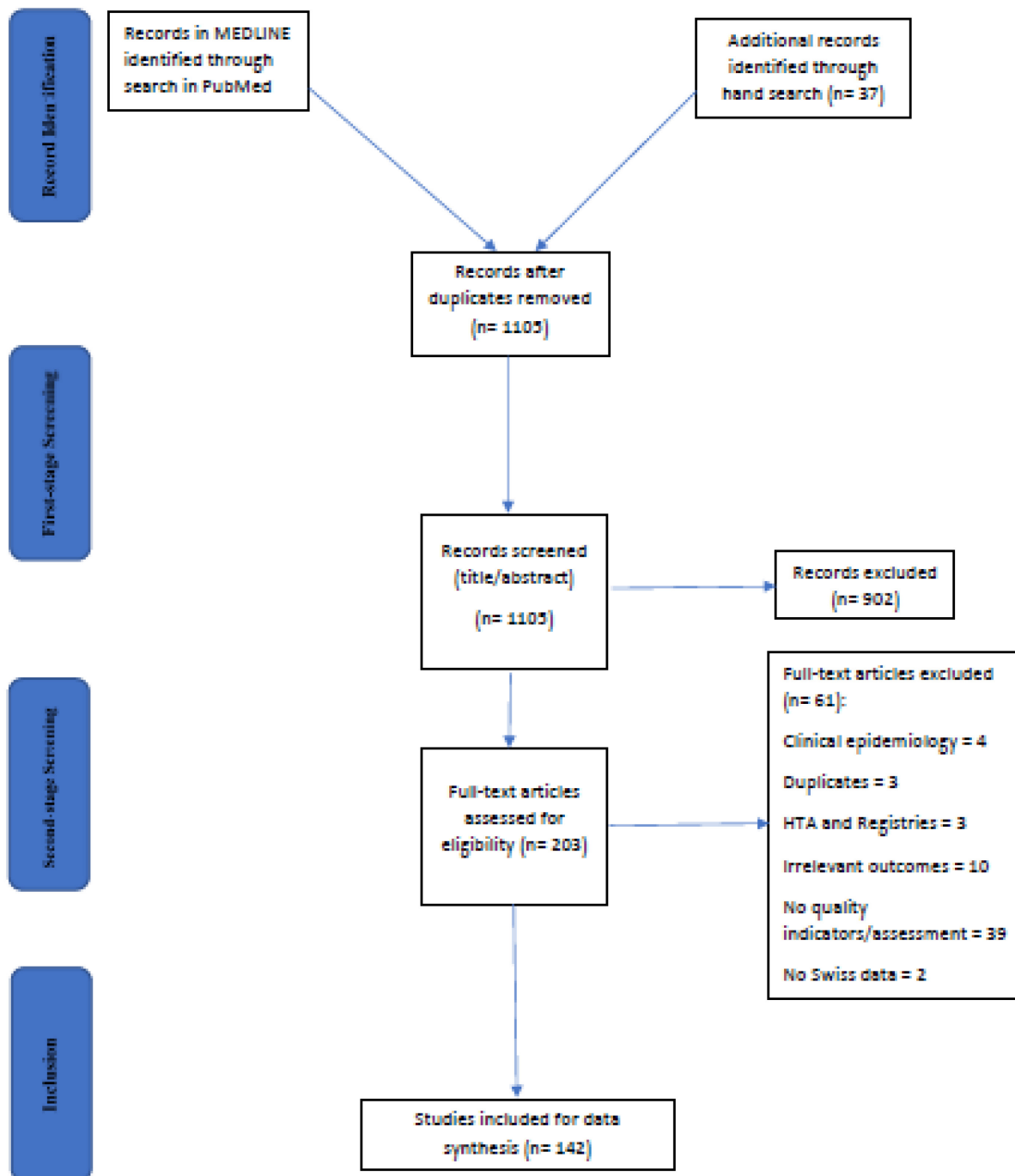
Appendix 3

Table 2 : Characteristics of included studies, and categories of indicators and evaluation

Study (Author, year)	Aim/purpose	Place (canton)	Interven-tion / disease / population	Indicators of quality	Indicators of patient safety	Adverse events	Appropriateness/adherence to guidelines	Medication/medical errors	Satisfaction / opinion surveys	Initiatives & projects	Evaluation & reviews
Aiken et al. 2012	assess patient safety, satisfaction and healthcare quality	international		1	1						1
Aiken et al. - 2017	determine the association of nursing skill mix with patient mortality and quality of care	Europe		1	1				1		
Aiken et al. 2013	nurse working condition and quality of care	Europe		1							
Auer et al. - 2014a	patient safety culture and development of trust				1						
Auer et al. - 2014b	quality of care after ACS		acute coronary syndrome	1							
Auras et Geraedts-	role of patients on practice accreditation				1						

2010												
Ausserhofer et al. - 2012	Patient safety climate in hospitals	National			1							
Ausserhofer et al. - 2013b	patient safety climate and patient outcomes	National			1							
Bausch et al. - 2018	assess late preterm infants and mortality	Geneva	assess late preterm infants and mortality				1					
Berger et al. - 2012	assess variability in survival of preterm infants	National					1					
Bianchi et al. 2013	determine quality indicators		colorectal cancer	1								
Blozik et al. - 2015	potentially inappropriate medication					1	1					
Blozik et al. - 2018	measurement of quality indicators			1	1							
Bouchet et al. -	assess late preterm	Geneva	preterm				1					

23

Author - Year	Objective	Setting	Condition								
2018	infants and mortality		deliveries								
Brenner et al. - 2011	determine the control of hypertension	National	Hypertension				1				
Bucher et al. - 2016	assess factors of drug-drug interactions		drug-drug interactions			1	1				
Buess et al. - 2017	COPD treatment		COPD				1				
Bulliard et al. - 2011	asses variation in mammography screening	Vaud/Geneva/Valais					1				
Busato et Kunzi - 2010	association of Interpersonal care and patient outcomes		any				1		1		
Cohidon et al. 2018a	Assess patients coping capability to health problems after a visit to a family doctor	National	Any								1
Cohidon et al. 2018a	Study the association of patients-reported experience with characteristics of patients, physicians and practice	National	Any								1
Collet et al. -	Determine the quality of primary care		primary care				1				

2011											
Cullati et al. - 2014	implementation of surgical safety checklist		surgery			1		1			
Daster et al. - 2016	Perioperative outcomes of esophageal cancer	Basel	Esophage ctomy	1							
Djalali et al. - 2014	Quality indicators for diabetes		diabetes	1	1						
Djalali et al. - 2015	assess quality indicators in primary care	National	primary care	1							
Drosler et al. - 2012	Patient safety indicators	internation al	any		1						
Egli Y et al. - 2014	routine data	national				1					
Eisold et Heller - 2016	safety culture in anesthesia		anesthesi a		1						
Erne et al. - 2015	outcomes of acute coronary syndrome/ palliative patients		palliative patients of ACS					1			1
Ess et al. -	breast cancer	National	breast								1

2011			cancer								
Fischer et al. - 2009	Preterm assess survival on infants < 26 wks and guideline impact	National	preterm infants< 26				1				1
Flatz et al. - 2015	Assess education and diabetes care association	Vaud	diabetes	1							1
Franzone et al. - 2017	transcatheter aortic valve implantation	Bern		1							1
Gehring and schwappach - 2014	determine safety risks and safety climate	German-speaking region	any		1						
Gehring et al. - 2015	Translation of safe climate survey into German and French	German- and French-speaking regions	any		1						
Glinz et al. - 2017	assess antibiotic use	National	disease-specific antibiotic prescribing				1	1			
Grass et al. - 2011	assess perioperative nutrition	Swiss-Austria survey	surgery				1				

Gnädinger et al. - 2017	adverse events drug	national survey	general medicine								
Halfon et al. 2017	Assess adverse events related to hospital care					1					
Haller et al. - 2011	assess pain program initiative	Geneva	pain managem ent							1	
Hubner et al. - 2011	assess surgical site infections	Western and Southern Switzerlan d	colon surgery				1				1
Januel et al. - 2018	assess occurrence of venous thromboembolism	International	venous thromboe mbolism after hip replaceme nt		1						1
Jochmann et al. - 2012	assess guideline adherence in COPD	National	COPD				1				
Juillerat et al. - 2010	assess infliximab in swiss IBD		IBD				1				
Junker	assess surgical site	Basel	surgery								1

et al. - 2012	infections											
Kaelin Agten et al. - 2017												
Kinnula et al. - 2012	assess variation of viral hospital associated infections		viral HAI in infants				1					1
Kohler et al. - 2013	to assess hospital-transmitted Clostridium difficile infections	St. Gall	Clostridium difficile associated diarrhoea cases				1					1
Konstantinidis et al. - 2017	practices of eye examination in diabetic patients	Vaud	diabetes				1					1
Kung et al. - 2013	Assess self-reported medication errors	Bern	cadiovascular surgery dpt					1				
Kurmann et al. - 2012	Asses surgical techniques		thyroid surgery				1					1
Kuster et al. - 2017	assess Surgical Site Infection Surveillance		Surgical Site Infection								1	

Kutz et al. - 2017	assess innovative transition models of inpatients		inpatients							1	
Le Pogam et al. - 2017											
Macinko et Guanais - 2015	Problems of primary care	International	any								1
Maillard et al. - 2014	appropriatness and biological therapy discontinuation in ulcerative colitis	National	ulcerative colitis				1				
Manser et al. - 2017	explore incident reporting systems	Switzerland/Germany	any								1
Martin et al. - 2014	Preventive care and chronic care of forced migrants	Basel/Geneva/Lausanne/Zürich	cardiovascular prevention	1							
Mascherek et al. - 2016	Assess implementation of surgical safety checklists	National	surgery							1	
Mascherek et Schwa	assess safety climate	Bern/Zürich	any			1					

ppach - 2017										
Mathieu et al. - 2008	assess anaemia control in dialysis patients	National	dialysis patients							1
Matter-Walstra et al. - 2015	assess use of healthcare during 30 days before cancer-related death	Basel/Ticino/Valais/Zürich	cancer patients at end-life stage			1				
Matter-Walstra et al. - 2017	estimate the number of days spent in acute hospitals <= 90 days before cancer-related death	Basel/Ticino/Valais/Zürich	cancer patients at end-life stage	1		1				
Meiltz et al. - 2008	check adherence to guidelines	Geneva	cardiologists			1				
Metsini et al. - 2018	Assess "point" prevalence of healthcare-associated infections		patients with healthcare-associated infections						1	
Midao et al. - 2018	Evaluate polypharmacy in elderly patients		Elderly patients with polypharmacy							1
Niedrig	assess impact of alerts of	Zurich	Patients						1	

et al. - 2016	paracetamol overdoses		recieved paracetam ol								
O Riordan et al. - 2018	assess prevalence of potentially inappropriate prescriptions	Europe (Bern)	Elderly patients					1			
Ortelli et al. - 2018	asses QI for prostate cancer patients	Ticino	prostate cancer	1							
Osborn et al. - 2014	assess patient-centered care problems in elderly patients	Internation al	elderly patients							1	1
Osborn et squires - 2011	assess patient engagement	Internation al								1	
Pavlic et al. - 2015	Process quality indicators of family medicine	Internation al		1							
Peytre mann- Brideva ux et al. - 2013	Evaluate the quality of care for diabetic patients	Canton Vaud	diabetes	1							
Pfeiffer et al. - 2013	assess motivational antecedants for incident reporting	Five swiss hospitals			1					1	

Pfeiffer et schwappach - 2016	assess safety alerts and recommendations applicability				1					1	
Pittet et al. - 2010	appropriateness of care	national	specalized care / Crohn's disease				1				
Pittet et al. - 2013	assess the evolution of anaesthesia care		anaesthesia care	1	1						
Praplan-Rudaz et al. - 2018	Assess use of mortality and morbidity conferences (M&MCs)	National	M&MCs use	1	1				1	1	
Pretto et al. - 2010	assess Outcomes of elderly hip fracture patients		elderly hip fracture patients						1	1	
Reed et al. - 2014	assess national critical incident reporting	National	anasesthesia and other departments						1		
Reich et al. - 2014	assess the prevalence of potentially inappropriate medications		elderly patients					1			
Richard et al. -	evaluate Speaking up in safety questionnaire		health workers		1					1	1

2017											
Robertson-Preidler et al. - 2017	Assess performance indicators in psychiatric patients/mental health		psychiatric inpatient	1							
Sauter et al. - 2016	inspect the use of new oral anticoagulants in hospitals and general practice		a sample of general practitioners				1				
Scherz et al. - 2016	assess secondary prevention of CAD in primary care		CAD patients	1							
Schimke et al. - 2018	assess compliance to guidelines	Bern and St.Gallen					1				
Schoen et al. - 2011	Evaluate coordination of care										1
Schoenenberger et al. - 2016	Use of guideline recommended therapies in ACS		ACS patients				1				
Schubert et al. - 2008	assess implicit rationing of nursing care and impact on hospital outcomes	eight swiss acute care hospitals								1	1
Schubert et al.	assess threshold for	Five Swiss-								1	1

- 2009	rationing nursing care	German and 3 Swiss-French hospitals									
Schwappach - 2008	assess patient experiences about safety-related events	two hospitals in Swiss-German region			1						
Schwappach - 2011	assess patient-reported medical and medication errors	National						1			
Schwappach et al. - 2011	evaluate Patients' experiences and perceptions of safety in Swiss hospitals				1						
Schwappach et al. - 2012	Evaluate communication barriers between pharmacists and foreign language patients				1						
Schwappach et al. - 2013a	Examine the attitude of healthcare providers towards patient's involvement in error prevention							1			
Schwappach et al.	Evaluate educational safety campaign on patient behaviors on				1	1					

2013b	safety and adverse events									
Schwappach et al. - 2012	assess patient safety in primary care offices	Swiss-German region			1					
Schwappach et al. - 2016	assess use of double-checking of medication in oncology				1			1		
Schwappach et al. - 2018	evaluate the attitudes and beliefs of chemotherapy medications double-check				1			1		
Schwappach et Gehring -2015	Evaluate frequency and predictors for withholding patient safety concerns	Swiss-German region			1					
Schwappach et Wernli - 2010	explore chemotherapy patients' perceptions of drug administration safety				1			1		
Selby et al. - 2018	Assess GPs acceptance and adherence to recommendations	National					1			
Spitale et al. - 2017	Assess quality indicators of colorectal cancer	Ticino		1						

Author	Description	Location											
Staines et al. - 2015	impact of a adverse drug event prevention collaborative					1							
Staszewicz - 2014	Assess surgical site infection surveillance					1							
Steurer et al. - 2015	assess variation in outcomes of neonates of preterm infants			1									1
Stewardson et al. - 2016	assess feedback and patient involvement in safety-related measures				1							1	
Taban et al. - 2013	assess quality of breast cancer care and managment in private network and public units	Geneva hospital		1									
Taegtmeyer et al. - 2012	assess drug-related problems and acceptance of recommendations by prescribers					1							
Tandjung et al. - 2013	assess guideline adherence on diagnosis and management of ACS						1						
Thommen et al. - 2014	compare length of stay, patient outcome and satisfaction before and after SwissDRG	Aarau and Basel								1			

Author	Aim	Setting								
Troillet et al. - 2017	Explore results of surgical site infections	National			1					1
Urben et al. - 2015	evaluate satisfaction of community treatment team of child and adolescent psychiatric disorders	Vaud (French-speaking region)							1	
Valentin et al. - 2013	assess safety climate reduction of medication and dislodgement errors	Europe(Austria/Germany/Switzerland)	1							
Van vegten et al. - 2011	Assess patient safety culture in hospitals	Zurich	1							
Viehl et al. - 2010	Assess quality of surveillance after colon cancer curation	National	1							1
Weber et al. - 2008	Assess the economic burden of surgical site infections	Basel			1					
Weiler et al. - 2014	Assess quality measures for risk factor control in primary care	Basel/Genava/Lausanne/Zurich	1							1
Zimmermann et al. - 2013	assess validation of safety attitudes questionnaire in Swiss settings	Bern and Basel		1					1	

			30	30	11	32	9	7	18	27
Zuercher et al. - 2014	explore characteristics and quality of care of a diabetic patients cohort	Vaud (French-speaking region)	1						1	
Zuercher et al. - 2017	determine the association of health literacy and outcomes of care	Vaud (French-speaking region)	1							
Zuniga et al. - 2015	explore care worker-reported quality of care and relation to other work variables	National	1							1
Total by category of indicators / evaluation			**30**	**30**	**11**	**32**	**9**	**7**	**18**	**27**

References

1. de Vries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. Qual Saf Health Care. juin 2008;17(3):216-23.

2. Le Pogam M-A, Quantin C, Reich O, Tuppin P, Fagot-Campagna A, Paccaud F, et al. Geriatric Patient Safety Indicators Based on Linked Administrative Health Data to Assess Anticoagulant-Related Thromboembolic and Hemorrhagic Adverse Events in Older Inpatients: A Study Proposal. JMIR Res Protoc. 2017;6(5):e82.

3. Schneider T. Qualitätsindikatoren der Schweizer Akutspitäler 2016. 2018.

4. Troillet N, Aghayev E, Eisenring M-C, Widmer AF. First Results of the Swiss National Surgical Site Infection Surveillance Program: Who Seeks Shall Find. Infect Control Hosp Epidemiol. juin 2017;38(6):697-704.

5. Hubner M, Diana M, Zanetti G, Eisenring M-C, Demartines N, Troillet N. Surgical site infections in colon surgery: the patient, the procedure, the hospital, and the surgeon. Arch Surg Chic Ill 1960. nov 2011;146(11):1240-5.

6. Staszewicz W, Eisenring M-C, Bettschart V, Harbarth S, Troillet N. Thirteen years of surgical site infection surveillance in Swiss hospitals. J Hosp Infect. sept 2014;88(1):40-7.

7. Junker T, Mujagic E, Hoffmann H, Rosenthal R, Misteli H, Zwahlen M, et al. Prevention and control of surgical site infections: review of the Basel Cohort Study. Swiss Med Wkly. 2012;142:w13616.

8. Metsini A, Vazquez M, Sommerstein R, Marschall J, Voide C, Troillet N, et al. Point prevalence of healthcare-associated infections and antibiotic use in three large Swiss acute-care hospitals. Swiss Med Wkly. 2018;148:w14617.

9. Kinnula S, Buettcher M, Tapiainen T, Renko M, Vepsalainen K, Lantto R, et al. Hospital-associated infections in children: a prospective post-discharge follow-up survey in three different paediatric hospitals. J Hosp Infect. janv 2012;80(1):17-24.

10. Kohler P, Bregenzer-Witteck A, Rafeiner P, Schlegel M. Presumably hospital-transmitted Clostridium difficile infections based on epidemiological linkage. Swiss Med Wkly. 2013;143:w13824.

11. Januel J-M, Romano PS, Couris CM, Hider P, Quan H, Colin C, et al. Clinical and Health System Determinants of Venous Thromboembolism Event Rates After Hip Arthroplasty: An International Comparison. Med Care. 2018;56(10):862-9.

12. Pittet V, Perret C, Moret V, Despond O, Burnand B. Evolution of anaesthesia care and related events between 1996 and 2010 in Switzerland. Acta Anaesthesiol Scand. nov 2013;57(10):1275-86.

13. Auer R, Gencer B, Raber L, Klingenberg R, Carballo S, Carballo D, et al. Quality of care after acute coronary syndromes in a prospective cohort with reasons for non-prescription of recommended medications. PloS One. 2014;9(3):e93147.

14. Erne P, Radovanovic D, Seifert B, Bertel O, Urban P. Outcome of patients admitted with acute coronary syndrome on palliative treatment: insights from the nationwide AMIS Plus Registry 1997-2014. BMJ Open. 2 mars 2015;5(3):e006218.

15. Schoenenberger AW, Radovanovic D, Windecker S, Iglesias JF, Pedrazzini G, Stuck AE, et al. Temporal trends in the treatment and outcomes of elderly patients with acute coronary syndrome. Eur Heart J. 21 avr 2016;37(16):1304-11.

16. Aiken LH, Sermeus W, Van den Heede K, Sloane DM, Busse R, McKee M, et al. Patient safety, satisfaction, and quality of hospital care: cross sectional surveys of nurses and patients in 12 countries in Europe and the United States. BMJ. 20 mars 2012;344:e1717.

17. Aiken LH, Sloane DM, Bruyneel L, Van den Heede K, Sermeus W. Nurses' reports of working conditions and hospital quality of care in 12 countries in Europe. Int J Nurs Stud. févr 2013;50(2):143-53.

18. Ausserhofer D, Schubert M, Engberg S, Blegen M, De G, Schwendimann R. Nurse-reported patient safety climate in Swiss hospitals: a descriptive-explorative substudy of the Swiss RN4CAST study. Swiss Med Wkly. 2012;142:w13501.

19. Zuniga F, Ausserhofer D, Hamers JPH, Engberg S, Simon M, Schwendimann R. Are Staffing, Work Environment, Work Stressors, and Rationing of Care Related to Care Workers' Perception of Quality of Care? A Cross-Sectional Study. J Am Med Dir Assoc. 1 oct 2015;16(10):860-6.

20. Selby K, Cornuz J, Cohidon C, Gaspoz J-M, Senn N. How do Swiss general practitioners agree with and report adhering to a top-five list of unnecessary tests and treatments? Results of a cross-sectional survey. Eur J Gen Pract. déc 2018;24(1):32-8.

21. Weiler S, Gemperli A, Collet T-H, Bauer DC, Zimmerli L, Cornuz J, et al. Clinically relevant quality measures for risk factor control in primary care: a retrospective cohort study. BMC Health Serv Res. 15 juill 2014;14:306.

22. Eggli Y, Desquins B, Seker E, Halfon P. Comparing potentially avoidable hospitalization rates related to ambulatory care sensitive conditions in Switzerland: the need to refine the definition of health conditions and to adjust for population health status. BMC Health Serv Res. 20 janv 2014;14:25.

23. Reich O, Rosemann T, Rapold R, Blozik E, Senn O. Potentially inappropriate medication use in older patients in Swiss managed care plans: prevalence, determinants and association with hospitalization. PloS One. 2014;9(8):e105425.

24. Blozik E, Rapold R, Reich O. Prescription of potentially inappropriate medication in older persons in Switzerland: does the dispensing channel make a difference? Risk Manag Healthc Policy. 2015;8:73-80.

25. Bucher HC, Achermann R, Stohler N, Meier CR. Surveillance of Physicians Causing Potential Drug-Drug Interactions in Ambulatory Care: A Pilot Study in Switzerland. PloS One. 2016;11(1):e0147606.

26. Kaelin Agten A, Passweg D, von Orelli S, Ringel N, Tschudi R, Tutschek B. Temporal trends of postpartum haemorrhage in Switzerland: a 22-year retrospective population-based cohort study. Swiss Med Wkly. 2017;147:w14551.

27. Walther D, Halfon P, Desseauve D, Vial Y, Burnand B, Le Pogam M. Postpartum Hemorrhage: Differences in Definition, Data and Incidence. Int J Popul Data Science. 2018;3:3186.

28. Macinko J, Guanais FC. Population experiences of primary care in 11 Organization for Economic Cooperation and Development countries. Int J Qual Health Care J Int Soc Qual Health Care. déc 2015;27(6):443-50.

29.   Schwappach DL. Frequency of and predictors for patient-reported medical and medication errors in Switzerland. Swiss Med Wkly. 2011;141:w13262.

30.   Gnadinger M, Conen D, Herzig L, Puhan MA, Staehelin A, Zoller M, et al. Medication incidents in primary care medicine: a prospective study in the Swiss Sentinel Surveillance Network (Sentinella). BMJ Open. 26 juill 2017;7(7):e013658.

31.   Midao L, Giardini A, Menditto E, Kardas P, Costa E. Polypharmacy prevalence among older adults based on the survey of health, ageing and retirement in Europe. Arch Gerontol Geriatr. oct 2018;78:213-20.

32.   Stewardson AJ, Sax H, Gayet-Ageron A, Touveneau S, Longtin Y, Zingg W, et al. Enhanced performance feedback and patient participation to improve hand hygiene compliance of health-care workers in the setting of established multimodal promotion: a single-centre, cluster randomised controlled trial. Lancet Infect Dis. déc 2016;16(12):1345-55.

33.   Bausch K, Roth JA, Seifert HH, Widmer AF. Overuse of antimicrobial prophylaxis in low-risk patients undergoing transurethral resection of the prostate. Swiss Med Wkly. 2018;148:w14594.

34.   Halfon P, Staines A, Burnand B. Adverse events related to hospital care: a retrospective medical records review in a Swiss hospital. Int J Qual Health Care J Int Soc Qual Health Care. 1 août 2017;29(4):527-33.

35.   Kung K, Carrel T, Wittwer B, Engberg S, Zimmermann N, Schwendimann R. Medication errors in a swiss cardiovascular surgery department: a cross-sectional study based on a novel medication error report method. Nurs Res Pract. 2013;2013:671820.

36.   Niedrig DF, Bucklar G, Fetzer M, Machler S, Gott C, Russmann S. Paracetamol overdosing in a tertiary care hospital: implementation and outcome analysis of a preventive alert programme. J Clin Pharm Ther. oct 2016;41(5):515-8.

37.   Staines A, Mattia C, Schaad N, Lecureux E, Bonnabry P. Impact of a Swiss adverse drug event prevention collaborative. J Eval Clin Pract. août 2015;21(4):717-26.

38.   Taegtmeyer AB, Curkovic I, Corti N, Rosen C, Egbring M, Russmann S, et al. Drug-related problems and factors influencing acceptance of clinical pharmacologists` alerts in a large cohort of neurology inpatients. Swiss Med Wkly. 2012;142:w13615.

39.   Schwappach DLB, Gehring K, Battaglia M, Buff R, Huber F, Sauter P, et al. Threats to patient safety in the primary care office: concerns of physicians and nurses. Swiss Med Wkly. 2012;142:w13601.

40.   Schwappach DLB, Pfeiffer Y, Taxis K. Medication double-checking procedures in clinical practice: a cross-sectional survey of oncology nurses' experiences. BMJ Open. 13 juin 2016;6(6):e011394.

41.   Schwappach DLB, Taxis K, Pfeiffer Y. Oncology nurses' beliefs and attitudes towards the double-check of chemotherapy medications: a cross-sectional survey study. BMC Health Serv Res. 17 févr 2018;18(1):123.

42.   Schwappach DLB, Gehring K. Frequency of and predictors for withholding patient safety concerns among oncology staff: a survey study. Eur J Cancer Care (Engl). mai 2015;24(3):395-403.

43. Schwappach DLB. « Against the silence »: development and first results of a patient survey to assess experiences of safety-related events in hospital. BMC Health Serv Res. 20 mars 2008;8:59.

44. Schwappach DLB, Wernli M. Chemotherapy patients' perceptions of drug administration safety. J Clin Oncol Off J Am Soc Clin Oncol. 10 juin 2010;28(17):2896-901.

45. Schwappach DLB, Frank O, Davis RE. A vignette study to examine health care professionals' attitudes towards patient involvement in error prevention. J Eval Clin Pract. oct 2013;19(5):840-8.

46. Kurmann A, Martens F, Inglin R, Schmid SW, Candinas D, Seiler CA. Impact of surgical technique on operative morbidity and its socioeconomic benefit in thyroid surgery. Langenbecks Arch Surg. oct 2012;397(7):1127-31.

47. Daster S, Soysal SD, Koechlin L, Stoll L, Peterli R, von Flue M, et al. Perioperative outcomes of esophageal cancer surgery in a mid-volume institution in the era of centralization. Langenbecks Arch Surg. sept 2016;401(6):787-95.

48. Matter-Walstra KW, Achermann R, Rapold R, Klingbiel D, Bordoni A, Dehler S, et al. Days spent in acute care hospitals at the end of life of cancer patients in four Swiss cantons: a retrospective database study (SAKK 89/09). Eur J Cancer Care (Engl). juill 2017;26(4).

49. Matter-Walstra KW, Achermann R, Rapold R, Klingbiel D, Bordoni A, Dehler S, et al. Cancer-related therapies at the end of life in hospitalized cancer patients from four Swiss cantons: SAKK 89/09. Oncology. 2015;88(1):18-27.

50. Gehring K, Schwappach D. [Patient safety in general practice]. Z Evidenz Fortbild Qual Im Gesundheitswesen. 2014;108(1):25-31.

51. Tandjung R, Senn O, Rosemann T, Loy M. Diagnosis and management of acute coronary syndrome in an outpatient setting: good guideline adherence in Swiss primary care. J Eval Clin Pract. oct 2013;19(5):819-24.

52. Haller G, Agoritsas T, Luthy C, Piguet V, Griesser A-C, Perneger T. Collaborative quality improvement to manage pain in acute care hospitals. Pain Med Malden Mass. janv 2011;12(1):138-47.

53. O Riordan D, Aubert CE, Walsh KA, Van Dorland A, Rodondi N, Du Puy RS, et al. Prevalence of potentially inappropriate prescribing in a subpopulation of older European clinical trial participants: a cross-sectional study. BMJ Open. 22 mars 2018;8(3):e019003.

54. Sauter TC, Melis C, Hautz WE, Ricklin ME, Exadaktylos AK. Direct new oral anticoagulants: follow-up, guidelines and bleeding complications in general practice-a survey of Swiss general internal medicine practitioners. SpringerPlus. 2016;5(1):2030.

55. Scherz N, Valeri F, Rosemann T, Djalali S. Quality of secondary prevention of coronary heart disease in Swiss primary care: Lessons learned from a 6-year observational study. Z Evidenz Fortbild Qual Im Gesundheitswesen. déc 2016;118-119:40-7.

56. Glinz D, Leon Reyes S, Saccilotto R, Widmer AF, Zeller A, Bucher HC, et al. Quality of antibiotic prescribing of Swiss primary care physicians with high prescription rates: a nationwide survey. J Antimicrob Chemother. 1 nov 2017;72(11):3205-12.

57. Peytremann-Bridevaux I, Bordet J, Burnand B. Diabetes care in Switzerland: good, but perfectible: a population-based cross-sectional survey. BMC Health Serv Res. 25 juin 2013;13:232.

58. Flatz A, Casillas A, Stringhini S, Zuercher E, Burnand B, Peytremann-Bridevaux I. Association between education and quality of diabetes care in Switzerland. Int J Gen Med. 2015;8:87-92.

59. Zuercher E, Diatta ID, Burnand B, Peytremann-Bridevaux I. Health literacy and quality of care of patients with diabetes: A cross-sectional analysis. Prim Care Diabetes. 2017;11(3):233-40.

60. Konstantinidis L, Carron T, de Ancos E, Chinet L, Hagon-Traub I, Zuercher E, et al. Awareness and practices regarding eye diseases among patients with diabetes: a cross sectional analysis of the CoDiab-VD cohort. BMC Endocr Disord. 7 sept 2017;17(1):56.

61. Djalali S, Frei A, Tandjung R, Baltensperger A, Rosemann T. Swiss quality and outcomes framework: quality indicators for diabetes management in Swiss primary care based on electronic medical records. Gerontology. 2014;60(3):263-73.

62. Schimke KE, Renstrom F, Meier S, Stettler C, Brandle M. Compliance with guidelines for disease management in diabetes: results from the SwissDiab Registry. BMJ Open Diabetes Res Care. 2018;6(1):e000454.

63. Buess M, Schilter D, Schneider T, Maurer M, Borer H, Thurnheer R, et al. Treatment of COPD Exacerbation in Switzerland: Results and Recommendations of the European COPD Audit. Respir Int Rev Thorac Dis. 2017;94(4):355-65.

64. Jochmann A, Scherr A, Jochmann DC, Miedinger D, Torok SS, Chhajed PN, et al. Impact of adherence to the GOLD guidelines on symptom prevalence, lung function decline and exacerbation rate in the Swiss COPD cohort. Swiss Med Wkly. 2012;142:w13567.

65. Brenner R, Waeber B, Allemann Y. Medical treatment of hypertension in Switzerland. The 2009 Swiss Hypertension Survey (SWISSHYPE). Swiss Med Wkly. 2011;141:w13169.

66. Collet T-H, Salamin S, Zimmerli L, Kerr EA, Clair C, Picard-Kossovsky M, et al. The quality of primary care in a country with universal health care coverage. J Gen Intern Med. juill 2011;26(7):724-30.

67. Martin Y, Collet T-H, Bodenmann P, Blum MR, Zimmerli L, Gaspoz J-M, et al. The lower quality of preventive care among forced migrants in a country with universal healthcare coverage. Prev Med. févr 2014;59:19-24.

68. Viehl CT, Ochsner A, von Holzen U, Cecini R, Langer I, Guller U, et al. Inadequate quality of surveillance after curative surgery for colon cancer. Ann Surg Oncol. oct 2010;17(10):2663-9.

69. Bulliard J-L, Ducros C, Dayer E, Arzel B, Levi F. Variation in performance in low-volume mammography screening programmes: experience from Switzerland. Cancer Epidemiol. juin 2011;35(3):293-7.

70. Meiltz A, Zimmermann M, Urban P, Bloch A. Atrial fibrillation management by practice cardiologists: a prospective survey on the adherence to guidelines in the real world. Eur Eur Pacing Arrhythm Card Electrophysiol J Work Groups Card Pacing Arrhythm Card Cell Electrophysiol Eur Soc Cardiol. juin 2008;10(6):674-80.

71. Juillerat P, Pittet V, Vader J-P, Burnand B, Gonvers J-J, de Saussure P, et al. Infliximab for Crohn's disease in the Swiss IBD Cohort Study: clinical management and appropriateness. Eur J Gastroenterol Hepatol. nov 2010;22(11):1352-7.

72. Maillard MH, Bortolotti M, Vader J-P, Mottet C, Schoepfer A, Gonvers J-J, et al. Appropriateness and long-term discontinuation rate of biological therapies in ulcerative colitis. J Crohns Colitis. août 2014;8(8):825-34.

73. Ess S, Joerger M, Frick H, Probst-Hensch N, Vlastos G, Rageth C, et al. Predictors of state-of-the-art management of early breast cancer in Switzerland. Ann Oncol Off J Eur Soc Med Oncol. mars 2011;22(3):618-24.

74. Taban F, Rapiti E, Fioretta G, Wespi Y, Weintraub D, Hugli A, et al. Breast cancer management and outcome according to surgeon's affiliation: a population-based comparison adjusted for patient's selection bias. Ann Oncol Off J Eur Soc Med Oncol. janv 2013;24(1):116-25.

75. Spitale A, Ortelli L, Mazzucchelli L, Bordoni A. Quality indicators of colorectal cancer care in southern Switzerland: results from a population-based study. Swiss Med Wkly. 2017;147:w14530.

76. Ortelli L, Spitale A, Mazzucchelli L, Bordoni A. Quality indicators of clinical cancer care for prostate cancer: a population-based study in southern Switzerland. BMC Cancer. 11 juill 2018;18(1):733.

77. Kuster SP, Eisenring M-C, Sax H, Troillet N. Structure, Process, and Outcome Quality of Surgical Site Infection Surveillance in Switzerland. Infect Control Hosp Epidemiol. oct 2017;38(10):1172-81.

78. Schubert M, Glass TR, Clarke SP, Aiken LH, Schaffert-Witvliet B, Sloane DM, et al. Rationing of nursing care and its relationship to patient outcomes: the Swiss extension of the International Hospital Outcomes Study. Int J Qual Health Care J Int Soc Qual Health Care. août 2008;20(4):227-37.

79. Schubert M, Clarke SP, Glass TR, Schaffert-Witvliet B, De Geest S. Identifying thresholds for relationships between impacts of rationing of nursing care and nurse- and patient-reported outcomes in Swiss hospitals: a correlational study. Int J Nurs Stud. juill 2009;46(7):884-93.

80. Ausserhofer D, Schubert M, Blegen M, De Geest S, Schwendimann R. Validity and reliability on three European language versions of the Safety Organizing Scale. Int J Qual Health Care J Int Soc Qual Health Care. avr 2013;25(2):157-66.

81. Ausserhofer D, Schubert M, Desmedt M, Blegen MA, De Geest S, Schwendimann R. The association of patient safety climate and nurse-related organizational factors with selected patient outcomes: a cross-sectional survey. Int J Nurs Stud. févr 2013;50(2):240-52.

82. Auer C, Schwendimann R, Koch R, De Geest S, Ausserhofer D. How hospital leaders contribute to patient safety through the development of trust. J Nurs Adm. oct 2014;44(10 Suppl):S38-44.

83. Drosler SE, Romano PS, Tancredi DJ, Klazinga NS. International comparability of patient safety indicators in 15 OECD member countries: a methodological approach of adjustment by secondary diagnoses. Health Serv Res. févr 2012;47(1 Pt 1):275-92.

84. Schoen C, Osborn R, Squires D, Doty M, Pierson R, Applebaum S. New 2011 survey of patients with complex care needs in eleven countries finds that care is often poorly coordinated. Health Aff Proj Hope. déc 2011;30(12):2437-48.

85. Osborn R, Squires D. International perspectives on patient engagement: results from the 2011 Commonwealth Fund Survey. J Ambulatory Care Manage. juin 2012;35(2):118-28.

86. Osborn R, Moulds D, Squires D, Doty MM, Anderson C. International survey of older adults finds shortcomings in access, coordination, and patient-centered care. Health Aff Proj Hope. déc 2014;33(12):2247-55.

87. Pavlic DR, Sever M, Klemenc-Ketis Z, Svab I. Process quality indicators in family medicine: results of an international comparison. BMC Fam Pract. 2 déc 2015;16:172.

88. Cohidon C, Wild P, Senn N. Patient experience in primary care: association with patient, physician and practice characteristics in a fee-for-service system. Swiss Med Wkly. 2018;148:w14601.

89. Cohidon C, Wild P, Senn N. Coping better with health problems after a visit to the family physician: associations with patients and physicians characteristics. BMC Fam Pract. 7 févr 2018;19(1):27.

90. Reed S, Arnal D, Frank O, Gomez-Arnau JI, Hansen J, Lester O, et al. National critical incident reporting systems relevant to anaesthesia: a European survey. Br J Anaesth. mars 2014;112(3):546-55.

91. Gehring K, Mascherek AC, Bezzola P, Schwappach DLB. Safety climate in Swiss hospital units: Swiss version of the Safety Climate Survey. J Eval Clin Pract. avr 2015;21(2):332-8.

92. Mascherek AC, Bezzola P, Gehring K, Schwappach DLB. Effect of a two-year national quality improvement program on surgical checklist implementation. Z Evidenz Fortbild Qual Im Gesundheitswesen. 2016;114:39-47.

93. Mascherek AC, Schwappach DLB. Patient safety climate profiles across time: Strength and level of safety climate associated with a quality improvement program in Switzerland-A cross-sectional survey study. PloS One. 2017;12(7):e0181410.

94. Bouchet N, Gayet-Ageron A, Lumbreras Areta M, Pfister RE, Martinez de Tejada B. Avoiding late preterm deliveries to reduce neonatal complications: an 11-year cohort study. BMC Pregnancy Childbirth. 8 janv 2018;18(1):17.

95. Steurer MA, Adams M, Bacchetti P, Schulzke SM, Roth-Kleiner M, Berger TM. Swiss medical centres vary significantly when it comes to outcomes of neonates with a very low gestational age. Acta Paediatr Oslo Nor 1992. sept 2015;104(9):872-9.

96. van Vegten A, Pfeiffer Y, Giuliani F, Manser T. [Patient safety culture in hospitals: experiences in planning, organising and conducting a survey among hospital staff]. Z Evidenz Fortbild Qual Im Gesundheitswesen. 2011;105(10):734-42.

97. Valentin A, Schiffinger M, Steyrer J, Huber C, Strunk G. Safety climate reduces medication and dislodgement errors in routine intensive care practice. Intensive Care Med. mars 2013;39(3):391-8.

98. Praplan-Rudaz I, Pfeiffer Y, Schwappach DLB. Implementation status of morbidity and mortality conferences in Swiss hospitals: a national cross-sectional survey study. Int J Qual Health Care J Int Soc Qual Health Care. 1 mai 2018;30(4):257-64.

99. Cullati S, Licker M-J, Francis P, Degiorgi A, Bezzola P, Courvoisier DS, et al. Implementation of the surgical safety checklist in Switzerland and perceptions of its benefits: cross-sectional survey. PloS One. 2014;9(7):e101915.

100. Pfeiffer Y, Briner M, Wehner T, Manser T. Motivational antecedents of incident reporting: evidence from a survey of nurses and physicians. Swiss Med Wkly. 2013;143:w13881.

101. Pfeiffer Y, Schwappach D. Taking up national safety alerts to improve patient safety in hospitals: The perspective of healthcare quality and risk managers. Z Evidenz Fortbild Qual Im Gesundheitswesen. 2016;110-111:26-35.

102. Mathieu CM, Teta D, Lotscher N, Golshayan D, Gabutti L, Kiss D, et al. Optimal and continuous anaemia control in a cohort of dialysis patients in Switzerland. BMC Nephrol. 11 déc 2008;9:16.

103. Short Report: Quality measures as stepping stones toward appropriate care? Some deliberations on mental health care monitoring in Switzerland. Z Für Evidenz Fortbild Qual Im Gesundheitswesen. 1 avr 2017;121:43-5.

104. Southern DA, Pincus HA, Romano PS, Burnand B, Harrison J, Forster AJ, et al. Enhanced capture of healthcare-related harms and injuries in the 11th revision of the International Classification of Diseases (ICD-11). Int J Qual Health Care J Int Soc Qual Health Care. févr 2016;28(1):136-42.

Literature Review 2:

Evidence of implementation of safety and quality interventions

Tanja Manser[1], Jan Schmutz[2] & Jasmina Bogdanovic[3]

[1] FHNW School of Applied Psychology, University of Applied Sciences and Arts Northwestern Switzerland, Riggenbachstrasse 16, 4600 Olten, Switzerland

[2] Department of Communication Studies, Northwestern University, Evanston, USA, Chicago, USA

[3] Institute of Nursing Science, University of Basel, Basel, Switzerland

Corresponding author:
Prof. Dr. Tanja Manser
Fachhochschule Nordwestschweiz
Hochschule für Angewandte Psychologie FHNW
Riggenbachstrasse 16
CH-4600 Olten

Abstract

There is a growing literature on the effectiveness of interventions to improve patient safety. However, there is a lack of overview to what degree patient safety improvement strategies have been implemented in Swiss healthcare and what evidence exists on their effectiveness. To fill this gap we conducted a literature search in six major databases. Inclusion criteria were: peer-reviewed journal articles published in English, German or French between January 2000 and November 2018 that report on the effects of a patient safety intervention or describe the degree to which specific improvement strategies have been implemented in Switzerland. Study quality was assessed using predefined quality indicators. We included 28 studies in this review; eight on implementation levels in Swiss healthcare and 20 on the effects of patient safety interventions. Information on implementation levels of patient safety interventions is highly fragmented. While there have been national surveys on clinical risk management and some more detailed reports on individual patient safety practices, there is no complete picture of patient safety improvement in Switzerland. Most interventions included in this review were implemented in a single unit/department. Common methods to record patient safety measures such as error rates and compliance with standards were retrospective record review, surveys and direct observation. We found indications of positive intervention effects in most studies. However, only few studies used patient outcomes as indicators of effectiveness. In conclusion, large-scale implementation research is required to allow for more rigorous testing of complex interventions to drive patient safety improvement in Switzerland.

Introduction

Although the incidence of specific types of patient harm is increasingly well known for many healthcare settings and their causes and contributing factors have been studied in detail, full comprehension of effective interventions and their successful and sustainable implementation is still rather limited. Also, little is known about the level of implementation of patient safety improvement strategies that have been shown to be effective in other contexts and have thus been recommended for implementation throughout healthcare.

This issue is not unique to Swiss healthcare and the international patient safety literature contains a number of articles aiming to summarise what is known about effective patient safety improvement and to provide recommendations regarding which patient safety strategies to implement. For example, in 2012, Pham and colleagues[1] reviewed key areas of adverse patient care events (i.e. medication errors, healthcare-acquired infections, falls, hand-off errors, diagnostic errors, and surgical errors), their causes and contributing factors, and corresponding error mitigation strategies pointing out evidence supporting their effectiveness. In 2013, Shekelle and colleagues reported on a multi-year project on an evidence-based assessment of patient safety strategies,[2] concluded that enough evidence existed to permit healthcare systems to move ahead and listed patient safety improvement strategies to be recommended for implementation. These reviews aim to inform the decisions of policy makers in healthcare as well as patient safety practitioners by providing the best available evidence for interventions targeting some of the most common patient safety concerns.

Despite the available knowledge concerning the incidence and causation of adverse events and effective strategies to prevent their occurrence or mitigate their effects, internationally as well as for the Swiss healthcare system, it is not yet known to what degree patient safety strategies have been implemented in Swiss healthcare and what evidence exists on their effectiveness.

Aim and focus of this review

This literature review addressed this gap and aims to provide an authoritative overview of what published evidence is currently available concerning patient safety improvement in Swiss healthcare. By focusing on intervention strategies specifically targeting patient safety improvement (i.e. aiming to reduce adverse events or strengthen those aspects of the healthcare system that help to maintain safety) in the Swiss healthcare system this report explicitly excludes interventions aiming for improved quality of care perceived by patients or efficiency-oriented process improvements to reduce healthcare costs[1].

The review will further focus on a number of core areas of the international patient safety literature. The rationale for the selection these areas was to set this review apart from drug development studies and drug-related clinical trials and from evidence-reviews on purely clinical interventions such as new surgical procedures or bundle interventions to prevent catheter-associated bloodstream infections or ventilator-

---

[1] This focus was defined during initial discussions of the aim of this review with the scientific lead on the National Report (Charles Vincent and Anthony Staines).

associated pneumonia. The mechanisms for integrating this evidence into clinical practice through guidelines and standards for clinical practice are well-established. We also excluded other infection prevention measures such as hand hygiene because there is an extensive literature on the effectiveness and sustainability of interventions in this area. However, international recommendations of patient safety improvement strategies to be implemented in healthcare comprise additional aspects for which the implementation pathways are less clear; especially when organisational factors are concerned. For example, Shekelle and colleagues[2] additionally mention checklists to prevent intra- and postoperative events, interventions related to the medication use process such as medication reconciliation, computerized provider order entry and the use of clinical pharmacists to reduce adverse drug events, team training and the use of simulation exercises, and the use of complementary methods for detecting adverse events or medical errors to monitor for patient safety problems. Similarly, Pham et al.[1] highlight the importance of interventions related to medication safety (i.e. computerized physician order entry systems and clinical decision support systems, bar-coding, standardized ordering and administration, medication reconciliation and the inclusion of pharmacists in rounds), teamwork and safety culture (e.g. interventions such as the Comprehensive Unit-based Safety Program or the TeamSTEPPS training programme) or patient hand-offs (i.e. structured hand-off tools, optimal hand-off environments).

To capture the developments of patient safety improvement in Switzerland in these areas, the focus areas of this report include, but are not restricted to:

- Interventions to improve the safety of the medication use process
- Checklists for surgical procedures and interventional diagnostics
- Rapid-response systems including the use of early-warning scores
- (Simulation-based) Team Training

The review offers an overview of the findings in each area, an assessment of the study quality, recommendations for further research and recommendations of future initiatives that would enhance patient safety in Swiss healthcare.

Methods

Definition of central concepts

Patient safety. For the purposes of this review, we define patient safety as "the avoidance, prevention, and amelioration of adverse outcomes or injuries stemming from the process of healthcare" following the definition by Vincent[3].

Interventions to improve patient safety. For the purposes of this review, we define interventions to improve patient safety as the implementation of any systematic change of practice at any level of a healthcare organisation. This comprises interventions such as the implementation of clinical risk management practices aimed at learning from incidents (e.g. incident reporting, morbidity & mortality meetings), educational interventions to improve skills of healthcare professionals or to raise the awareness of

healthcare professionals and patients of patient safety issues and practices, standardisation efforts for safety-critical care processes and procedures.

This does not include clinical improvements such as, for example, new surgical procedures, new formulation of drugs, new imaging technology. We also excluded infection prevention because this is the focus of a short report commissioned as part of the national report.

Rationale for key methodological decisions

Limiting search window to year 2000 onwards. After the hallmark report of 'To err is human' pointed out the need for a comprehensive approach to patient safety improvement in 1999[4], there has been a growing awareness of patient safety issues around the globe. Subsequently the field of patient safety emerged as an active, interdisciplinary research domain first addressing mainly the detection and systematic analysis of adverse events and later, the development of systematic improvement approaches and the testing of their effects on patient care. Corresponding to this development, the scientific publications on patient safety increased abruptly and steadily from the year 2000 onwards[5]. While other important foundational work of patient safety had been carried out before this date, the term "patient safety" started being used more consistently in the publications. For these reasons we decided to limit our search to publications from 2000 onwards.

Approach to limiting the search to Swiss healthcare. Since this review explicitly focuses on patient safety improvement in Swiss healthcare we were only interested in studies reporting on data collected in Switzerland. While this may comprise studies where data was collected in more than one country, the data of the Swiss sample had to be identifiable in the results to allow for any kind of conclusion for Swiss healthcare. An initial search showed that authors of relevant studies used many different ways of reporting the origin of their data such as stating the language region, the canton(s), the city or the name of the healthcare institution, network of healthcare institutions or simulation/training centre involved in the study. Also, in some studies none of this information was included in the title, abstract or keywords of the publication. We therefore decided to use the author affiliation as a search field as it is likely that no study would be conducted in Swiss healthcare without the involvement of at least one local researcher. This strategy, however, revealed another challenge. With the World Health Organization (WHO) based in Geneva, Switzerland, this search strategy would lead to a huge number of hits referring to studies conducted in other regions of the world and to policy documents. However, as it is unlikely for a study conducted in Swiss healthcare not to involve at least one other author affiliated to an organisation within Switzerland, it was considered reasonable to exclude author affiliations to the WHO from our search.

Screening of references instead of applying more restrictive search terms. A key decision when defining the aims of this review was to exclude purely clinical interventions (e.g. studies targeting specific diseases, studies evaluating the effects of new surgical techniques, new scanning devices, novel applications of existing drugs and studies assessing the safety and tolerability of new drugs). However, excluding all these areas of intervention by restricting the search terms did not appear feasible;

especially as some patient safety programs include clinical as well as non-clinical components. Given that the number of references identified with the wider search was not excessive, we decided to systematically screen references applying these exclusion criteria.

Inclusion and exclusion criteria

We included studies recording the effects of any kind of intervention on healthcare outcomes related to patient safety such as:
a) objective indicators of patient safety (e.g. morbidity-mortality data),
b) reported or observed indicators of unsafe care practices (e.g. medication errors, key diagnostic or treatment tasks not performed),
c) reported or observed indicators of safe care practices (e.g. adherence to protocols and guidelines) and
d) subjective patient safety ratings performed by experts (e.g. assessments of clinical performance during a specific procedure).

We further included research articles reporting on the level of implementation of patient safety practices (i.e. the degree to which a specific approach to address patient safety issues has been adopted throughout Swiss healthcare).

We excluded studies using safety climate measures as a substitute outcome, assessing other components of the quality of patient care based on the definition by the WHO of quality of care (i.e. "the extent to which health care services provided to individuals and patient populations improve desired health outcomes. In order to achieve this, health care must be safe, effective, timely, efficient, equitable and people-centred") or staff outcomes that may adversely impact on patient safety such as burnout.

Search strategy

We searched six databases (CINAHL, Embase, Medline, Psyndex, Science direct, Web of Knowledge) for research articles published in peer-reviewed journals between 2000-2018 (search date November 19, 2018) in English, French or German. In order to obtain all relevant results, we applied rather broad research strategy. We used "patient safety" as the main search term and restricted our search to articles published by at least one author with a Swiss affiliation excluding "World Health Organization" or "WHO" as an affiliation.

Screening and selection procedure

Since the research strategy had been rather broad, we first screened the meta-data and then the titles, abstract and keywords of all references applying a number of screening strategies. Two raters (TM and either JB or JS) then independently screened all retained references of research articles published in peer-reviewed journals in either English, French or German. At the first stage, we screened the title and abstract to identify studies describing an intervention to improve patient safety in any healthcare setting in Switzerland. Disagreements between raters at this stage led to inclusion. At

the second stage, we reviewed the remaining full texts to select those studies a) reporting on the effects of the intervention drawing on either qualitative or quantitative data and b) describing the level of implementation of a patient safety improvement strategy. Disagreements between TM and any of the other raters at the second stage were resolved by consensus discussion.

Data extraction

For all intervention studies we extracted a brief description of the intervention, the scope (i.e. pilot application, unit/department, organisation-wide, regional, national), the method applied including the patient safety measure(s), study setting, sample and participants as well as the main results focusing on the findings reported on the patient safety measure(s) but also including other relevant findings. Data extraction was performed by JB and JS and double-checked by TM.

Rating of study quality

Since the intervention studies included in this review were not only randomized controlled trials but covered a range of study designs, we did not employ the GRADE system[6] usually recommended for assessing the quality of evidence for clinical guidelines. Instead, we assessed the study quality, using a rating system that was a slightly adapted version of the one proposed by Buckley and colleagues.[7] Because of the importance of external validity for study quality, we replaced the single item used by Buckley and colleagues with two items from a checklist by Downs and Black.[8] Further, we added three items specific to intervention studies from Downs and Black, leaving out the item on triangulation because the focus of this review was on the effect of the intervention and we did not necessarily expect authors of intervention studies to triangulate multiple methods.

For the complete set of items used to evaluate study quality including the origin of each item as well as a brief description of all quality indicators see Table 2.

Each item was rated by either JB or JS as '0' (not fulfilled), '0.5' (partially fulfilled) or '1' (complete). We rated an item as 'not mentioned' (i.e. relevant information not explicitly provided so that it cannot be assessed whether or not the criterion has been fulfilled) or as 'not applicable' if it was considered not relevant for the specific study. A random sample of four studies was rated independently by JS and JB to assess rater agreement. We achieved consistency of 91%. Disagreements between raters were due to different interpretations of the information provided in the included articles.

We performed no quality assessment of the studies describing the implementation levels of patient safety practices in Swiss healthcare because these studies were qualitative or purely descriptive.

Results

Search and screening results

As summarized in Figure 1 our search obtained 3368 references of which 3062 were retained after removal of duplicates. Screening the meta-data of these references we further removed non-research articles (e.g. commentaries, editorials), study protocols, reviews, abstracts or proceedings of conferences (n=269) and references not listing an author (n=73). Screening the titles and abstracts of the remaining 2720 references, we removed another 622 that reported data from other countries, always retaining those studies that only reported to have been conducted in Europe, or international studies that either did not specify the participating countries or mention inclusion of a Swiss healthcare organisation or patient sample. After excluding drug studies (e.g. focusing on pharmacokinetics or drug tolerability) and references reporting data on a specific illness (e.g. diabetes or coronary disease) 1158 references were retained for independent screening.

After both stages of independent screening, a final set of 20 studies reporting on the effects of interventions to improve patient safety in a Swiss healthcare setting and eight articles, reporting on the level of implementation of patient safety improvement strategies that have been shown to be effective in other contexts, were retained for detailed analysis.

Figure 1. Systematic literature search and record selection

8
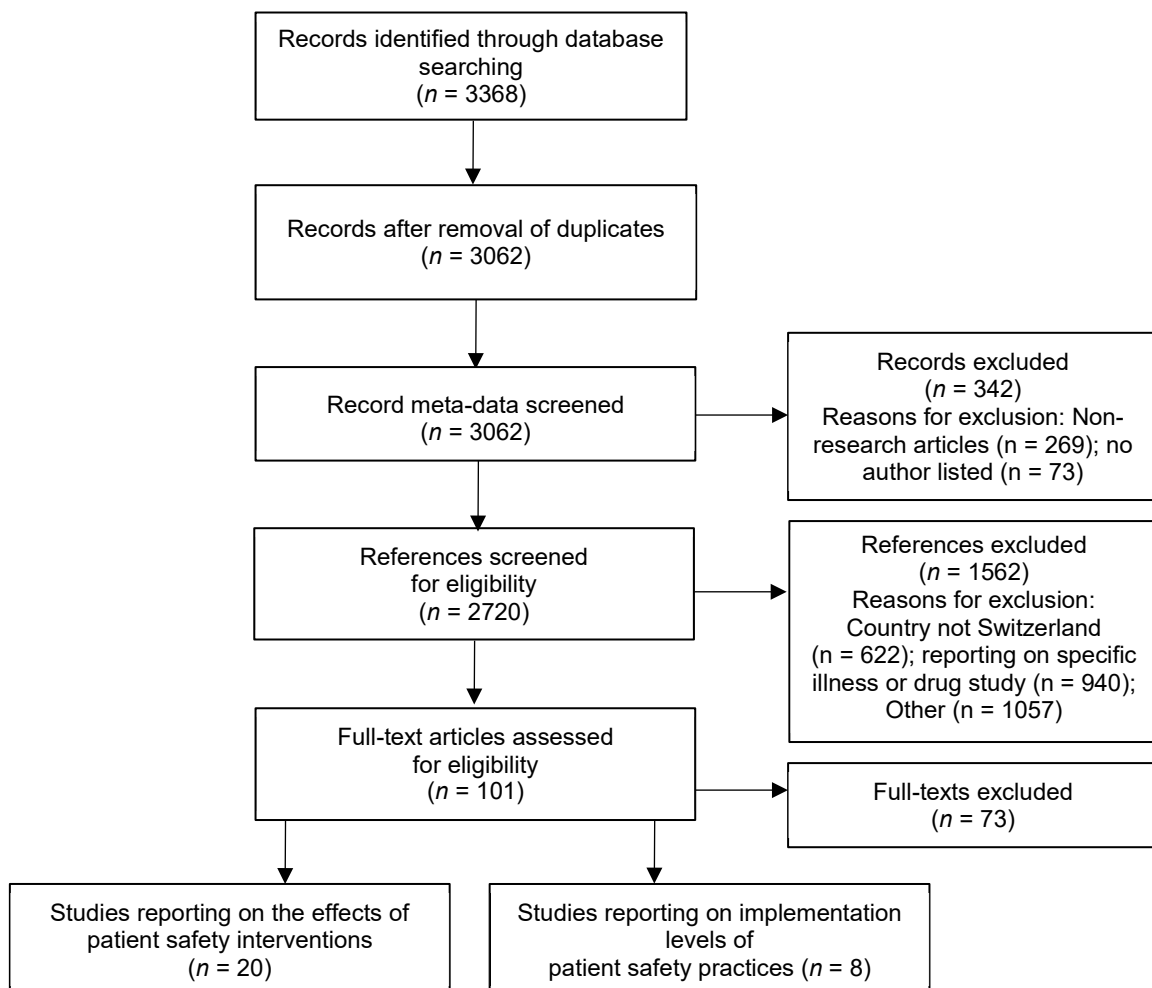
Level of implementation of patient safety improvement strategies

This review identified eight studies reporting in some form on the level of implementation of one or more strategies to improve patient safety in Swiss healthcare.[9-16] While this excludes studies assessing only knowledge of attitudes towards these practices, some studies did incorporate both aspects.[11,13,15]

One of the included studies reports on data of a national survey on **Clinical Risk Management (CRM) practices** in the hospital sector conducted in 2007/2008[9]. This survey provides an overview of the stages of implementation for a range of CRM practices such as incident reporting, use of simulation-based training or error disclosure based on the transtheoretical model[17] (i.e. "Not yet examined", "Examined, but so far no implementation plan", "Implementation planned in the next 12 months", "Not systematically implemented", "Systematically implemented/Deliberate decision against implementation").[18] The results of this survey provide a good starting point for more detailed investigations into specific CRM practices. This study also identified three key enablers fostering CRM implementation: establishing a central role for CRM coordination, assuring dialogue with and between the departments/services, and developing strategic CRM objectives.[9]

In the following, we briefly summarise studies describing the implementation of individual strategies for patient safety improvement in Switzerland. For the intervention studies included in this review, their level of implementation is described in the following section of this report and included in Table 1.

Three studies investigated implementation of **checklists in the context of surgical safety**.[10,11,13] Cullati and colleagues[11] analysed a rather small sample of 152 responses (response rate 35.1%). Of these, 64.7% reported use of a checklist similar to the one recommended by the WHO with reported compliance rates being higher to sign-in and time-out than for sign-out. In another study using observation to evaluate compliance during time-out and sign-out, Cullati and colleagues[10] found that checklist compliance (i.e. whether an item was checked) was 84% for time-out and 58% for sign-out while validation (i.e. confirmation of the checked items by at least one other team member was rather unsatisfactory with 50% and 41%, although slightly improved in high-risk procedures. In a later survey addressing a larger population, Mascherek and colleagues[13] found that of the 1378 respondents to the survey (23.3% response rate), 1090 (79.1%) reported the use of a surgical checklist. Of these, 532 (38.6%) used the Swiss Patient Safety Foundation recommendations to avoid wrong site surgery based on the Universal Protocol, 346 (25.1%) used the WHO-checklist and 212 (15.7%) used other checklists.

Another three studies addressed **strategies for learning from error** with one of them focusing on morbidity and mortality (M&M) conferences,[16] one on incident reporting systems[12] and one on the uptake of safety alerts[15]. Praplan-Rudaz and colleagues[16] conducted a national survey on the implementation status of M&M conferences in Swiss hospitals in which 321 chief physicians from a range of disciplines participated (35.2% response rate). 69.5% indicated that M&M conferences were currently conducted in their department, usually quarterly, and the majority of other respondents indicated considering implementation. In their cross-national comparison between Swiss and

German hospitals Manser and colleagues[12] provide a descriptive characterisation of IRS implemented in the two countries and identify context factors such as hospital type and the existence of a central role for CRM coordination and of strategic CRM objectives (both identified a success factors before)[9] that influence the ways in which IRS are implemented. Finally, Pfeiffer and colleagues[15] report on the uptake of national safety alerts based on a sample of 116 healthcare quality and risk managers (response rate 39%). The study showed that participants used the alerts strategically to support their own patient safety agenda but did not feel responsible for dissemination or incorporation of their content into improvement programmes within their organisations.

A survey on **error disclosure standards** in Swiss hospitals conducted in 2011 extended the information available from the previous surveys on Clinical Risk Management practices that had only asked for disclosure of errors leading to patient harm.[14] The study showed that 62% of the 205 participating hospitals (54% response rate) either had an internal hospital standard on open disclosure (46%) or planned to implement one within a year (16%). This study also revealed significant association between hospital type and the implementation of error disclosure with psychiatric, rehabilitation and specialty clinics being significantly more likely to have no error disclosure standard (53%) than university and acute care hospitals (25%); $\chi^2_{(1, n=183)}$=15.55, p <0.001.

Interventions to improve patient safety in a Swiss healthcare setting

For an overview of the 20 intervention studies included in this review see Table 1. These interventions cover all the pre-defined focus areas of this review but also go beyond this focus (e.g. an organisational intervention of merging two dispatch centres or an intervention to ensure adequate staffing during patient transport).

Publication dates. The earliest of these studies was published in 2006[19] and most studies (N=5) appeared in 2016.[20-24]

Healthcare setting. All but one study, which investigated the effects of a merger of two emergency dispatch centres[25] were designed for a hospital environment with one study reporting on data collected in a simulated surgical setting[26].

Scope. Most interventions included in this review have been implemented at the unit or department level.[19-22,27-34] One of these studies investigated the effect of a national working time directive for residents but used data from a single department.[30] Organisation-wide implementation was reported in five studies: three investigated team training interventions[28,35,36], one the WHO Surgical Safety Checklist[10] and one the merger of two emergency dispatch centres[25]. Only one study which included four intensive care units was located at the regional level[37] and one study including ten hospitals was considered as "national level".[24] The remaining studies were considered pilot implementations of educational interventions,[23,26] although for many other studies there was also no information available on the continuation of the intervention after the study had been completed.

Table 1. Characteristics of intervention studies aiming to improve patient safety in Swiss healthcare

Study	Intervention/ Scope*	Method/Patient safety measure	Setting/Sample/Participants	Main results	Study quality score (max=15)	No. of items „not mentioned" or "not applicable"
Benoit et al. 2012[27]	**Intervention:** 1. Two documents merged into one single form, 2. Standardised highly structured form, 3. Drug names, units, and fixed routes pre-printed, 4. Physicians and nurses trained to use form **Scope:** unit/department	**Method:** Assessment of medication errors using an adapted version of the American Society of Health-System Pharmacists Guideline **Patient safety measure:** Error rates per line of drug, per 1000 patient days and per types of error (i.e. omission, not discontinued, wrong frequency, wrong dosage, wrong rate, missed target, wrong route, wrong drug)	**Setting:** Multidisciplinary ICU of a tertiary care teaching hospital **Sample:** 9298 lines of drugs for 294 patients, 754 patient-days, six time-series that lasted for 85 days **Participants:** ICU residents (medication prepared by nurses)	1. Error rate per line of drug Pre: 229, Post: 100 errors; error rate per line of drug decreased from 4.95% to 2.14% = reduction of 56.8% (P<0.001). OR 0.42 (95% CI = 0.33-0.53), P<0.001. 2. Error rate per 1000 patient days Pre: 234 (total error rate per 1000 patient days 627), Post: 104 (total error rate per 1000 patient days 273); patient days without any error increased from 59.3% to 79.8% (P<0.001); patient days with more than one error decreased from 15% to 4.7% (P<0.001) 3. Error rate per types of error (statistically significant decrease only) Total: OR 0.42 (0.33-0.53), P<0.001 -Omission: OR 0.62 (0.43-0.90), P=0.012 -not discontinued: OR 0.02 (0.00-0.14), P<0.010 -wrong frequency: OR 0.40 (0.21-0.76), P<0.006 -wrong rate: OR 0.29 (0.11-0.79), P=0.015 -wrong route: OR 0.20 (0.06-0.68), P=0.010	12.5	0
Corbel et al. 2016[20]	**Intervention:** Structured, algorithm-based patient medication interview **Scope:** unit/department	**Method:** Comparison of medication history obtained with the algorithm to the medication list retrieved from the electronic medical record **Patient safety measure:** Average concordance rates between (1) a medication list obtained with a one-page structured medication history algorithm developed for the obstetrical setting and (2) the medication list reported in medical records and obtained by open-ended questions based on standard procedures, medication names, routes, doses, or frequency of	**Setting:** Obstetrical, prenatal unit at a University Hospital **Sample:** 53 medication interviews with help of the algorithm **Participants:** 93 patients considered eligible during the study period	1. The algorithm-based method obtained a higher average concordance rate than the standard method: 90.2% [CI95% 85.8–94.3] vs. 24.6% [CI95% 15.3–34.4] (p<0.01) 2. After removing vitamins, mineral supplements, iron and homeopathic preparations, average concordance rates were 91.0% [CI95% 84.9–95.9] vs. 43.8% [CI95% 31.7–57.4] for the algorithm-based and standard approaches (p<0.01)	12.5	0

		administration				
Cullati et al. 2013[10]	**Intervention:** Checklist based on the WHO Surgical Safety Checklist **Scope:** organisation-wide (for elective surgical procedures)	**Method:** Direct observations during Time Out and Sign Out of elective procedures **Patient safety measure:** Checklist compliance and items properly checked (i.e. orally 'confirmed' by one member of the team and validated by another)	**Setting:** 2000-bed hospital with 38 operating theatres **Sample:** 79 periods of Time Out and 80 periods of Sign Out **Participants:** Theatre staff during elective procedures in a range of surgical specialties	1. Overall, compliance rate of 99% 2. 50% of items validated during Time Out and 41% of items validated during Sign Out	12	1
Frey et al. 2016[21]	**Intervention:** Interdisciplinary and interprofessional morbidity and mortality conference (MMC) focusing on patient safety **Scope:** unit/department	**Method:** Retrospective analysis of the minutes of the MMCs held over 5.5 years, from January 2009 to June 2014 **Patient safety measure:** 1. Contents discussed during MMCs 2. Interventions derived from discussions	**Setting:** 23-bed tertiary interdisciplinary neonatal ICU; Children's Hospital Zurich **Sample:** Minutes of 48 mortality and morbidity conferences	1. Unsafe processes/medical errors identified and discussed in 37 MMCs (77%). In seven cases, new autopsy findings prompted the discussion of a possible error. Ethical issues discussed during four MMCs. The 48 MMCs identified 50 errors, including 30 in which an interface problem was a contributing factor. 2. 54 improvements identified in 34 MMCs: 21 at the unit-level, 21 at the hospital level, 12 outside the hospital.	12	1
Haller et al. 2008[28]	**Intervention:** CRM-based team training programme designed to improve teamwork and communication skills **Scope:** organisation-wide	**Method:** Before-and-after cross-sectional survey **Patient safety measure:** 36-item survey to assess participants' learning	**Setting:** Women's hospital affiliated Geneva University (approx. 4000 childbirths per year) **Sample:** 239 training participants **Participants:** Midwives, nurses, technicians and physicians (anaesthesia, obstetrics and paediatrics)	Significant improvement on 29 of the 36 items evaluating participants' learning *Other findings:* *63-90% of participants rated their level of satisfaction with the course very highly. Positive change in team and safety climate [OR 2.9, 95%CI (1.3–6.3) to OR 4.7, 95%CI (1.2–17.2)] and improved stress recognition [OR 2.4, 95%CI (1.2–4.8) to OR 3.0, 95% CI (1.0–8.8)].*	13.5	0
Huber et al. 2017[29]	**Intervention:** IT-guided checklist for medication history taking at admission **Scope:** unit/department	**Method:** Assessment of the medication history conducted by pharmacist (defined as gold standard) with that of the admitting physician before and after intervention **Patient safety measure:** Medication discrepancies in the medication history	**Setting:** Vascular and visceral surgery ward with 26 beds at Kantonsspital Aarau **Sample:** 735 medications checked before and 677 medications checked after the intervention **Participants:** 228 patients (113 before and 115 patients after intervention)	1. After intervention, medication histories with at least one discrepancy declined from 69.9 to 29.6% (p < 0.0001). Mean medication discrepancy per patient was reduced from 2.3 to 0.6 (p < 0.0001) 2. Most common error (i.e. omission of a regularly used medication) reduced from 76.4 to 44.1% (p < 0.001).	13.5	0
Huckels et al. 2016[22]	**Intervention:** Installation of separate medication rooms **Scope:** unit/department	**Method:** Direct structured observation of nurses during medication preparation and daily self-reporting of medication errors by nurses **Patient safety measure:** 1. Interruption rate	**Setting:** Two wards in a major teaching hospital **Sample:** 72 medication preparation cycles on nine weekdays pre- and post-intervention; 1498 medications prepared for 366 patients **Participants:** 42 nurses	1. Interruption rate significantly reduced from 51.8 to 30 interruptions per hour (P < 0.01) 2. Mean medication error rate per day significantly reduced from 1.3 to 0.9 errors per day (P <0.05)	13.5	0

		2. Error rate				
Kaderli et al. 2012[30]	**Intervention:** Implementation of 50-hour working time restriction (weekly limit) **Scope:** unit/department	**Method:** Retrospective evaluation of patients pre- and post-implementation **Patient safety measure:** 1. In-hospital mortality 2. Postoperative surgical complication rate 3. Intraoperative medical complications frequency 4. Post-operative medical complication frequency	**Setting:** Surgical unit **Sample:** Records of 1259 patients pre- and 1427 post-implementation patients **Participants:** 2686 common surgeries performed by residents	1. and 2.: In-hospital mortality and postoperative surgical complication rate higher after implementation of the 50-hour weekly limit 3. and 4.: No differences observed in intraoperative and post-operative medical complication frequency	12.5	0
Kandler et al. 2016[23]	**Intervention:** Educational video based on institutional standard protocol **Scope:** pilot application	**Method:** Prospective intervention study (pre-period: 4.9 months; post-period: 5.9 months); observation using checklist of safety-critical tasks **Patient safety measure:** 1. Failure of anaesthesia teams to adhere to safety-critical tasks 2. Performance of 14 safety-critical tasks on iPad (e.g. correct drug preparation, patient in head-up position, use of appropriate induction agent etc.)	**Setting:** Seven operating areas with 30 individual operating theatres at University Hospital Zurich **Sample:** 425 anaesthesia procedures (pre: 148 days, post: 179 days), pre: 516 members of theatre teams; post: 575 members of theatre teams **Participants:** Pool of 45 consultants, 100 residents, and 200 certified and student anaesthesia nurses	1. The odds for failure of adherence to safety-critical tasks between the pre- and post-intervention period were reduced, OR 0.34 (95%CI 0.27–0.42, P<0.001) 2. The risk for failure of adherence was reduced significantly for eight of the 14 safety-critical tasks (all P<0.001).	12.5	1
Lübbeke et al. 2013[31]	**Intervention:** Intraoperative checklist in high-risk surgical patients **Scope:** unit/department	**Method:** Quasi-experiment pre-post checklist implementation; data extraction from electronic patient information system **Patient safety measure:** 1. Unplanned return to operating room 2. Reoperation for surgical site infection (SSI) 3. Unplanned admission to intensive care unit (ICU) 4. In-hospital death within 30 days	**Setting:** Surgical department in a large teaching hospital **Sample:** 2427 patients (609 pre and 1818 post checklist implementation) **Participants:** High-risk (ASA score 3-5) surgical patients	1. Unplanned return to operating room: Pre 7.4% vs. post 6.0% RR=0.82; not significant 2. Reoperation for SSI: 3.0% vs 1.7% RR=0.56; significant reduction 3. Unplanned admission to ICU: Pre 2.8% vs 2.6% RR=0.90, not significant 4. In-hospital death: 4.3% vs 5.9% RR=1.44, not significant	11.5	1
Mascherek et al. 2016[24]	**Intervention:** National improvement programme	**Method:** 3 questionnaires at two measurement	**Setting:** Ten hospitals **Sample:** Depending on	1. Significant increase in frequency of use (F(1,1001) = 340.9, p < 0.001), satisfaction with	11.5	0

	for surgical checklist use[38] **Scope:** national level (10 selected hospitals)	points 15 months apart **Patient safety measure:** 1. Frequency of, satisfaction with and knowledge of checklists use	questionnaire sample consists of 217-1966 individuals (T1) and 142-1086 individuals (T2) **Participants:** Members of the OR teams at participating hospitals (doctors, nurses, scrub nurses, surgical technicians, attendants for surgical positioning)	use ($F_{(1,1232)}$ = 25.6, $p < 0.001$) and knowledge about checklist use ($F_{(1,1294)}$ = 184.5, $p < 0.001$). *Other findings:* *Increase in norms ($F_{(1,1284)}$ = 17.9, $p < 0.001$) and intentions for checklist use ($F_{(1,1284)}$ = 7.8, $p < 0.01$). No change in attitudes towards checklists ($F_{(1,1284)}$ = 0.1, n.s.). Small increase of safety climate ($F_{(1,3555)}$ = 11.8, $p < 0.001$) and teamwork ($F_{(1,3554)}$ = 24.6, $p < 0.001$)*		
Mir et al. 2009[32]	**Intervention:** Computerized physician order entry (CPOE) system (PreDiMed) **Scope:** unit/department	**Method:** Classification of prescription lines (Pre and post) by two pharmacists according to 3 modes of administration (oral or other non-parenteral; parenteral or via nasogastric tube; pro re nata PRN) **Patient safety measure:** compliance with prescription accuracy requirements (i.e. missing info, incomplete, erroneous, ambiguous, illegible)	**Setting:** Two internal medicine departments from two regional hospitals (39 and 38 beds) **Sample:** Each department contributed 100 files (50 pre, 50 post) = 200 files; 2,099 prescription lines **Participants:** Files from internal med patients	Before CPOE implementation: In 2,099 prescription lines, the total number of non-compliant items was 2,265 or 1.079 non-compliant items per line. Two-thirds of these were due to missing information, and the remaining third to incomplete information. After CPOE implementation: In 2,074 prescription lines, the number of non-compliant items had decreased to 221 or 0.107 non-compliant items per line, a dramatic 10-fold decrease (chi-square = 4615; $P<10^{-6}$).	10.5	1
Moser et al. 2017[25]	**Intervention:** Merging of two emergency dispatch centres (DC) **Scope:** organisation-wide	**Method:** Retrospective analysis of the triage performance for the 12 months pre- and post-merger **Patient safety measure:** Under- and over-triage rates	**Setting:** Two emergency dispatch centres in Vaud and Neuchâtel in the French-speaking part of Switzerland **Sample:** 35'677 missions before merger, 38'748 missions post-merger	Before merger: DC A: over-triage 78.0% and under-triage 4.6%; DC B: over-triage 83.9% and under-triage 6.5% Post-merger: over-triage 70.8%, under-triage 3.0%	12.5	0
Pagnamenta et al. 2012[37]	**Intervention:** Multifaceted strategy to reduce drug-related AE **Scope:** regional	**Method:** Prospective, multi-centre before and after study employing a self-report survey for AE **Patient safety measure:** Risk index for drug-related AE	**Setting:** Four intensive care units (ICUs) of non-university teaching hospitals in the Italian-speaking part Switzerland **Sample:** 2047 AEs reported for 6404 patients **Participants:** Patients admitted to one of the four ICUs during the 24-month study period	Significant decrease of mean risk-index score for medication errors improved from the first 12-month period to the second 12-month period from 10.01 ± 2.7 to 8.72 ± 3.52 (absolute risk difference 1.29; 95% CI 0.88-1.7; $p < 0.01$)	13.5	0
Rosenthal et al. 2013[26]	**Intervention:** 2-day endovascular training course **Scope:** Pilot application	**Method:** Structured observation of simulated arterial access task before and after training **Patient safety measure:**	**Setting:** Simulation-centre **Sample:** 50 trainee doctors (28 course participants, 22 control group) **Participants:** Course	Course participants more likely to pass the global assessment at final testing than control group (OR = 59; 95%CI 9.5-656; $P< 0.001$). Estimated difference in percentage score at final testing between intervention and control group	13	0

		Baseline and final assessment of technical skills using OSATS[39]	participants during conference (intervention group) and trainees recruited at the radiology and surgery department of the Basel University Hospital (control group)	was 26% (95% CI 18-34; P < 0.001) for the task-specific checklist percentage score and 29% (95% CI 19-40; P < 0.001) for the global rating scale percentage score.		
Schwappach et al. 2013[33]	**Intervention:** Implementation and testing of the Swiss patient safety advisory **Scope:** unit/department	**Method:** Discharge survey **Patient safety measure:** 1. Performance of safety related behaviours 2. Patients' likelihood to experience a safety-related incident or unsafe situation	**Setting:** Surgical department of one large non-university hospital in the German-speaking part of Switzerland **Sample:** 420 completed surveys (218 control, 202 intervention) **Participants:** Patients admitted to the surgical department	1. Performance of safety-related behaviours was unaffected by the intervention. 2. Patients in the intervention group were less likely to experience any safety-related incident or unsafe situation (OR for intervention group = 0.57, CI 0.38–0.87, P = 0.009). *Other findings:* *3. Patients in the intervention group less likely to feel poorly informed about medical errors (OR = 0.55, P = 0.043).* *4. 73.1% patients in the intervention and 84.3% in the control group underestimated the risk for infection (OR = 0.51, CI 0.31–0.84, P = 0.009).* *5. Perceived behavioural control was lower in the control group (mean $_{Con}$ = 3.2, mean $_{Int}$ = 3.5, P = 0.010).* *7. There were no differences in concerns for errors during hospitalisation.* *8. 96% of patients (intervention) would recommend other patients to read the advisory.*	13	0
Tscholl et al. 2015[34]	**Intervention:** Introduction of anaesthesia pre-induction checklist **Scope:** unit/department	**Method:** Between subject control group design, on site observation and survey **Patient safety measure:** Clinical performance	**Setting:** Surgical department at University Hospital Zurich **Sample:** 105 teams using the checklist vs. 100 teams not using the checklist before a standard anaesthesia procedure **Participants:** teams consisting of anaesthesia nurses, residents and consultants	Clinical performance: 93% vs 93% not significant *Findings on other team-level outcomes:* *1. Information exchange: 100% vs 33%** *2. Knowledge of critical information: 100% vs 90%** *3. Perception of safety: 91% vs 84%** *4. Perception of teamwork: 90% vs 86%**	14	0
Voeffray et al. 2006[19]	**Intervention:** Introduction of chemotherapy protocols into the CPOE system **Scope:** unit/department	**Method:** Assessment of number of errors or interventions recorded by pharmacy service, which lead to either an inquiry for additional information or a correction; 15 months before and 21 months after introduction of CPOE protocol **Patient safety measure:**	**Setting:** Multidisciplinary oncology centre with1500 inpatient and 20000 outpatient treatments per year; University Hospital Lausanne **Sample:** Pre: 940 handwritten prescriptions, post: 527 handwritten and 978 CPOE prescriptions	Before CPOE protocol: 141 errors recorded for 940 prescribed chemotherapy regimens (15%). After introduction of CPOE protocol: 75 errors recorded for 1505 prescribed chemotherapy regimens (5%). Of these errors, 69 (92%) were recorded in prescriptions that did not use a CPOE protocol. The types of errors shifted but are difficult to interpret with only six errors	12	0

					13	0
			Error rates in handwritten vs. CPOE prescriptions			
Wasserfallen et al. 2008[35]	**Intervention:** Algorithm defining transfer categories according to destination, equipment monitoring, and medication **Scope:** organisation-wide	**Method:** Survey filled in after transfers pre-post algorithm implementation **Patient safety measure:** 1. Compliance with transfer algorithm 2. Perception of safety	**Setting:** University Hospital, Lausanne **Sample:** During an initial 6-month period (1467 transfers), reassessment during first (1461 transfers) and second (1535 transfers) 6-month evaluation period **Participants:** Staff involved in transfers	1. During the initial period, 31% and 56% of transfers requiring an accompanying nurse/physician according to the algorithm, were accompanied by a nurse /physician. During the first and second evaluation period, 100% and 93% of transfers requiring an accompanying nurse were accompanied by a nurse. For accompanying physicians the respective values were 38% and 35%. 2. Percentage of perceived unsafe transfers decreased from 6% to 4%. 20% of transfers considered safer than necessary. *Other findings:* *Over study period the number of transfers increased by 40%, percentage of patients requiring equipment decreased from 34% to 14%, oxygen and drug requirement remained stable.*	13	0
Zimmermann et al. 2015[36]	**Intervention:** Team and resuscitation training programme (iSTaRT) using inter-professional in-situ simulation as an educational strategy **Scope:** organisation-wide (i.e. across several hospital departments)	**Method:** Cross-sectional survey **Patient safety measure:** 1. Self-perceived impact and self-efficacy after every training session 2. Training needs based on assessment of team performance with TeamMonitor after simulation and real emergencies during study period 3. Identified latent safety threats and system changes	**Setting:** Lucerne tertiary children's hospital (emergency department, ICU and intermediate care) **Sample:** 95 simulation training participants **Participants:** nurses and physicians of participating departments	1. Self-reported improvement in teamwork 99%, technical skills 80%, knowledge 90% and anxiety 76% 2. Items for which urgent training need was identified: Team member understanding of his/her role, verbalisation of team member activities, and repeating back or paraphrasing instructions and clarifications to indicate that they were heard correctly 3. 23 different latent safety threats detected during the iSTaRT sessions (1.1 per session) and following real events (1.4 per event)	13	0

* Scope: pilot application, unit/department, organisation-wide, regional, national

Methods and patient safety measures. The most frequently applied method to collect information on the patient safety measures was retrospective record review (8 out of 20 studies) followed by surveys (6 studies) and direct observation (5 studies). Across the 20 intervention studies, the most common patient safety measure were errors such as prescription errors, errors during medication preparation, or under-triage (9 studies), followed by compliance with or adherence to procedural guidelines and checklists (7 studies). Morbidity and mortality (M&M) data were analysed in two studies and clinical performance was assessed in two studies. Two studies assessed learning as a result of the intervention with one study additionally capturing latent safety threats identified during the intervention. One study analysed meeting notes from M&M conferences for their content and interventions derived from the conference discussion.

Focus area "Interventions to improve the safety of the medication use process". Our review identified seven studies aiming to improve safety at various stages of the medication use process. These interventions aimed for standardised performance of key tasks such as taking a medication history during patient interviews[20,29] as well as tools to support standardised task performance.[19,27,29,32] One study describes a change in workplace layout (i.e. the introduction of separate medication preparation rooms) to minimise interruptions during safety-critical tasks.[22].

While most of these studies targeted a rather narrow window in the medication use process and consisted of one interventional component, the study by Pagnamenta and colleagues describes a more complex 24-month improvement project in the intensive care setting that led to significantly reduced risk of medication errors.[37] Their intervention combined several procedural and equipment-oriented components: a) basic electronic prescription without clinical decision support tools, b) standardised labeling of continuously infused medications, c) identical models of perfusors/infusion pumps, and d) part-time pharmacist involvement to check all electronic prescriptions for drug-dosing adjustments for hepatic and/or renal dysfunction, drug interactions, and compatibility checking of the patient's intravenous medications.[37]

Focus area "Checklists for surgical procedures and interventional diagnostics". Our review identified three studies investigating interventions aiming at standardised procedures for the checking of safety critical information before, during and after surgical procedures and interventional diagnostics.[10,24,31] Two of these studies assessed the checklist performance rather than their effects on patient care and patient outcomes. During their observations, Cullati and colleagues found high compliance rates with less validation of checklist items during sign-out.[10] Mascherek and colleagues found a significant increase in self-reported frequency of use of the checklist in a national programme as well as improved knowledge about and satisfaction with checklist use.[24] Only the study by Lübbeke and colleagues who found an effect on patient outcome measures with a significant reduction in reoperation rates due to surgical side infections.[31] All other outcome measures showed no significant change.

Another two studies also employed a procedural standardisation approach but were limited to a pre-induction checklist for the anaesthesia team rather than the information exchange on safety-critical aspects among the theatre team. Tscholl and colleagues[34] found no statistically significant effect on clinical performance but on team-level outcomes such as knowledge of safety-critical information and perception of teamwork

and safety. Kandler and colleagues found a positive effect of a video-based educational approach to increase protocol adherence focusing on the performance of safety-critical tasks.[23]

Focus area "Rapid-response systems including the use of early-warning scores". Our review identified no studies evaluating the effects of introducing a rapid-response system or medical emergency teams in a Swiss hospital setting. Also, we were unable to identify empirical evidence on the introduction or use of early-warning scores (EWS) to detect deteriorating patients at an early stage. These two findings are interdependent because EWS are frequently part of a rapid response system. EWS support clinical staff in the peripheral wards in identifying patients that could benefit from advanced care by a medical emergency team to prevent further deterioration possibly leading to a medical emergency and (re-)admission to a unit that provides a higher level of care.

Focus area "(Simulation-based) Team Training". Our review identified three studies investigating team training interventions with very different aims for improvement.[26,28,36] The study by Rosenthal and colleagues showed a positive training effect concerning surgical trainees' technical performance.[26] However, this study should be considered a pilot study because the intervention was not implemented within the organisation. In contrast, the study by Haller and colleagues was implemented for all members of the obstetrics team in a large hospital but used only self-report data to evaluate the effects on participants' learning instead of more objective indicators of team performance or patient safety.[28] The study by Zimmermann and colleagues found positive training effects concerning technical and non-technical aspects of performance, but again used self-reports.[36] In addition, this study reports on the detection of latent safety threats detected during the simulation sessions that have led to system changes in the participating unit.

Other interventions. In addition to the focus areas of this review, we identified several other intervention studies conducted in a Swiss healthcare context. Two studies targeted triage performance based on predefined criteria of patient requirements and associated risks. One study showed a positive effect of a merger of two emergency dispatch centres on avoiding under- or over-triage of patients[25] and one intervention showed improvements in patient transfers being performed according to predefined requirements (e.g. concerning accompanying staff member category).[35] One study investigating the effects of the 50-hour working time restriction found no effects on the frequency of medical complications intra- and post-operatively, but contrary to the intended effects a higher post-operative surgical complication rate and higher in-hospital mortality after the intervention.[30] Only one study focused on learning from incidents by investigating M&M conferences and the interventions derived from these conferences.[21] While there is no direct link to improved patient outcomes there is a clear effect on the understanding and management of safety problems at the local level. Finally, one study evaluating a patient safety advisory found that patients in the intervention group were less likely to experience adverse incidents but no change in the performance of safety-relevant behaviours.[33]

Study quality. For each study, the overall score resulting from the quality rating is included in Table 1. The rating of all items for each study is provided in Appendix 1. In general, study quality was found to be high (M=12.45, SD=1.02) with ratings ranging

from 10 to 14 out of 15 possible points. Table 2 gives a detailed overview of how many studies fulfilled each quality item and indicates strengths and weaknesses in the field. Overall, research questions were clearly stated, data collection methods and analyses were appropriate and the conclusions were clearly justified in all included studies. All studies were rated as reproducible and carried out with adequate samples resulting in high external validity. Five studies did not mention ethical issues in the text. However, we do not think that these issues were not addressed, but were not reported in the published article.

We would like to highlight three weaknesses that were prevalent in the intervention designs. First and most importantly, long-term effects of the studied interventions were only assessed in two studies using additional follow-up measurement.[28,35] One study partially fulfilled this aspect with multiple post-measures but over a short period of time[19]. Second, only half the studies adequately included control variables in their design. This presents a significant limitation for intervention studies. Third, only four studies used a design with a clear treatment and control group. The majority of studies (N=13) used a pre-post design which we rated as partially fulfilled (0.5 points), since this design is more likely to be affected by confounding variables that occur during the intervention period (e.g. other hospital wide changes or campaigns, increasing experience of participants over time).

Table 2: Overall results for each quality indicator to assess study quality

Quality indicator	Short description	Reference for source of item	No. of studies with item fulfilled	No. of studies with 'not mentioned' or 'not applicable'
Research question	Is the research question or hypothesis clearly stated?	7	20 (all)	0
Data collection	Are the methods used reliable and valid for the research question and context?	7	20 (all)	0
Analysis of results	Are the statistical or other methods of results analysis used appropriate?	7	20 (all)	0
Conclusion	Is it clear that the data justify the conclusions drawn?	7	20 (all)	0
Reproducibility	Could the study be repeated by other researchers?	7	20 (all)	0
External validity 1	Were those subjects who were prepared to participate representative of the entire population of investigation?	8	20 (all)	0
External validity 2	Were the places and facilities where the study was executed, representative of a real medical environment? *(Note: "0.5" points for simulation scenarios)*	8	20 (all)	0
External validity 3	Were the places and facilities where the study was executed, representative of a real medical environment?	7	20 (all)	0
Intervention 1	Are the interventions of interest clearly described?	8	19.5	1
Completeness of data	Have subjects dropped out? Is the attrition less than 50%? If applicable, is the questionnaire response rate acceptable (60% or above)?	7	18	1
Ethical issues	Were all relevant ethical issues addressed?	7	15.5	4
Prospective	Does the study look forwards in time rather than backwards?	7	13	0
Intervention 2	Is there a comparison between treatment and control group?	8	10.5	0
Control for confounding	Have multiple factors or variables been removed or accounted for where possible?	7	10	1
Intervention 3	Was there an additional follow up control measure after the intervention (to investigate long-term effects)?	7	2.5	0

*Each indicator was scored as 1=fulfilled, 0.5=partially fulfilled, 0=not fulfilled, and 'not mentioned'/'not applicable' which reduced the overall possible score

Discussion

This report provides an overview and synthesis of the available evidence on the degree to which patient safety strategies have been implemented in Swiss healthcare and what evidence exists on their effectiveness. In the following we provide a summary and critical reflection of the key findings of this review and make recommendations for future initiatives to enhance patient safety in Swiss healthcare.

Knowledge of implementation levels in Swiss healthcare

In Switzerland, as in other countries, surveys on the implementation of specific patient safety practices have been conducted.[9-16] These studies indicate moderate levels of adoption and do not allow for an evaluation of the overall approach to patient safety improvement due to a limited focus. Also, some of these studies were investigated at the level of healthcare organisations while others had a specialty or care setting focus. For example, one study not identified by our search strategy because only indexed in German and French, reports on the level of implementation of incident reporting in Swiss intensive care based on a survey conducted in 2004.[40] 65% of participating intensive care units indicated to use incident reporting. The study reports higher than average adoption and thus points at differences between care settings in terms of involvement in patient safety initiatives. However, since no data exists on the actual distribution and the data is already more than ten years old, this statement should be interpreted with caution.

Apart from these narrowly focused surveys, two national surveys on CRM in hospitals were conducted in 2007/08[41] and 2010[42] providing a descriptive overview of the maturity reached for different patient safety practices at the national level and allowing for an identification of success factors or enablers for CRM implementation.[9] These enablers can be seen as leading indicators making successful implementation more likely and thus provide guidance for the hospital leadership. On the one hand, having conducted these surveys sets Swiss healthcare apart from many other countries. Only Germany has published findings from a comparable national survey in 2010[43] and 2015[44] allowing at least in part for a cross-national comparison.[12] On the other hand, the potential of these surveys to guide and monitor national patient safety improvement initiatives has not been utilised. The second CRM survey conducted in 2010[42] explicitly aimed to evaluate the requirements for implementing a continuous national monitoring system for CRM practices in Switzerland. However, so far no funding has been made available to establish such a monitoring system.

Interventions to improve patient safety in a Swiss healthcare setting

This review found evidence for three of the four predefined focus areas and, given the small size of Switzerland, we were rather surprise by the number of studies included in this review.

The most frequent type of interventions included in this review aimed to **improve the safety of the medication use process**. This finding is not surprising given that medication safety has been an international patient safety priority for many years and that many studies have looked into the types and causes of medication-related adverse events in Swiss healthcare.[45,46] All interventions included in this review achieved

significant reductions in medication errors. However, some of them focused on single steps of the medication use process in a specific care setting thus limiting their impact. Only one study described a complex multi-facetted intervention project that could serve as a model for other care environments.[37] However, it has to be noted that the patient safety measure used in this study was less objective than the record review data used in other studies. Another intervention that has the potential for wider application is a change in workplace layout to minimise interruptions during safety-critical tasks.[22] While it may be difficult to introduce separate medication preparation rooms in existing units, alternative interventions such as the wearing of safety vests showed promising results in terms of reduced interruption rates in an initial evaluation.[47] However, this last study had to be excluded from this review as no patient safety measure was recorded.

We reviewed three interventions that introduced **checklists for surgical procedures**[10,24,31] and two for anaesthesia.[23,34] No studies reporting on similar interventions for other invasive procedures or interventional diagnostics were identified bin this review. The evaluation was limited to compliance with checklist use and adherence to the checklist items in all studies except for the one by Lübbeke and colleagues.[31] Given the strong focus of surgical societies internationally and in Switzerland on implementation of checklists for surgical procedures, it can be assumed that it is more widely established than indicated by this review. However, the positive effects on clinical performance, teamwork and communication during the procedure, improvements in post-operative care and patient outcomes documented by other studies[48-50] are not well documented for the Swiss healthcare context.

This review identified only limited evidence on the effectiveness of **(simulation-based) team training** interventions in Swiss healthcare. All three studies grouped into this category made use of simulation technology[26,28,36] with one focusing more on individual technical skills than on team aspects.[26] The limited number of studies makes it difficult to assess the level of evidence in this area. However, our finding that positive effects were found mainly on teamwork-related aspects instead of patient outcomes, that evaluations were based on surveys instead of changes in patient care and that follow-up measures were not used consistently is in line with much of the international literature.

Given that Switzerland has been one of the first countries in Europe to adopt simulation-based team training with the Department of Anesthesiology at the University Hospital Basel introducing patient simulators for research and training purposes in 1994[51,52], it is a rather surprising finding that the evidence on simulation-based team training interventions in Swiss healthcare is this limited. Also, some very active research groups studying team performance in acute care settings are based in Switzerland and have contributed significantly to the literature underpinning team training in these settings.[53-61] Given this background, we would have expected the number and quality of team training research to be higher. In this review, we identified no publications that evaluate other team training formats such as the internationally widely used approach TeamSTEPS.[62,63]

This contrast between a widespread use of at least some form of simulation-based team training in Swiss hospitals and the lack of published reports might be due to the methodological challenges of training hospital staff. There is pertinent evidence coming

from meta-analyses and reviews that team training has a positive effect on attitudes, learning and behaviour.[64,65] It can be assumed that this change then positively influences patient safety. However, there is insufficient evidence to support long-term impacts. It is difficult to implement a comprehensive team training initiative reaching a majority of hospital staff. Compared to interventions targeting processes or tools (e.g. checklists, reporting systems) team training is often much more time and resource intensive and evaluations would require even more resources. Therefore, robust evidence is still scare. Future patient safety initiatives in Switzerland need to take on the challenges of rigorous testing of team training interventions including adequate controls and follow-up measurement to assess their long-term effects on patient outcomes.

While this review did not find empirical evidence on the effects of introducing **rapid-response systems** in a Swiss hospital setting with or without the use of **early-warning scores** (EWS), there are indications that this patient safety improvement strategy is starting to be considered. In 2017, the Swiss Academy of Medical Sciences launched a research project to develop recommendations for the implementation, necessary adaptions, and use of EWS in Swiss hospitals. The project consisted of two sub-studies: a) assess chief physicians' knowledge and attitudes towards EWS as well as the perceived need for introducing EWS and b) pilot EWS in one Swiss hospital. The main findings of the first study have been published[66] and showed limited knowledge of EWS-systems (43.2% of responding chief physicians) with only 20.3% reporting use of such systematic assessment tools. Given the 33% response rate of the survey this can be interpreted as rather low; especially in light of a 93.2% agreement with the statement that unnoticed clinical deterioration of patients is a problem for patient safety and the evidence from other countries on the positive effects on morbidity and mortality[67,68] by avoiding the so-called "failure to rescue".[69]

There are some **apparent gaps** in the spectrum of interventions and research approaches to assess their effectiveness identified by this review. First, in line with much of the research on the prevalence of adverse events in healthcare and the factors contributing to their occurrence or mitigation, the interventions included in this review were almost exclusively developed for the hospital setting. The **lack of improvement approaches targeting primary care settings** may reflect that patient safety research has addressed this setting much later but also that primary care is much more decentralised and thus requires different measurement approaches and collaborative implementation approaches. For example, Goetz and colleagues[70] conducted a longitudinal study in Swiss primary care showing the benefits of the systematic implementation and repeated measurement of the European Practice Assessment tool on a range of measures including quality and safety. Specifically, they found significant improvements concerning process-oriented outcomes such as "complaint management", "analysis of critical incidents", "quality development, quality policy" and "detection of quality and safety problems". While this study did not investigate effects on patient outcomes, the findings are in line with those of other studies indicating that a systematic, strategically guided approach[9] and collaboration among healthcare professionals in implementing this approach, contributes to improvements in established indicators of the quality and safety of care.[71] Another study in primary care investigated the effects of quality circles between general practitioners and pharmacists finding positive long-term effects concerning cost efficiency.[72] This points at the relevance of

boundary-spanning interventional approaches to fully utilize the complementary expertise of other disciplines and bridge the gaps between healthcare settings. While both studies were not included in this review for reasons discussed beforehand with the scientific lead, they provide valuable sources of information on interventional approaches or successful implementation strategies.

Second, the **methodological approaches** sometimes limit the value of the information gained from the studies included in this review. The patient safety measures used to evaluate the interventions included in this review were sometimes limited to proxy measures with only two studies using actual patient outcome data. The most frequently used patient safety measures were error rates and compliance. This finding is related to the large proportion of reviewed interventions that aimed for standardisation and introduced technological systems, especially along the medication use process, to enforce standardised task performance. While the detection of medication errors in patient records can easily be broken down into different types of errors using internationally established classification systems, they do not provide information on the ways in which the intervention contributed to the observed error reduction or, in case of no intervention effect, what might have prevented this. This discussion is not unique to studies in Swiss healthcare and is gaining importance when aiming to evaluate complex patient safety interventions.[73] Further, we observed that most studies used a pre-post-test design which is more likely to be affected by confounding variables than a design using a treatment and control group. Also, the long-term effects of the interventions were not adequately addressed. Although these two design features will increase the complexity of future intervention studies this will result in more robust data, allow for an understanding of the mechanisms behind the effects and learn more about the sustainability of patient safety interventions.

Third, many of the interventions identified in this review targeted a specific procedural step (e.g. medication history taking) instead of multi-facetted complex interventions to improve patient safety. Our review found **no attempt of addressing organisation- or system-wide issues underpinning many patient safety problems** such as a safety-oriented design of the work environment, managerial strategies such as the composition of healthcare teams (for example concerning the skill grade mix[74]) and organisational factors impacting on healthcare providers' health[75-77] through targeted interventions. While this is in line with some of the patient safety practices recommended for implementation[1,2], that are often focused on clinical aspects (e.g. bundle interventions to prevent central-line associated bloodstream infections) and were excluded from this review.

Recommendations for monitoring of improvement efforts and implementation research

As indicated by this review, the scientific literature does not provide a sufficient basis for understanding the level of implementation as well as the barriers and facilitators of successful and sustainable implementation of patient safety improvement. One possibility would be the continuation of the CRM survey to monitor implementation of patient safety practices at a national level to understand the maturity level of participating organisations and identify support needs. Such a **national monitoring system** would have to be embedded in a sustainable system for regularly updating the

content based on new developments in the patient safety literature and linked to strategic goals to drive national safety programmes.

Internationally the focus of patient safety research has shifted towards improvement and implementation science and many countries have begun to address the lack of progress at a national level. Such an approach requires leadership based on a strategic plan for patient safety improvement at the national level. **Internationally recommended patient safety improvement strategies** should be encouraged[2] and the evaluation of their implementation should be a requirement. For example, given the evidence on patient harm resulting from inadequate management of deteriorating patients, medical societies need to make the combined introduction of rapid-response systems including the use of early-warning scores a focus of their patient safety initiatives. In implementing and evaluating these strategies, the need for adaptation to Swiss healthcare should be addressed explicitly to facilitate wider dissemination. While the national quality improvement programmes in Switzerland have partially addressed this issue, the duration of comparable projects in other countries has been considerably longer[78] and substantial research funding was made available to evaluate not only short-term effects. A deeper understanding of the barriers and facilitators to implement and sustain change is required to get more than just pilot projects that are not sustainable without the external funding. The involvement of front-line staff responsible for implementing improvements are critical to avoid that initiatives are abandoned shortly after their introduction.[79] Also, implementation research has pointed out the relevance of organisational readiness[80,81] and culture[79,82] for the acceptance and continued support of improvement efforts.

Finally, this review found patient safety improvement efforts in Swiss healthcare to be concentrated on the hospital sector. Thus, patient safety improvement efforts need to **expand to other healthcare settings** with the necessary adaptations or as new developments. Studies on patient safety issues in mental health and in primary care have been conducted in Switzerland already[83-85] thus providing first empirical insights into the most relevant areas for improvement and necessary adaptations.

In summary, we make the following recommendations:

- Patient safety improvement efforts and the accompanying research need to be expanded to other healthcare settings beyond the hospital sector. This will require adaptations of existing strategies or new developments depending on the specific patient safety issues and the care context.
- Patient safety improvement requires complex interventions and accordingly sophisticated research designs for evaluation.
- Given that even promising interventions often are abandoned shortly after the end of the project phase point at a need for support in the transition between the study period and the routine practice. The involvement of front-line staff responsible for implementing improvements and longer project durations are critical to sustain the effects long-term.
- A national monitoring system for patient safety improvement that is adaptive new developments in the patient safety literature and linked to strategic patient safety goals to drive national safety programmes should be implemented at the national level.

- To ensure these changes a stronger commitment at the policy level including appropriate funding for large-scale projects is required.

Limitations

First, although we employed a very broad search strategy, relevant studies may have been missed. This can partly be attributed to a lack of consensus concerning the definition of patient safety interventions but may also be due to characteristics of our search strategy such as the exclusion of sources other than scientific journals or the limitation to articles published in English, French or German and the use of English search terms. However, we compensated for this limitation by thoroughly screening references instead of using restrictive search terms for the initial database-search. Second, the reporting quality of the included articles naturally influenced the quality of data extraction. We account for this limitation by conducting a structured assessment of quality. This also helped in exploring the strengths and weaknesses of the intervention studies included in this review and informed the recommendations for future research. Third, qualitative studies might have provided additional insights, especially concerning barriers and facilitators. Nevertheless, we excluded purely qualitative studies because they did not allow for assessing either the level of implementation or the effects of patient safety interventions which were the focus of this review. Finally, because the selected studies were conducted almost exclusively in the hospital setting the implications of this review for patient safety interventions in other healthcare settings, such as primary care, may be limited.

Conclusions

Despite being limited to Switzerland, this review identified considerable research evidence for a number of patient safety improvements. Nevertheless, publishing more actively on the improvement efforts occurring in Swiss healthcare such as for example the National Patient Safety week is one area for improvement. The challenges for the next years will be to expand patient safety research and improvement beyond the hospital sector, to design and evaluate complex intervention approaches and to use sophisticated research designs for their evaluation. Switzerland is well positioned to tackle these challenges given the research capacity of patient safety experts. However, to sustainably implement such a research-based improvement programme at a national level a stronger commitment including appropriate funding for large-scale projects is required.

Refrences

1. Pham JC, Aswani MS, Rosen M, Lee H, Huddle M, Weeks K, Pronovost PJ. Reducing medical errors and adverse events. Annual review of medicine 2012; 63: 447–63.
2. Shekelle PG, Pronovost PJ, Wachter RM, McDonald KM, Schoelles K, Dy SM, Shojania K, Reston JT, Adams AS, Angood PB, Bates DW, Bickman L, Carayon P, Donaldson L, Duan N, Farley DO, Greenhalgh T, Haughom JL, Lake E, Lilford R, Lohr KN, Meyer GS, Miller MR, Neuhauser DV, Ryan G, Saint S, Shortell SM, Stevens DP, Walshe K. The top patient safety strategies that can be encouraged for adoption now. Ann Intern Med 2013; 158: 365-8.
3. Vincent C. (2012) The Essentials of Patient Safety. Retrieved from: http://www1.imperial.ac.uk/resources/5D671B2E-1742-454E-9930-ABE7E417856 1/vincentessentialsofpatientsafety2012.pdf. [www document]
4. Kohn LT, Corrigan JM, Donaldson MS. To err is human: building a safer health system. Washington, D.C.: National Academy Press, 1999.
5. Sendlhofer G, Schaffer P. A tri-national view on patient safety from Austria, Germany and Switzerland - are there any achievements up to now? Z Evidenz Fortbild Q 2016; 114: 1-4.
6. Kunz R, Burnand B, Schunemann H, Grading of Recommendations A, Evaluation Working G. The GRADE System. An international approach to standardize the graduation of evidence and recommendations in guidelines. Internist 2008; 49: 673-80.
7. Buckley S, Coleman J, Davison I, Khan KS, Zamora J, Malick S, Morley D, Pollard D, Ashcroft T, Popovic C, Sayers J. The educational effects of portfolios on undergraduate student learning: a Best Evidence Medical Education (BEME) systematic review. BEME Guide No. 11. Med Teach 2009; 31: 282-98.
8. Downs SH, Black N. The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. J Epidemiol Community Health 1998; 52: 377-84.
9. Briner M, Manser T, Kessler O. Clinical risk management in hospitals: strategy, central coordination and dialogue as key enablers. J Eval Clin Pract 2013;19:363-9.
10. Cullati S, Le Du S, Raë AC, Micallef M, Khabiri E, Ourahmoune A, Boireaux A, Licker M, Chopard P. Is the Surgical Safety Checklist successfully conducted? An observational study of social interactions in the operating rooms of a tertiary hospital. BMJ Qual Saf 2013; 22: 639-46.
11. Cullati S, Licker MJ, Francis P, Degiorgi A, Bezzola P, Courvoisier DS, Chopard P. Implementation of the surgical safety checklist in Switzerland and perceptions of its benefits: cross-sectional survey. PLoS One 2014; 9: e101915.
12. Manser T, Imhof M, Lessing C, Briner M. A cross-national comparison of incident reporting systems implemented in German and Swiss hospitals. Int J Qual Health Care 2017; 29: 349-59.
13. Mascherek AC, Schwappach DLB, Bezzola P. Frequency of use and knowledge of the WHO-surgical checklist in Swiss hospitals: A cross-sectional online survey. Patient Safety in Surgery 2013; 7.

14. McLennan S, Engel S, Ruhe K, Leu A, Schwappach D, Elger B. Implementation status of error disclosure standards reported by Swiss hospitals. Swiss Med Wkly 2013; 143: w13820.

15. Pfeiffer Y, Schwappach D. Taking up national safety alerts to improve patient safety in hospitals: The perspective of healthcare quality and risk managers. Z Evid Fortbild Qual Gesundhwes 2016; 110-111: 26-35.

16. Praplan-Rudaz I, Pfeiffer Y, Schwappach DLB. Implementation status of morbidity and mortality conferences in Swiss hospitals: a national cross-sectional survey study. Int J Qual Health Care 2018; 30: 257-64.

17. Prochaska JM. A Transtheoretical Model for Assessing Organizational Change: A Study of Family Service Agencies' Movement to Time-Limited Therapy. Fam Soc 2000.

18. Briner M, Kessler O, Pfeiffer Y, Wehner T, Manser T. Assessing hospitals' clinical risk management: Development of a monitoring instrument. BMC Health Serv Res 2010; 10: 337.

19. Voeffray M, Pannatier A, Stupp R, Fucina N, Leyvraz S, Wasserfallen JB. Effect of computerisation on the quality and safety of chemotherapy prescription. Quality and Safety in Health Care 2006; 15: 418-21.

20. Corbel A, Baud D, Chaouch A, Beney J, Csajka C, Panchaud A. Utility of an algorithm to increase the accuracy of medication history in an obstetrical setting. PLoS ONE 2016; 11.

21. Frey B, Doell C, Klauwer D, Cannizzaro V, Bernet V, Maguire C, Brotschi B. The Morbidity and Mortality Conference in Pediatric Intensive Care as a Means for Improving Patient Safety. Pediatr Crit Care Med 2016; 17: 67-72.

22. Huckels-Baumgart S, Baumgart A, Buschmann U, Schupfer G, Manser T. Separate Medication Preparation Rooms Reduce Interruptions and Medication Errors in the Hospital Setting: A Prospective Observational Study. J Patient Saf 2016.

23. Kandler L, Tscholl DW, Kolbe M, Seifert B, Spahn DR, Noethiger CB. Using educational video to enhance protocol adherence for medical procedures. Br J Anaesth 2016; 116: 662-9.

24. Mascherek AC, Bezzola P, Gehring K, Schwappach D. Effect of a two-year national quality improvement program on surgical checklist implementation. Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen 2016; 114: 39-47.

25. Moser A, Mettler A, Fuchs V, Hanhart W, Robert CF, Della Santa V, Dami F. Merger of two dispatch centres: does it improve quality and patient safety? Scandinavian journal of trauma, resuscitation and emergency medicine 2017; 25: 40.

26. Rosenthal R, Mujagic E, Jacob AL, Seelos R, Schafer J, Gurke L. Impact of an intensive 2-day endovascular training course on technical performance of trainees. Annals of vascular surgery 2013; 27: 1173-81.

27. Benoit E, Eckert P, Theytaz C, Joris-Frasseren M, Faouzi M, Beney J. Streamlining the medication process improves safety in the intensive care unit. Acta Anaesthesiologica Scandinavica 2012; 56: 966-75.

28. Haller G, Garnerin P, Morales MA, Pfister R, Berner M, Irion O, Clergue F, Kern C. Effect of crew resource management training in a multidisciplinary obstetrical setting. International Journal for Quality in Health Care 2008; 20: 254-63.

29. Huber T, Brinkmann F, Lim S, Schroder C, Stekhoven DJ, Marti WR, Egger RR. Implementation of an IT-guided checklist to improve the quality of medication history records at hospital admission. Int J Clin Pharm 2017; 39: 1312-19.

30. Kaderli R, Businger A, Oesch A, Stefenelli U, Laffer U. Morbidity in surgery: impact of the 50-hour work-week limitation in Switzerland. Swiss Med Wkly 2012; 142: w13506.

31. Lübbeke A, Hovaguimian F, Wickboldt N, Barea C, Clergue F, Hoffmeyer P, Walder B. Effectiveness of the surgical safety checklist in a high standard care environment. Medical care 2013; 51: 425–29.

32. Mir C, Gadri A, Zelger GL, Pichon R, Pannatier A. Impact of a computerized physician order entry system on compliance with prescription accuracy requirements. Pharm World Sci 2009; 31: 596-602.

33. Schwappach DLB, Frank O, Buschmann U, Babst R. Effects of an educational patient safety campaign on patients' safety behaviours and adverse events. Journal of Evaluation in Clinical Practice 2013; 19: 285-91.

34. Tscholl DW, Weiss M, Kolbe M, Staender S, Seifert B, Landert D, Grande B, Spahn DR, Noethiger CB. An Anesthesia Preinduction Checklist to Improve Information Exchange, Knowledge of Critical Information, Perception of Safety, and Possibly Perception of Teamwork in Anesthesia Teams. Anesth Analg 2015; 121: 948-56.

35. Wasserfallen JB, Meylan N, Schaller MD, Chioléro R, Fishman D. Impact of an intervention to control risk associated with patient transfer. Swiss Med Wkly 2008; 138: 211-18.

36. Zimmermann K, Holzinger IB, Ganassi L, Esslinger P, Pilgrim S, Allen M, Burmester M, Stocker M. Inter-professional in-situ simulated team and resuscitation training for patient safety: Description and impact of a programmatic approach. BMC Med Educ 2015; 15: 189.

37. Pagnamenta A, Rabito G, Arosio A, Perren A, Malacrida R, Barazzoni F, Domenighetti G. Adverse event reporting in adult intensive care units and the impact of a multifaceted intervention on drug-related adverse events. Annals of intensive care 2012; 2: 47.

38. Kobler I, Mascherek A, Bezzola P. Wie kann die Implementierung von Patientensicherheitsprogrammen gelingen? Ein Beispiel aus der Schweiz. Zeitschrift für Evidenz, Fortbildung und Qualität im Gesundheitswesen 2015; 109: 132-37.

39. Buerkle B, Rueter K, Hefler LA, Tempfer-Bentz EK, Tempfer CB. Objective Structured Assessment of Technical Skills (OSATS) evaluation of theoretical versus hands-on training of vaginal breech delivery management: a randomized trial. Eur J Obstet Gynecol Reprod Biol 2013; 171: 252-6.

40. Bocion C, Sennhauser FH, Frey B. Critical Incident Monitoring in schweizerischen Intensivstationen. Verbreitung, Einstellung und Faktoren, welche die Meldehäufigkeit beeinflussen. Bulletin des médecins suisses| Schweizerische Ärztezeitung| Bollettino dei medici svizzeri 2006; 87: 20.

41. Briner M, Kessler O, Pfeiffer Y, Wehner T, Manser T. Erste Schweizer Erhebung zum klinischen Risikomanagement im Spital: Zusammenfassung der Ergebnisse. Schweiz Arzteztg 2009; 90: 635-38.

42. Briner M. Zweites nationales Monitoring zum klinischen Risikomanagement im Spital: Zusammenfassung der Ergebnisse 2010. Schweiz Arzteztg 2011; 92: 463-66.

43. Lauterberg J, Blum K, Briner M, Lessing C. Befragung zum Einführungsstand von klinischem Risiko-Management (kRM) in deutschen Krankenhäusern. Abschlussbericht available online at http://www.ifpsbonn.de/projekte/projekte/ abschlussbericht-befragung-krm-2010.pdf. Bonn: Institut für Patientensicherheit der Universität Bonn, 2012.

44. Manser T, Frings J, Heuser G, Mc Dermott F. The German clinical risk management survey for hospitals: Implementation levels and areas for improvement in 2015. Z Evid Fortbild Qual Gesundhwes 2016; 114: 28-38.

45. Huckels-Baumgart S, Manser T. Identifying medication error chains from critical incident reports: a new analytic approach. Journal of clinical pharmacology 2014; 54: 1188-97.

46. Meyer-Massetti C, Conen D. Assessment, frequency, causes, and prevention of medication errors - a critical analysis. Therapeutische Umschau 2012; 69: 347-52.

47. Huckels-Baumgart S, Niederberger M, Manser T, Meier CR, Meyer-Massetti C. A combined intervention to reduce interruptions during medication preparation and double-checking: a pilot-study evaluating the impact of staff training and safety vests. J Nurs Manag 2017; 25: 539-48.

48. Haynes AB, Weiser TG, Berry WR, Lipsitz SR, Breizat AH, Dellinger EP, Herbosa T, Joseph S, Kibatala PL, Lapitan MC, Merry AF, Moorthy K, Reznick RK, Taylor B, Gawande AA, Safe Surgery Saves Lives Study G. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med 2009; 360: 491-9.

49. Haugen AS, Søfteland E, Almeland SK, Sevdalis N, Vonen B, Eide GE, Nortvedt MW, Harthug S. Effect of the World Health Organization checklist on patient outcomes: a stepped wedge cluster randomized controlled trial. Annals of surgery 2015; 261: 821–28.

50. Russ S, Rout S, Sevdalis N, Moorthy K, Darzi A, Vincent C. Do safety checklists improve teamwork and communication in the operating room? A systematic review. Annals of surgery 2013; 258: 856–71.

51. Marsch S. Team oriented medical simulation. In: Henson LC, Lee AC, eds. Simulators in Anesthesiology Education. New York: Plenum Press, 1998: 51-55.

52. Sexton B, Marsch S, Helmreich R, Betzendoerfer D, Kocher T, Scheidegger D, Team T. Participant evaluation of team oriented medical simulation. Simulators in Anesthesiology Education 1998: 109-10.

53. Kuenzle B, Zala-Mezo E, Wacker J, Kolbe M, Spahn DR, Grote G. Leadership in anaesthesia teams: the most effective leadership is shared. Qual Saf Health Care 2010; 19: e46.

54. Kolbe M, Burtscher MJ, Wacker J, Grande B, Nohynkova R, Manser T, Spahn DR, Grote G. Speaking up is related to better team performance in simulated anesthesia inductions: an observational study. Anesth Analg 2012; 115: 1099-108.

55. Tschan F, Semmer NK, Hunziker S, Kolbe M, Jenni N, Marsch SU. Leadership in different resuscitation situations. Trends in Anaesthesia and Critical Care 2014; 4: 32–36.
56. Marsch SC, Muller C, Marquardt K, Conrad G, Tschan F, Hunziker PR. Human factors affect the quality of cardiopulmonary resuscitation in simulated cardiac arrests. Resuscitation 2004; 60: 51-6.
57. Tschan F, Semmer N, Gautschi D, Hunziker PR, Spychiger M, Marsch S. Leading to recovery: group performance and coordinative activities in medical emergency driven teams. Human Performance 2006; 19: 277-304.
58. Semmer NK, Tschan F, Seelandt J, Keller S, Kurmann A, Candinas D, Beldi G. Impact of Communication within the surgical team on surgical Site Infections: Content, Time, and tasks. 2014.
59. Keller S, Tschan F, Semmer NK, Holzer E, Candinas D, Brink M, Beldi G. Noise in the Operating Room Distracts Members of the Surgical Team. An Observational Study. World J Surg 2018; 42: 3880-87.
60. Schmutz JB, Lei ZK, Eppich WJ, Manser T. Reflection in the heat of the moment: The role of in-action team reflexivity in health care emergency teams. Journal of Organizational Behavior 2018; 39: 749-65.
61. Parker SH, Schmutz JB, Manser T. Training Needs for Adaptive Coordination: Utilizing Task Analysis to Identify Coordination Requirements in Three Different Clinical Settings. Group & Organization Management 2018; 43: 504-27.
62. Ballangrud R, Husebo SE, Hall-Lord ML. Cross-cultural validation and psychometric testing of the Norwegian version of the TeamSTEPPS(R) teamwork perceptions questionnaire. BMC Health Serv Res 2017; 17: 799.
63. Beiler J, Opper K, Weiss M. Integrating Research and Quality Improvement Using TeamSTEPPS: A Health Team Communication Project to Improve Hospital Discharge. Clin Nurse Spec 2019; 33: 22-32.
64. O'Dea A, O'Connor P, Keogh I. A meta-analysis of the effectiveness of crew resource management training in acute care domains. Postgraduate medical journal 2014; 90: 699-708.
65. Hughes AM, Gregory ME, Joseph DL, Sonesh SC, Marlow SL, Lacerenza CN, Benishek LE, King HB, Salas E. Saving lives: A meta-analysis of team training in healthcare. J Appl Psychol 2016; 101: 1266-304.
66. Richard A, Frank O, Schwappach D. Chief physicians' attitudes towards early warning score systems in Switzerland: Results of a cross-sectional survey. J Eval Clin Pract 2018; 24: 331-37.
67. Dacey MJ, Mirza ER, Wilcox V, Doherty M, Mello J, Boyer A, Gates J, Brothers T, Baute R. The effect of a rapid response team on major clinical outcome measures in a community hospital. Critical Care Medicine 2007; 35: 2076-82.
68. Rashid MF, Imran M, Javeri Y, Rajani M, Samad S, Singh O. Evaluation of rapid response team implementation in medical emergencies: A gallant evidence based medicine initiative in developing countries for serious adverse events. Int J Crit Illn Inj Sci 2014; 4: 3-9.
69. Ghaferi AA, Birkmeyer JD, Dimick JB. Hospital volume and failure to rescue with high-risk surgery. Med Care 2011; 49: 1076-81.

70. Goetz K, Hess S, Jossen M, Huber F, Rosemann T, Brodowski M, Künzi B, Szecsenyi J. Does a quality management system improve quality in primary care practices in Switzerland? A longitudinal study. BMJ Open 2015; 5.

71. Staines A, Amherdt I, Lecureux E, Petignat C, Eggimann P, Schwab M, Pittet D. Hand Hygiene Improvement and Sustainability: Assessing a Breakthrough Collaborative in Western Switzerland. Infect Control Hosp Epidemiol 2017;38: 1420-27.

72. Niquille A, Ruggli M, Buchmann M, Jordan D, Bugnon O. The nine-year sustained cost-containment impact of swiss pilot physicians-pharmacists quality circles. The Annals of pharmacotherapy 2010; 44: 650-7.

73. Petticrew M, Anderson L, Elder R, Grimshaw J, Hopkins D, Hahn R, Krause L, Kristjansson E, Mercer S, Sipe T, Tugwell P, Ueffing E, Waters E, Welch V. Complex interventions and their implications for systematic reviews: A pragmatic approach. International journal of nursing studies 2015; 52: 1211–16.

74. Aiken LH, Sloane D, Griffiths P, Rafferty AM, Bruyneel L, McHugh M, Maier CB, Moreno-Casbas T, Ball JE, Ausserhofer D, Sermeus W, Heede KVD, Lesaffre E, Diya L, Smith H, Jones S, Kinnunen J, Ensio A, Jylhä V, Busse R, Zander B, Blümel M, Mantas J, Zikos D, Diomidous M, Scott A, Matthews A, Staines A, Sjetne IS, Holter IM, Brzostek T, Kózka M, Brzyski P, Fuentelsaz-Gallego C, Gonzalez-María E, Gomez-Garcia T, Tishelman C, Lindqvist R, Smeds L, De Geest S, Schubert M, Schwendimann R, Heinen M, Schoonhoven L, Van Achterberg T, For the RNCC. Nursing skill mix in European hospitals: Cross-sectional study of the association with mortality, patient ratings, and quality of care. BMJ Qual Saf 2017; 26: 559-68.

75. Aiken LH. Hospital Nurse Staffing and Patient Mortality, Nurse Burnout, and Job Dissatisfaction. JAMA 2002; 288: 1987.

76. Teng CI, Shyu YI, Chiou WK, Fan HC, Lam SM. Interactive effects of nurse-experienced time pressure and burnout on patient safety: a cross-sectional survey. Int J Nurs Stud 2010; 47: 1442-50.

77. Welp A, Meier LL, Manser T. Emotional exhaustion and workload predict clinician-rated and objective patient safety. Front Psychol 2015; 5: 1573.

78. Foundation TH. Continuous improvement of patient safety. The case for change in the NHS. London: The Health Foundation, 2015.

79. Dixon-Woods M, Baker R, Charles K, Dawson J, Jerzembek G, Martin G, McCarthy I, McKee L, Minion J, Ozieranski P, Willars J, Wilkie P, West M. Culture and behaviour in the English National Health Service: overview of lessons from a large multimethod study. BMJ quality & safety 2014; 23: 106-15.

80. Burnett S, Benn J, Pinto A, Parand A, Iskander S, Vincent C. Organisational readiness: exploring the preconditions for success in organisation-wide patient safety improvement programmes. Qual Saf Health Care 2010; 19: 313-17.

81. Weiner B. A theory of organizational readiness for change. Implement Sci 2009; 4.

82. McCulloch P, Mishra A, Handa A, Dale T, Hirst G, Catchpole K. The effects of aviation-style non-technical skills training on technical performance and outcome in the operating theatre. Qual Saf Health Care 2009; 18: 109-15.

83. Mascherek AC, Schwappach DL. Patient safety priorities in mental healthcare in Switzerland: a modified Delphi study. BMJ Open 2016; 6: e011494.

84. Richard A, Mascherek AC, Schwappach DLB. Patient safety in the care of mentally ill people in Switzerland: Action plan 2016. Pflege 2017; 30: 357-64.

85. Gehring K, Schwappach DLB, Battaglia M, Buff R, Huber F, Sauter P, Wieser M. Frequency of and harm associated with primary care safety incidents. Am J Managed Care 2012; 18: E323-E37.

Appendix 1. Quality ratings for each article

Quality items	Benoit et al. 2012[27]	Corbel et al. 2016[20]	Cullati et al. 2013[10]	Frey et al. 2016[21]	Haller et al. 2008[28]	Huber et al. 2017[29]
Research question - Is the research question(s) or hypothesis clearly stated?	1	1	1	1	1	1
Data collection methods - Are the methods used reliable and valid for the research question and context?	1	1	1	1	1	1
Analysis of results - Are the statistical or other methods of results analysis used appropriate?	1	1	1	1	1	1
Conclusions - Is it clear that the data justify the conclusions drawn?	1	1	1	1	1	1
Reproducibility - Could the study be repeated by other researchers?	1	1	1	1	1	1
External Validity 1 - Were the subjects asked to participate in the study representative of the entire population of investigation?	1	1	1	1	1	1
External Validity 2 - Were those subjects who were prepared to participate representative of the entire population of investigation?	1	1	1	1	1	1
External Validity 3 - Were the places and facilities where the study was executed, representative of a real medical environment?	1	1	1	1	1	1
Intervention 1 Are the interventions of interest clearly described?	1	1	1	1	1	1
Completeness of data - Have subjects dropped out? Is the attrition less than 50%? Is the questionnaire response rate acceptable (60% or above)?	1	1	1	1	1	1
Ethical issues - Were all relevant ethical issues addressed?	1	0.5	not mentioned	1	1	1
Prospective - Does the study look forwards in time rather than backwards?	0	0	1	1	1	1
Intervention 2 Is there a comparison between treatment and control group?	0.5	1	0	0	0.5	0.5
Control for confounding - Have multiple factors or variables been removed or accounted for where possible?	1	1	1	not applicable	0	1
Intervention 3 Was there an additional follow up control measure after the intervention (to check long-term effects)?	0	0	0	0	1	0

Appendix 1 (continued). Quality ratings for each article

Quality items	Huckels et al. 2016[22]	Kaderli et al. 2012[31]	Kandler et al. 2016[23]	Lübbeke et al. 2013[32]	Mascherek et al. 2016[24]	Mir et al. 2009[33]	Moser et al. 2017[25]
Research question - Is the research question(s) or hypothesis clearly stated?	1	1	1	1	1	1	1
Data collection methods - Are the methods used reliable and valid for the research question and context?	1	1	1	1	1	1	1
Analysis of results - Are the statistical or other methods of results analysis used appropriate?	1	1	1	1	1	1	1
Conclusions - Is it clear that the data justify the conclusions drawn?	1	1	1	1	1	1	1
Reproducibility - Could the study be repeated by other researchers?	1	1	1	1	1	1	1
External Validity 1 - Were the subjects asked to participate in the study representative of the entire population of investigation?	1	1	1	1	1	1	1
External Validity 2 - Were those subjects who were prepared to participate representative of the entire population of investigation?	1	1	1	1	1	1	1
External Validity 3 - Were the places and facilities where the study was executed, representative of a real medical environment?	1	1	1	1	1	1	1
Intervention 1 Are the interventions of interest clearly described?	1	1	1	1	1	1	1
Completeness of data - Have subjects dropped out? Is the attrition less than 50%? Is the questionnaire response rate acceptable (60% or above)?	1	1	not applicable	1	0	1	1
Ethical issues - Were all relevant ethical issues addressed?	1	1	1	not mentioned	1	not mentioned	1
Prospective - Does the study look forwards in time rather than backwards?	1	1	1	0	0	0	1
Intervention 2 Is there a comparison between treatment and control group?	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Control for confounding - Have multiple factors or variables been removed or accounted for where possible?	1	0	1	1	1	0	0
Intervention 3 Was there an additional follow up control measure after the intervention (to check long-term effects)?	0	0	0	0	0	0	0

Appendix 1 (continued). Quality ratings for each article

Quality items	Pagnamenta et al. 2012[38]	Rosenthal et al. 2013[26]	Schwappach et al. 2013[34]	Tscholl et al. 2015[35]	Voeffray et al. 2006[19]	Wasserfallen et al. 2008[36]	Zimmermann et al. 2015[37]
Research question - Is the research question(s) or hypothesis clearly stated?	1	1	1	1	1	1	1
Data collection methods - Are the methods used reliable and valid for the research question and context?	1	1	1	1	1	1	1
Analysis of results - Are the statistical or other methods of results analysis used appropriate?	1	1	1	1	1	1	1
Conclusions - Is it clear that the data justify the conclusions drawn?	1	1	1	1	1	1	1
Reproducibility - Could the study be repeated by other researchers?	1	1	1	1	1	1	1
External Validity 1 - Were the subjects asked to participate in the study representative of the entire population of investigation?	1	1	1	1	1	1	1
External Validity 2 - Were those subjects who were prepared to participate representative of the entire population of investigation?	1	1	1	1	1	1	1
External Validity 3 - Were the places and facilities where the study was executed, representative of a real medical environment?	1	1	1	1	1	1	1
Intervention 1 Are the interventions of interest clearly described?	1	1	1	1	1	0.5	1
Completeness of data - Have subjects dropped out? Is the attrition less than 50%? Is the questionnaire response rate acceptable (60% or above)?	1	1	1	1	1	1	1
Ethical issues - Were all relevant ethical issues addressed?	1	1	1	1	1	1	not mentioned
Prospective - Does the study look forwards in time rather than backwards?	1	1	1	1	0	1	0
Intervention 2 Is there a comparison between treatment and control group?	0.5	1	1	1	0.5	0.5	0
Control for confounding - Have multiple factors or variables been removed or accounted for where possible?	1	0	0	1	0	0	0
Intervention 3 Was there an additional follow up control measure after the intervention (to check long-term effects)?	0	0	0	0	0.5	1	0

Swiss National Report on Quality and Safety in Healthcare

The state of quality and safety in Swiss healthcare

Author: Swiss Society for Quality Management in Health Care (sQmh)

Contact address: Philipp Schneider, St. Alban-Rheinweg 54, 4052 Basel
mail.schneider@bluewin.ch
or
sQmh Secretariat, Bahnhofstrasse 55, 5001 Aarau, info@sqmh.ch

Summary

The sQmh is the connecting element for quality issues in healthcare which tries to involve the various participants and stakeholders and establish a constructive dialogue. From the sQmh's point of view, the discussion and work with quality issues in the healthcare system has seen an extreme increase over the last fifteen to twenty years, and has been intensified. This diversity of activities is gratifying, and some of the objectives and improvements have been achieved. From the user's point of view, however, the results are viewed critically, and the lack of an overall concept is criticised. Using a few examples, the report shows that requirements that require organisations to put in a lot of effort that makes little sense, as well as a lack of quality in measurements and key figures, call into question the legitimate efforts to achieve transparency. This triggers a critical to negative attitude on the part of those affected. Experts at grass roots level (quality managers) and users/service providers should be increasingly involved to avoid the development of further meaningless measurements of "non-quality" and the creation of further false incentives. The inclusion of users should be assured by giving the sQmh a seat on federal government's quality commission.

Zusammenfassung

Die sQmh ist das verbindende Element für Qualitätsfragen im Gesundheitswesen, das versucht, die vielfältig Beteiligten einzubinden und einen konstruktiven Dialog herzustellen. Aus Sicht der sQmh hat die Auseinandersetzung und die Arbeit mit Qualitätsfragen im Gesundheitswesen in den letzten fünfzehn bis zwanzig Jahren extrem zugenommen und wurde vertieft geführt. Diese Vielfalt an Aktivitäten ist erfreulich. Einige der angestrebten Ziele und Verbesserungen wurden erreicht. Aus Sicht der Anwender werden jedoch die Resultate kritisch beurteilt und ein fehlendes Gesamtkonzept bemängelt. Anhand einiger Beispiele wird im Report gezeigt, dass Vorgaben, die für die Organisation viel, aber oft wenig nachvollziehbaren Aufwand bedeuten, sowie ungelöste Probleme bei Messungen und Kennzahlen, die eigentlich berechtigten Bemühungen nach Transparenz in Frage stellen. Dadurch wird bei den Betroffenen eine kritische bis negative Haltung ausgelöst. Mit dem vermehrten Einbezug von Fachleuten der Basis (Qualitätsmanager) und der Anwender/Leistungserbringer soll vermieden werden, dass weitere „Nicht-Qualität"-Messungen ohne Mehrwert entwickelt und damit weitere falsche Anreize gesetzt werden. Der Einbezug der Anwender durch einen Sitz der sQmh in der Qualitätskommission des Bundes würde die Vernetzung zur Basis sicherstellen.

Background

In its capacity as an influential and broadly recognised expert body in matters related to healthcare quality management, since its establishment in 2003 the sQmh has guided, observed and supported activities and developments in quality and risk management. The sQmh's members include the majority of hospitals in German-speaking Switzerland and organisations in the spitex (home nursing), old people's and nursing home sectors. Together with its counterparts in Germany and Austria (the Deutsche Gesellschaft für Qualitätsmanagement in der Gesundheitsversorgung e.V. (GQMG) and the Austrian Fachgesellschaft für Qualität und Sicherheit im Gesundheitswesen (ASQS)), the sQmh forms a trinational community that aims to discuss and develop quality matters and stage joint events.

On a national level the sQmh sees itself as a connecting element in healthcare, endeavouring to involve the wide range of parties concerned (acute care, rehabilitation, psychiatric and long-term care, as well as insurance companies, pharma and policymakers) and build constructive dialogue, within the framework of symposia, working groups devoted to specific issues, or bilateral projects. Building on the conviction that quality is a fundamental attitude that adds business value, the sQmh's endeavours are geared to sustainable quality-related work. This means that quality is more than a mere glossy brochure or marketing instrument, and always involves leadership and aspects of ethics and morality as well. From the outset, the sQmh has also advocated the role of quality managers and their status within healthcare as a whole and within individual organisations. One of the keys to assuring quality is for quality professionals to perform, co-create and develop their role in line with the requirements. The Swiss Report is also to be seen in this light.

Snapshot of current situation

In the last 15 to 20 years there has been growing and increasingly in-depth engagement with and work on issues of quality management in healthcare. This is reflected both in the number of organisations and research projects explicitly devoted to quality, and in the way existing bodies, professional associations and care providers have engaged and intensified their efforts. In addition to this, there has been massively greater emphasis on quality metrics, key performance indicators, internal and external audits, and patient satisfaction surveys, which in turn has triggered a process of professionalization, particularly on the inpatient side. In this context, clinical risk management has also become much more important as a component of quality management. These days practically all hospitals in Switzerland use a clinical incident reporting system (CIRS) and employ qualified specialists, sometimes in their own specialist departments and/or teams, often reporting direct to management, as part of their quality and risk management efforts. The focus on quality has been further intensified by the new hospital funding arrangements and the introduction of diagnosis related grouping (DRG) in acute care.

This variety of activities and endeavours is gratifying, and in some cases the desired and targeted improvements and targets have been met. Examples include the way error reports, audits and certifications are handled.

Unresolved issues

The successes achieved so far have been reported frequently and with gusto, both when it comes to documenting the quality of the Swiss healthcare system and averting more stringent measures planned by the regulators. Users, by contrast – the professionals involved and affected at the grass roots level – view the results more critically and question the alleged successes. Seen from this point of view, until now there has been a lack of an authoritative, generally accepted overall concept (where and what is the whole picture). There are justified doubts as to the efficacy of current efforts to assure and improve quality, and as to whether the essential quality management issues are really being addressed in more depth. Particularly when it comes to obligatory measurement and the quality and impact of individual indicators, scepticism prevails as to whether the desired improvements in the quality of treatment and care can be achieved. An example of this is the ANQ's decubitus ulcer measurements, which are conducted several times a year at great effort but which fail to bring organisations any new insight. Another example is the ongoing debate on rehospitalisation rates. Here there are justified doubts as to whether this metric really constitutes a quality indicator. The metric fails to capture deliberate and meaningful cooperation between hospitals, instead presenting it as rehospitalisation! These examples show that quality is still measured inadequately and on a fragmented basis. This is problematic, and possibly even counterproductive, from the perspective of increasing KPI transparency. It should also be pointed out that measurements of falls, decubitus ulcers, etc., are actually indicators of a lack of quality rather than of the presence of quality. Interfaces and points of cooperation are largely neglected, and as a result each institution assures and manages quality more or less for itself. To a large extent there is no cross-sectoral approach to quality management, and the requirements ignore the fact that in integrated care the majority of patients often go along the entire path from referrer to acute hospital and subsequent institution. To date the federal government has not managed to adopt and enforce a clear, all-encompassing stance and position on quality. In this connection, reference should also be made to the 2015 dispatch on the new quality act, which noted that the delegation of powers by the Federal Council to the tariff partners had had little effect, and that too few concepts and programmes for promoting quality had been implemented at a national level.

Overarching factors

Requirements that often entail a lot of work for individual organisations but have little informative value or impact are leading to a growing collective aversion to the undisputedly important topic of quality. A lack of coordination between the federal government, the cantons and the insurers is resulting in a disproportionate amount of counterproductive administrative work, which additionally feeds dissatisfaction and reservations regarding quality. Internal resources primarily go to collecting and conducting measurements and meeting the requirements, meaning there is a lack of resources for developing and implementing actual quality-related activities. Competing requirements from the federal government, professional associations and insurers give those at grass roots level the impression of power struggles, creating annoying friction and a feeling of helplessness in the face of the struggle for the final say to which healthcare institutions are subject. An example is the constant stream of new requirements, for example audits or the gathering of additional KPIs from individual health insurers without consultation and coordination with the FOPH. The

hospitals are required to provide similar but not identical information and verification. The sQmh is open and neutral when it comes to the requirements and instruments for assuring and developing quality. However, it does have a vested interest in ensuring that quality-related work is always objective, transparent and coordinated, and done on the basis of scientific insight, and that it represents a reasonable balance between effort and benefit. The sQmh rejects requirements that because of conflicts of interest favour one side or are created for inexplicable reasons.

The role of the federal authorities

To date the federal government has not managed to adopt and enforce a clear, all-encompassing stance and position on quality. The FOPH, in its capacity as a pan-partisan, neutral agency, has not succeeded in coordinating its approach, demands and requirements with the rank and file and their capabilities and, as mentioned above, has failed to protect the institutions from abuse and take the necessary responsibility. There is still potential in terms of the way care providers are involved and in terms of cooperation with the rank and file. What from the grassroots point of view is seen as isolated engagement with only a small number of organisations – and always the same organisations – is not felt to be very constructive. The goal must be to put professional considerations above political considerations so that the measures taken have broad support in the rank and file. Greater weight should be given to technical and professional input and thus the incentive for those affected in practice to develop quality on a comprehensive basis. Failing this broader involvement it should come as no surprise if the implementation of requirements of this sort finds little support, and if basically highly motivated quality specialists at grassroots level experience requirements as a burden rather than as help or support. This adds up to a real deficit in terms of enforcement and implementation.

Indicators and metrics

This deficit, this defensive stance, becomes particularly noticeable when it comes to dealing with KPIs. In quality management, KPIs are important indicators of development and improvement. Valuable KPIs and insights from internal audits and error reports can be used to rapidly identify problems and initiate improvements. However, KPIs are only relevant and useful if they are adapted to the needs and the context of care providers, users and all their stakeholders. Preparing and interpreting KPIs requires a great amount of expertise and understanding of context. If KPIs gathered in-house are no longer understandable for those affected or seem flawed, they will be experienced as unjustified exposure rather than as a support. Without an interim step of interpretation, the complexity of metrics and KPIs is reduced to such an extent that misunderstandings easily arise, and all efforts to provide transparency are nullified. The result is media reports that do more harm than good because they propagate what is often false information as dangerous superficial knowledge on the basis of reduced and undifferentiated data.

Last but not least, attention should be drawn to false and/or a lack of incentives. From the point of view of the sQmh and its members, the current incentives primarily put economic aspects and factors related to structural quality at the centre of quality management efforts. Actual quality-related work is rewarded too little or not at all.

Recommendations:

- Increased, more systematic involvement of organisations affected that are involved in the subsequent implementation and use of data and measures for improving quality.
- Collaboration between the FOPH and sQmh when it comes to selecting these organisations, to boost acceptance and practicability of decisions. Involvement of the sQmh in the planned quality committee and/or in other bodies is therefore important and makes sense.
- This cooperation between the FOPH and sQmh is also important as a means of assuring overarching coordination and funding of metrics/measurements and avoiding the current overlaps between the activities of the different stakeholders involved.
- Specialists agree that isolated indicators never give the full picture. So the focus should be on meaningful metrics, and quality indicators should be chosen with an eye to integrated care/the entire patient path; looking at what's happening elsewhere, and abroad.
- More must be done to ensure that the focus is on both the effectiveness <u>and</u> efficiency of measures. There is a lack of resources everywhere at grassroots level, and care providers must be able to use the available resources to meet the quality requirements and trigger the necessary improvements on the basis of the feedback.
- To assure that indicators are fair, useful and transparent and avoid false incentives, the quality and meaningfulness of indicators must be improved significantly. In cases of doubt external publication should be put back. Besides transparency, which goes without saying, the utility for care providers, and comprehensibility for patients, must also be borne in mind.
- To avoid situations in the future where individual care providers unjustifiably come under fire in the media, the FOPH needs to adopt a coordinated communications strategy and media relations, in consultation with the partners, when information is published on quality-relevant topics and findings.

Aarau, 07. März 2019

The current status of quality and (patient) safety in the Swiss healthcare system from the perspective of the Swiss Academy for Quality in Medicine (SAQM/FMH)

A paper produced by the authors in response to an invitation to contribute to the national report on quality and safety in the Swiss healthcare system

Authors:
- Dr Christoph Bosshard, Vice Chair of the FMH, director responsible for the data, demographics and quality department of the FMH
- Lic. rer. oec. Esther Kraft, head of the data, demographics and quality (DDQ) department of the FMH
- Roxane Kübler, MA, deputy head of the data, demographics and quality (DDQ) department of the FMH

Bern, 8 January 2019

Abstract

The Swiss Academy for Quality in Medicine SAQM is the physicians' own quality organisation of the Swiss Medical Association FMH. It promotes medical quality work and ensures networking among medical organisations and with all important players in the healthcare system. Seventy-one medical organisations have signed the voluntary quality charter launched by the SAQM, thereby making a commitment to quality.

The SAQM provides a comprehensive portfolio of services which ranges from networking in various committees, imparting knowledge in the form of online platforms for medical guidelines, registers and quality projects, a medical education course (CAS) to basic and position papers on fundamental issues and new developments.

With its quality projects, the SAQM has brought about numerous improvement measures, including an interprofessional peer review procedure in the field of acute care and a cross-sectoral treatment pathway for colorectal cancer.

The pilot projects and the various quality initiatives of the medical profession have produced many positive results, which are the basis for further development and implementation.

The central success factor of the SAQM's quality efforts is comprehensive networking among all actors in the health care system. Another important factor is the pursuit of bottom-up processes in the implementation of quality aspects, which the SAQM ensures by involving the medical organisations.

Zusammenfassung

Die Schweizerische Akademie für Qualität in der Medizin SAQM[1] ist die ärzteeigene Qualitätsorganisation der Verbindung der Schweizer Ärztinnen und Ärzte FMH[2]. Sie fördert die ärztliche Qualitätsarbeit und stellt die Vernetzung unter Ärzteorganisationen und mit allen wichtigen Akteuren im Gesundheitswesen sicher. 71 Ärzteorganisationen haben die von der SAQM lancierte, freiwillige Qualitäts-Charta unterzeichnet und damit ein Commitment zu Qualität abgegeben.

Die SAQM erbringt ein umfassendes Dienstleistungsangebot, das von der Vernetzung in diversen Gremien über das Vermitteln von Wissen in Form von Online-Plattformen für Medizinische Guidelines, Register und Qualitätsprojekte, einen Weiterbildungslehrgang bis hin zu Grundlagen- und Positionspapieren zu Grundsatzfragen und neuen Entwicklungen reicht.

Die SAQM hat mit ihren Qualitätsprojekten zahlreiche Verbesserungsmassnahmen bewirkt, zu denen ein interprofessionelles Peer Review Verfahren im Bereich der Akutsomatik sowie ein sektorenübergreifender Behandlungspfad für das Kolorektalkarzinom zählen.

Aus den Pilotprojekten und den verschiedenen Qualitäts-Initiativen der Ärzteschaft resultieren viele positive Resultate, auf welchen aufgebaut und Projekte weiterentwickelt und implementiert werden können.

Zentraler Erfolgsfaktor der Qualitätsbestrebungen der SAQM ist die umfassende Vernetzung unter allen Akteuren im Gesundheitswesen. Ein weiterer wichtiger Faktor ist die Verfolgung von Bottom-up-Prozessen bei der Umsetzung von Qualitätsaspekten, welche die SAQM durch den Einbezug der Ärzteorganisationen sicherstellt.

---

[1] https://www.fmh.ch/themen/qualitaet-saqm/saqm.cfm
[2] https://www.fmh.ch/ueber-die-fmh.cfm

SAQM report

Introduction

Founded in 2012, the Schweizerische Akademie für Qualität in der Medizin (Swiss Academy for Quality in Medicine or SAQM) promotes quality-related work in medicine for the benefit of patients, their families and doctors, and takes a pioneering role in quality in medicine by coordinating quality-related issues on a national level in collaboration with the various disciplines, up- and downstream institutions, and the interfaces between the various specialisations.

In demonstration of a strong commitment to an all-encompassing culture of quality, 72 physicians' organisations have already signed the SAQM quality charter[3], a document launched in 2016 on the pillars of transparency, commitment and sustainability. The goal of the quality charter is to maintain a self-motivated, structured examination of the aspects that make up quality, and to harness synergy within the framework of the networking enabled by the bodies of the SAQM.

Convinced that quality starts with bottom-up processes at grass roots level, the SAQM deliberately does not lay down central guidelines for Swiss doctors or formulate a binding definition of quality[5][4]. The SAQM does not have the authority to conduct quality controls, impose sanctions or issue certification. Quality control is a matter for the professional associations and the cantonal medical societies[5].

This report talks about quality issues from the perspective of the Swiss medical profession, which on the basis of its professional ethos and the legal framework has always concerned itself with optimum quality in the provision of its services.

Responses to questions

1 What is known about the safety, quality and impact/effectiveness of Swiss healthcare?

Quality and thus quality management have long been evaluated in Switzerland[7]. According to international studies and surveys, the quality standards, safety and efficiency of Swiss healthcare have a leading position worldwide, a fact demonstrated by regular exchange and benchmarks with other countries[6, 7, 8, 9, 10, 11, 12].

The SAQM's quality-related services in Switzerland
In its capacity as an independent quality association, the SAQM provides comprehensive services

---

[3] https://saez.ch/de/article/doi/saez.2018.17275/

[4] https://www.fmh.ch/themen/qualitaet-saqm/saqm.cfm

[5] https://www.fmh.ch/themen/qualitaet-saqm/saqm.cfm

[6] European Observatory on Health Systems and Policies: Switzerland Health system review. De Pietro C et al. Brussels 2015.

[7] Fraser Institute: Lessons from Abroad. A Series on Health Care Reform: Health Care Lessons from Switzerland. Esmail N et al. Toronto 2013.

[8] OECD: Health at a Glance 2017. OECD Indicators, OECD Publishing, Paris, https://doi.org/10.1787/health_glance-2017-en. http://www.oecd.org/health/health-at-a-glance-19991312.htm

[9] Commonwealth Fund Foundation: Research reports on the International Health Policy Survey (IHP) https://international.commonwealthfund.org/

[10] European Observatory for Health Systems and Policies: «Health Systems in Transition. Vol. 17 No 4 2015. Switzerland Health System Review. De Pietro, C. et al. http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits/full-list-of-country-hits/switzerland-hit-2015

[11] The Lancet. Volume 390, Issue 10091, P231-266, July 15, 2017. Healthcare Access and Quality Index based on mortality from causes amenable to personal health care in 195 countries and territories, 1990–2015: a novel analysis from the Global Burden of Disease Study 2015. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(17)30818-8/fulltext

[12] Euro Health Consumer Index 2018: https://healthpowerhouse.com/ehci-2018/

around the fulfilment of quality standards and expectations by medicine and healthcare. Besides the doctor's profession, via its coordinating bodies the SAQM also covers the numerous interfaces to other actors in other areas of healthcare (hospitals, nursing, etc.). Examples of this include active exchange with partners in Swiss healthcare via the "Dialog Qualität SAQM[13]" quality dialogue committee, the involvement of quality managers from the medical organisations represented on the medical association via the "Forum Qualität SAQM[14]" quality forum, and the newly introduced interprofessional peer review procedure[15] in cooperation with hospitals and nursing.

The SAQM's services are available to medical and partner associations as well as to individuals and third parties. The SAQM provides support with general technical quality-related questions, embarking on and submitting new topics, the networking and coordination of medical quality-related issues, and on a selective basis also with funding quality-related projects.

FMH policy and position papers
The policy papers[16] and position papers[17] based on them issued by the Swiss Medical Association (FMH) on current topics, which also cover all the relevant quality-related issues, play a key role in ensuring standardised procedures in the Swiss medical profession. The documents published in September 2018 on PROMs[18] were viewed several thousand times within a very short space of time. Since 2008 the SAQM has published 16 policy papers on various quality-related topics.

Online platform for quality initiatives
Since 2007 the FMH/SAQM have documented a range of quality-related activities[19] on their website. The resulting platform for knowledge-sharing and connecting quality-related efforts reflects the breadth of medical quality assurance and development in Switzerland. Non-medical professional groups and organisations can also document and publish their quality-related activities on this platform.

Annual snapshot of activities
The broad-based knowledge relating to the quality-related activities of medical organisations gathered by the SAQM through its networking and coordination enables the exploitation of synergies within the medical profession and the optimum exchange of available know-how. Since 2013 the SAQM has taken an annual snapshot of the quality-related activities developed, recommended and planned by the medical organisations by doing an online survey of their quality officers. There are four blocks of questions covering activities related to their quality strategy, quality committee, standardised quality instruments (recommended and developed by the organisations themselves) and other work related to quality[20].

SAQM "Innovation Qualité" quality award
A current example of the FMH's ongoing efforts to give even greater emphasis to issues of quality in the medical and healthcare professions is the SAQM's newly-created Innovation Qualité[21] quality prize, awarded for the first time in 2018 to tried-and-tested quality projects in Swiss healthcare. The prize, awarded every two years, covers three categories.
The focus in 2018 was on "rethinking patient care". Of the 37 submissions, a number of projects related to patient safety and from the medical organisations received an award. To network those doing pioneering thinking on medical quality in a wide range of disciplines and professions and the quality projects that received an award, the award-winning projects were announced in the Schweizerische Ärztezeitung[22] journal and in the broad media.

---

[13] https://www.fmh.ch/themen/qualitaet-saqm/saqm/organigramm.cfm
[14] https://www.fmh.ch/themen/qualitaet-saqm/saqm/organigramm.cfm#i130585
[15] https://www.fmh.ch/files/pdf18/Peer_Review_Factsheet_Pilotprojekt_Allianz_V1.1_160606_D.pdf
[16] https://www.fmh.ch/themen/qualitaet-saqm/publikationen.cfm#i113327
[17] https://www.fmh.ch/themen/qualitaet-saqm/publikationen.cfm#i113325
[18] https://saez.ch/de/article/doi/saez.2018.17188/
[19] https://www.fmh.ch/themen/qualitaet-saqm/projekte/qualitaetsinitiativen.cfm
[20] https://www.fmh.ch/files/pdf20/SAQM_Qualitatsbericht_2017_D.pdf
[21] https://www.fmh.ch/themen/qualitaet-saqm/innovation-qualite.cfm
[22] https://saez.ch/de/article/doi/bms.2018.06646/

Training and continuing education

In 2019, for the first time applications will be invited for a newly developed interprofessional and cross-sectoral CAS, sponsored by the SAQM, on quality in medicine for patient-centred working practice (Qualität in der Medizin für die patientennahe Arbeitspraxis). This certificate of advanced study in healthcare quality and safety covers the relevant aspects of day-to-day clinical practice and is geared to health professionals who work close to or directly with patients (doctors, medical practice assistants, nurses, health professionals, physiotherapists and occupational therapists). The goal of the course is to give health professionals confidence and mastery in relation to quality-related work in medicine.

Candidates learn the theoretical principles and how to apply the necessary tools to deliver quality management projects (q-development, q-assurance and q-improvement). The CAS is designed to cover the entire range of patient care, emphasising the importance of involving all the relevant partners (including co-workers, patients, families and other people bearing responsibility) in quality development.

Quality circle in basic medical care

Quality circles have a long tradition in Switzerland[23], supporting the continuing education that is key to quality development. Currently more than 80% of physicians in basic medical care are involved in quality circles, and a large number are organised in networks. Quality circles are a key instrument for quality development among peers. Quality circles are facilitated by trained moderators, and the doctors participating are able to apply their newly-acquired knowledge in practice.

2 What key improvements have been undertaken in terms of quality and safety within Swiss healthcare?

The quality and thus the safety of treatment depend on whether validated procedures are used and treatments are conducted in line with the latest knowledge. The SAQM supports the Swiss medical professional with diverse measures designed to assure these standards and propagate the necessary know-how.

Medical guidelines

Medical guidelines play a major role in this, and demonstrably result in better-quality outcomes. They help when it comes to making evidence-based decisions in the interests of providing the best possible treatment to patients. To allow a better overview of the countless guidelines and make the latest versions available in each case, the SAQM has created an online platform called Guidelines Schweiz[24] (Guidelines in Switzerland). Since 2017 professional associations, hospitals, clinics and other healthcare organisations have been able to document guidelines recognised by them on this online platform.

Interprofessional peer review procedure

The FMH/SAQM, H+ and Swiss Nurse Leaders have joined forces to create the Allianz Peer Review CH alliance and launch a single national interprofessional peer review procedure[25] in acute care, based on the IQM Standards[26]. The procedure can be applied in the event of statistical abnormalities. Together with external (professional) peers, hospitals analyse patient dossiers to identify potential for improving treatment workflows. At the same time the procedure can also be used to validate or relativize the statistical abnormalities. For the purposes of the detailed concept the IQM approach was adapted to the linguistic and cultural peculiarities of Switzerland, and unlike Germany the principle of interprofessionalism was incorporated for the first time to allow for

---

[23] http://www.hausaerzteschweiz.ch/fileadmin/user_upload/hausaerzteschweiz/Kommissionen/Qualitaet/7c_2005-12-28_Empf_med_QZ_V41.pdf

[24] https://www.guidelines.fmh.ch/index.cfm?l=1

[25] https://www.fmh.ch/files/pdf18/Peer_Review_Factsheet_Pilotprojekt_Allianz_V1.1_160606_D.pdf

[26] https://www.initiative-qualitaetsmedizin.de/

interprofessional improvements in addition to those on a cross-hospital or cross-disciplinary level. The insights and experience gained in the course of the pilot project show close practical relevance, and the procedure has now been adopted for the long term[27]. Given the success of the procedure in acute care, a single national peer review procedure is now also being set up for psychiatric care.

Medical registers
High-quality medical registers are key to the evaluation of treatment quality and the assessment of care delivery structures. They also provide important data for health policy and planning. The SAQM's online platform Forum medizinische Register Schweiz[28] (Swiss medical register forum) represents an important quality improvement project, structuring information via registers and making them transparently accessible, facilitating networking among those operating registers, and serving as a point of orientation when setting up new registers.

Recommendations on setting up and operating health-related registers
Together with the ANQ, H+, SAMW and unimedsuisse, the SAQM is drawing up recommendations for setting up and operating health-related registers. These recommendations contribute to quality assurance and contain minimum standards for the set-up and operation of registers, including requirements regarding data protection and data quality[29]. As part of a pilot project, ten registers already in operation have now been reviewed in light of the recommendations. As a result, among other things the recommendations for a minimum data protection and data quality standard are being reviewed, which in turn will create a basis for optimising the quality of future registers and those already in operation.

ReMed: support network for doctors in crisis situations
ReMed[30] is a support network for doctors. It propagates knowledge and experience related to health promotion and prevention for doctors, raising their awareness of their own health. ReMed offers a broad range of support for doctors in crisis situations, designed to maintain their health and ability to function as physicians, and assure patient safety and a high quality of medical care. In such critical moments ReMed offers timely support to doctors and guides them on their way out of the crisis. For every contact, an experienced physician from the advisory team gets in touch within 72 hours and discusses the doctor's personal situation. In 2017, 141 doctors made use of ReMed's services. ReMed is an independent programme funded by the FMH.

Healthcare research dialogue group
Since 2009, the healthcare research dialogue group (Dialoggruppe Versorgungsforschung)[27], under the leadership of the SAQM, has served as an information and dialogue platform where representatives of the FMH, NewIndex and the ISPM Bern research group regularly discuss current and planned work in the field of healthcare research. The dialogue group also organises events. In 2018 it staged an event on Switzerland's status in terms of registers in medicine (Register in der Medizin – Wo steht die Schweiz?), which was attended by experts in science, policy and care provision from Switzerland and abroad.

Interprofessional, cross-sectoral treatment path
Progress in the treatment of disease and specialisation require the involvement of more and more specialists in the treatment chain. This means that patients are treated by different medical specialists, either in sequence or in parallel. This has significantly increased the importance of treatment paths. Together with around 20 professional medical associations and non-medical professional groups, in a pilot project the SAQM has developed and approved an interprofessional, cross-sectoral treatment path for colorectal cancer[31].

---

[27] https://www.fmh.ch/files/pdf17/Abschlussbericht_Pilotprojekt_Interprofessionelle_Peer_Reviews__V1.1_20160606_D.pdf
[28] https://www.fmh.ch/themen/qualitaet-saqm/register/medizinische-register.cfm
[29] https://www.fmh.ch/themen/qualitaet-saqm/register.cfm#i113068
[30] https://www.fmh.ch/dienstleistungen/mitgliedschaft/remed.cfm
[31] https://www.fmh.ch/files/pdf17/Faktenblatt_Behandlungspfad_CRC_Juni_2016.pdf

Alongside guidelines and recommendations describing the treatment standard for care providers, the idea is to augment key interventions and the treatment path with high-quality patient information material that can help those affected when making decisions. Together with the Dialog Ethik ethics institute, the FMH/SAQM has drawn up overarching and specific criteria for evaluating patient information material. These quality criteria are designed to support patients in their own deliberations and decisions and help them prepare for consultations with each specialist.

The total costs (including the hours worked by the SAQM and the organisations involved and the unpaid hours put in by members of the project team) of developing and approving this treatment path come to around CHF 700,000. This expense was borne entirely by the care provider organisations involved.

PROMs

Patient-reported outcome measures[32] (PROMs) provide information from the patient's point of view on their state of health and the effects of a treatment. PROMs facilitate patient-oriented treatment, communication between patients and doctors, and patient management (monitoring and adapting the course of treatment, recognising unidentified conditions, etc.). They allow conclusions to be drawn about the medical utility and indication. Building PROMs into the daily treatment routine fosters quality assurance and patient-oriented treatment. At the healthcare system level, PROMs can facilitate the evaluation of treatment options, for example via a medical register, and augment medical guidelines in the context of examples of best practice. Last but not least, PROMs are ideal for use with digital tools. Ideally their use should lead to better self-efficacy, fewer visits to emergency wards, improved quality of life and better chances of survival for cancer patients. The integration of PROMs in daily treatment routine and the utility of doing so have to be evaluated. To this end the SAQM has conducted a pilot project called Patient Centered Outcome Registry (PCOR)[33] with the aim of capturing information from patients on their diagnosis, therapy, suffering and complaints, quality of life, indirect costs and achievement of the treatment goal. This enables evaluation of the patient-centred indication and the outcome, facilitates needs-appropriate treatment, and optimises decisions on therapy.

The SAQM does not currently have any results regarding our "Patient centered outcome registry (PCOR)" project, which would fall into the PROMS category.

In the "Patient-reported outcome measures: die Patientensicht zählt (the patient view counts)" the benefits, limits and challenges of implementing PROMs, and the necessary measures, are discussed on the basis of the scientific literature. In the "PROMs fördern die patientenorientierte Behandlung" (PROMs promote patient-oriented treatment) position paper, the SAQM/FMH describe the goals pursued by the SAQM/FMH in terms of PROMS to give a recommendation to the professional associations and other healthcare organisations regarding PROMs.

3 What are the results of this, and what is known about their sustainability?

Via the SAQM the medical profession signals to the outside world that it takes quality assurance and development very seriously; the SAQM therefore constitutes an important strategic step for the medical profession. The findings of an external evaluation of the SAQM show that it is perceived by its target audiences and meets with acceptance and interest across the circle of different people involved in its various bodies. The SAQM has been able to initiate and implement many activities and developments that can be deemed to be positive, for example input for projects that have emerged from improved knowledge transfer between the interested actors, or the pilot project to create a cross-sectoral treatment path for colorectal cancer.

The repositories of medical guidelines and those of the Swiss medical register forum both constitute a major contribution to transparency and easier access to medical knowledge. They are being

---

[32] https://saez.ch/de/article/doi/saez.2018.17188/
[33] https://www.fmh.ch/files/pdf20/2018-04-03_PCOR_Faktenblatt_D.pdf

constantly expanded to ensure the work done has a sustained impact.

Results of annual snapshot
Regular surveys of the FMH members involved in the SAQM, for example the annual snapshot, show that continuous quality-related work embedded in daily routine has an impact and is sustainable. The last annual snapshot in 2017 saw the participation of 51 medical organisations, an outstanding response rate of 74 per cent[34]. Medical organisations have been getting actively involved, and the number of organisations with quality recommendations has increased steadily since 2013.

Further results
The results of innovative projects such as the CRC treatment path, the introduction of PROMs, the introduction of interprofessional peer review procedures, and the creation of a new CAS programme on quality in medicine for patient-centred working practice are further evidence of how the work of the SAQM is adding comprehensive value for doctors, patients, their families and society as a whole.

4 What are the keys to success?

The main key to the success of the SAQM's projects and activities is the coordination role the SAQM plays within the medical profession as well as for the numerous other actors in the Swiss healthcare system as a whole. The SAQM's Quality Forum and Quality Dialogue platforms are good examples of this.
The Quality Forum assures the involvement of all physicians' organisations, while Quality Dialogue assures the involvement of the most important healthcare partners. Close, transparent involvement of physicians' and partner organisations enables the SAQM to launch activities and projects with the support and backing of these organisations and thus get the necessary commitment (e.g. the SAQM quality charter, the cross-sectoral treatment path, the CAS in quality in medicine, the Peer Review CH alliance, and recommendations for setting up and operating health-related registers).

Another key success factor is the SAQM's grass roots orientation and systematic adherence to bottom-up processes[35] in the development and optimisation of quality-related aspects. This is the only way of making sure that the consolidated knowledge of the various organisations can feed into the work and be actively used by all the actors involved. The policy and position papers also fall into this category: they do not constitute central FMH requirements, but are designed to create the basis for a scientifically-based discussion of professional policy.

The SAQM works in accordance with the latest standards, placing great emphasis on interprofessionalism, a systematic and transparent approach concomitant with the digital age, introducing and evaluating new approaches such as cross-sectoral treatment paths, and the latest trends such as the implementation of PROM (patient-recorded outcome monitoring) and PCOR (patient-centred outcomes research).

The SAQM fosters close cooperation with the Foundation for Patient Safety (Stiftung Patientensicherheit). For example, in its capacity as a founder member of the foundation the FMH is co-funding the new structural aids to be created for future interprofessional morbidity and mortality conferences[36] (MoMo). The aim of the project is to reinforce MoMo as a central vehicle for organisational and individual learning in Switzerland and as an important tool for promoting patient safety.

---

[34] https://www.fmh.ch/files/pdf20/SAQM_Qualitatsbericht_2017_D.pdf
[35] https://saez.ch/de/article/doi/bms.2017.05675/
[36] https://www.patientensicherheit.ch/forschung-und-entwicklung/morbiditaets-und-mortalitaetskonferenzen/

5 What obstacles and challenges have the measures encountered?

The most significant inhibiting factor has been a lack of human and financial resources. The scheduled tariff-based compensation of medical and administrative services is posing challenges for doctors. Ensuring optimum care for patients and doing the quality-related work this entails is part and parcel of the daily work of any physician. The growing administrative burden on doctors, which according to various studies has increased in recent years, constitutes a major challenge[37].

The SAQM advocates transparency in medical quality. This transparency can only be achieved if a fair, fact-based discussion takes place. The SAQM works for a high level of quality in our healthcare system and genuine competition on quality. However, this is only possible if quality data are gathered and evaluated correctly. The needs of patients must always be at the centre of these endeavours, which is why the SAQM supports target-group-specific transparency. Not all quality data are equally useful or able to be interpreted for the different stakeholder groups, which means that not all quality data are suitable for broad publication. Incomplete, incorrect or incorrectly analysed or published medical quality data distort reality and prevent the medical profession from demonstrating the good quality of its work. Last but not least, this can also result in the public being misled, undermining its trust in the healthcare system unjustifiably. A positive impact through the right incentives can only be achieved by publishing complete and correct quality data that recipients can understand.

6 What peculiarities of the Swiss environment facilitate or hinder interventions?

The high level of quality-consciousness among the Swiss medical profession and the wide range of different quality-related work it does are supporting factors that have an influence on the entire healthcare system. The SAQM quality charter is a typically Swiss example where federalist structures are constructively deployed on a self-motivated basis, rather than with coercion, to the substantial benefit of society as a whole.

Inhibiting factors are the amount of time and coordination necessitated by consultation procedures within the association. The reward, however, is broadly-based consolidated positions. Account also has to be taken of the multilingualism and regional cultures peculiar to Switzerland, although this should be seen as an asset.

A major complicating factor is that resource-intensive quality development and assurance work is still not recognised as additional service provision and therefore does not receive firm funding[38]. This can inhibit doctors' motivation to take on the additional administrative burden necessary for quality assurance.

Recommended improvements

1) The SAQM and the entire FMH intend to build on the existing organisations to continue the coordinated quality efforts already undertaken. The approach adopted within the SAQM and its affiliated bodies, firmly established as a bottom-up process in the associations, creates commitment, uses synergy, and involves the consolidated knowledge of the organisations concerned, systematically and efficiently. Quality is delivered on a routine, self-motivated basis by those at grass roots level.

2) The SAQM and FMH are actively working for the creation of legislation on the basis of draft

---

[37] https://www.fmh.ch/files/pdf21/Revision_TARMED_final.pdf
[38] https://saez.ch/de/article/doi/bms.2018.06622/

amendments (15.083) to the Federal Health Insurance Act. Among other things, there have to be binding arrangements for the funding of quality-related work. Care providers have made considerable preliminary investments in terms of content and funds in the form of projects already delivered by the individual associations and the SAQM. The legislator must also recognise the medical quality development and assurance work done by doctors and provide firm funding for it, either within the tariff framework or as separate compensation.

Disclosure
No conflicts of interest

The understanding of quality management by SanaCERT Suisse

Maja Mylaeus-Renggli[1], Christoph Cottier[2], Markus Betschart[3], Peter Ueberschlag[4],

Contribution to the Swiss National Report on Quality

Bern, 9th April 2019

[1] MA, RN, executive manager
[2] MD, retired Head of Internal Medicine, Regional Hospital Burgdorf, former peer.
[3] MD, retired cantonal chief physician of St. Gallen, president of the board
[4] MD, Senior Physician Cantonal Hospital St. Gallen, vice president of the board

Abstract

SanaCERT Suisse, a Non-Profit Foundation accredited by the Swiss authorities, has extensive experience in accrediting management systems of hospitals and long-term care facilities according to patient-centered quality standards. The accreditation focuses on the cycle of continuous quality improvement and the evaluation is carried out by peers, acting as an interprofessional audit-team. SanaCERT Suisse also assists other bodies in the healthcare sector to apply this method for accreditation in different specialties.

Three main factors promote sustainability of the accreditation SanaCERT Suisse. Collaboration in interprofessional and interdisciplinary core groups enhance shared value among professionals. The quality standards form a dynamic system that is revised regularly. The method helps commitment towards quality development, being flexible to meet the needs of the institution.

Institutions accredited by SanaCERT Suisse appreciate the following key factors of the method. The standards are close to core business and readily applicable. There is a wide range of standards and a free choice of approach for implementation. The majority of the standards require cross-departmental and interprofessional collaboration which has a positive impact on treatment safety and promotes networking in the institution. Evaluation is carried out by peers in a mutual appreciative manner.

A drawback of the method SanaCERT Suisse is the lack of any benchmark across institutions. The financial challenge is perceived in a good balance between expenditure and benefits of the quality accreditation process.

For the development of quality and safety, the authors recommend to ask for evidence on continuous improvements of processes and structure but to allow a choice of method.

SanaCERT Suisse is a Non-Profit Foundation for accreditation of quality management and improvements in health care accrediting management systems of hospitals and long-term care facilities according to standards in order to improve basic health care services across Switzerland. Since 2006 SanaCERT Suisse has been accredited by the Swiss authorities for accreditation of management systems based on ISO/IEC 17021-1.

The SanaCERT Suisse Foundation was founded in 2001 by experts in this field and Swiss healthcare institutions. At that time, the Swiss Association for Quality in Health Care (VQG) was dissolved and transferred to the SanaCERT Suisse Foundation. The VQG, founded in 1994, can be described as the real pioneer in the Swiss healthcare system, initiating early quality development in hospitals based on continuous improvement of patient-centred care. Inspired by the system of the Joint Commission on Accreditation of Healthcare Organizations[5] the founders were guided by the principle that quality development should be based on accreditation with quality standards and an interprofessional peer review method. In 2013 the initial model was adapted to enable accreditation first of long-term care facilities and then of institutions with vertical or horizontal integrated health care service. The website of SanaCERT Suisse provides an overview of accredited institutions.

SanaCERT Suisse has acquired a considerable expertise in developing standards for structural, process and outcome quality. Currently there are 25 quality standards for acute somatic and 16 for long-term care[6]. The standards serve the institutions as guidelines for their process modelling, especially with new issues. The patient-oriented and practical approach in the standards facilitates the understanding by the professionals and helps create a common language. A periodic revision of the standards as well as the development of new standards guaranties to keep up with overall changes in health care.

Institutions that aim for accreditation have to adhere to some mandatory standards and choose a given number of quality standards out of the available standards. All quality standards have been developed by experts based on scientific evidence and in interdisciplinary and interprofessional exchange. The standards focus on the quality (structure, process and outcome) of interprofessional and interdisciplinary care addressing all health care workers in an institution with a particular focus on patient centred care. Audits include an evaluation of accomplished Plan-Do-Check-Act cycles of every standard.

SanaCERT Suisse pioneered a systematically applied peer review method with interprofessional teams for auditing. Consequently, the evaluation is carried out exclusively by peers. For auditing hospitals each audit-team consists of a leading auditor, a health care manager, a physician and a nurse in a leading position. The leading auditor is a qualified auditor with a health professional background. His function is to ensure the adherence with the norms of ISO 17021-1. For long-term care facilities the audit-team is constituted by a leading auditor, a nursing home manager and a nursing manager or clinical nurse specialist. Once a year SanaCERT Suisse offers training courses for all peers.

In accordance with the philosophy of continuous quality improvement and of shared acceptance and esteem, SanaCERT Suisse systematically asks accredited institutions to evaluate the audit-process and audit team. This has enabled SanaCERT Suisse to continuously develop the process of auditing.

---

[5] www.jointcommission.org
[6] The current set of standards, along with the criteria of evaluation are available on www.sanacert.ch.

Conformity with standards is examined every three years by on site audits. During these audits two main elements are assessed and rated: compliance with the standard elements and application of the Plan-Do-Check-Act cycle as well as the degree of institution wide implementation and adherence to the standards. Audits include evaluation of documents, interviews with collaborators and a site visit. In the case of nonconformity, the audit team defines conditions or recommendations that need to be appropriately addressed within a given period to maintain the accreditation.

SanaCERT Suisse also attributes a great importance to quality management improvement. During the audits a conscious discussion is sought on quality development strategies focusing on further standard implementation but also on a larger vision of quality improvement.

Between accreditation audits, sustainability of adherence to quality standards is confirmed based on yearly self-reports and visits on site by a leading auditor. During on-site visits, the leading auditor assesses whether the requirements from the previous accreditations have been satisfied and whether the institution is involved in the further work and development of its quality management. This enables a constant evaluation and support towards quality improvement.

The foundation also acts as an independent audit body for quality management on behalf of professional's associations and the authority in the healthcare sector[7]. SanaCERT Suisse assists its partners by developing and operationalizing discipline-specific quality indicators, training peers as auditors, and conducting audits in accordance with the ISO Norm 17021-1. Thus, the auditing of the following labels or confirmation of quality assurance and improvements is modelled according to the core elements of SanaCERT Suisse method: Q-Label for breast care centres, Label for Baby friendly hospitals, accreditation for stroke centres and units, confirmation of adherence to cantonal quality requirements in Aargau, Accreditation of Curaviva Zurich, Label of swiss cancer network and q-label for palliative care. The method seems particularly popular with professional associations because of their own professional criteria being applied as standards and reviewed by their own experts.

What is known about the sustainability of the SanaCERT Suisse method?

Currently 20 institutions are accredited, with some of them over a period of 16 years. 3 new institutions are in the accreditation process.

In our experience the accreditation SanaCERT Suisse shows three main assets.

- Accredited hospitals and long-term care facilities form interprofessional and interdisciplinary core groups to implement the standards. Moreover, they provide initial training for all newcomers as well as continuous training on quality standards for all staff. Both aspects enhance the development of shared values among the professionals and the embedding of the standards into daily work. Besides feed-back on further potentials regular audits serve as acknowledgement of good performance and as such maintain motivation to engage into quality improvement processes.

---

[7] The Swiss Cancer Foundation, UNICEF Switzerland, the Swiss Federation of Clinical Neuro-Societies, the authorities of Canton Aargau, Curaviva Canton Zurich, the Association of Swiss Hospitals H+, the Swiss Medical Association FMH, the Swiss Society of Medical Oncology SGMO.

- The existing quality standard sets have undergone numerous evaluations and revisions proving the dynamics of the system. The accredited institutions are actively involved in standard adaptation and creation to ensure their feasibility. Since the same standards are applied in different institutions and are peer reviewed, we observe an increasing exchange of good practice models among institutions.
- During audits we observe a high level of motivation and commitment towards quality development among collaborators. Our method is based on an active involvement of collaborators and flexible in the priorities the individual institution needs to define, both elements might facilitate the motivation. Many institutions replace standards after two periods of accreditations, i.e. six years in order to focus on new, emerging topics. Furthermore, the quality management based on the Plan-Do-Check-Act Cycle allows the institutions to detect any deterioration of quality performance in a replaced standard in time and to respond appropriately at early stages of deterioration.

SanaCERT Suisse also conducted a survey in 2017 among accredited institutions that allowed identifying the following success factors: practical relevance of the standards, focus on clinical issues, peer review method, interprofessional and interdisciplinary approach. These factors will be discussed in greater detail below.

Which key factors characterize the SanaCERT Suisse method?

One main feature lies in the fact that the quality standards are close to the core business of medicine and care. The standards are developed and reviewed by experts who are familiar with the subject; experts who are able to identify the keys to high quality treatment and patient care. The standard "Pain Management", to name one example, requires guidelines, proof of regular training of staff and evaluation of treatment. The standards' language and the quality criteria can be easily understood by physicians and nurses. In a survey with health care professionals, the standards were described as readily applicable in every day work (2017).

The institutions themselves define the action they undertake to meet the requirements of the standards. This is another outstanding feature. The standards do not prescribe the contents of guidelines, the structure of training or the process of the evaluation of quality measures. Each accredited institution is free to choose its own preferred approaches or can even adapt proven practices from other institutions. This makes the standards suitable for a wide range of institutions, varying in size and the care provided.

Most standards require cross-departmental and interprofessional collaboration. In the 2018 version, this applies to 22 out of 25 quality standards for acute care and to all 16 standards for long-term care. A good example for this requirement is again the quality standard "Pain Management". Historically in-house hospital guidelines have often been defined at the level of clinics or departments. Consequently, pain management might differ between the surgical and the medical department of the same hospital. The anaesthetist specialized in pain management, working in both departments, must then be familiar with different guidelines. The SanaCERT Suisse standard calls on the health professionals of all departments of a hospital to agree on one guideline for pain management, which enhances the safety of the treatment.

The accreditation process of SanaCERT Suisse encourages interprofessional and inter-disciplinary teamwork, strengthening the horizontal network of an institution. The audit

team itself, consisting of peers from different fields like hospital management, medicine and nursing, conveys a strong signal that the goals of quality management can only be achieved through close interprofessional and interdisciplinary collaboration

The variety of standards enables an institution to set different priorities in quality improvement over time. SanaCERT Suisse demands for the accreditation of the quality management of a hospital the review of a set of eight standards, including the mandatory basic standard "Quality Management". This leaves the hospital to choose seven standards according to its own preferences. For nursing care facilities seven standards are required with the following three mandatory ones addressing the topics: "Quality Management", "Rights of the Residents" and "Nursing and Care". This freedom of choice of standards is highly appreciated by the accredited institutions. It enables the institutions to choose the standards where quality improvement is most wanted and to set the pace for the choice of new standards according to the resources available. Experience has shown that the institutions apply the lessons learnt from the audited standards to good measures in other areas as well.

Another key feature lies in the way of working that values mutual esteem between the institution and the reviewers. This attitude leads to mutual trust and allows an open discussion of problems, of future quality improvements, and the best possible use of resources. The above mentioned 2017 survey showed a high appreciation for such contributions by the reviewers and was regarded as a significant added value to the accreditation process. Mutual respect allows peers to draw attention to issues that the institution is not fully aware of. Care is taken to ensure that the accrediting body does not suggest any solutions, but only refers to the problems.

What are the barriers and challenges encountered?

An accreditation of SanaCERT Suisse requires the commitment of the management of various departments, which for some institutions presents a high barrier. On the other hand, although SanaCERT Suisse demands key figures as part of the Plan-Do-Check-Act cycle the system doesn't allow a benchmark across institutions. Hospitals, in particular, are increasingly under pressure to compete with other institutions and to provide comparative figures with the focus having shifted towards statistical analysis of outcome measures in recent years.

Quality management requires resources to maintain a system allowing quality assurance and improvement. Decreasing resources in quality management might not result in an immediate reduction of care quality but have serious consequences on the long term. Over the last years financial cuts in the Swiss health care system forced institutions to reconsider their allocation of resources. Some experts argue that quality management can be time-consuming and thus reduce time that health care providers could spend in direct patient care. Furthermore, evidence of a functioning quality management system is still not rewarded and varies widely between cantons. Nevertheless, recently we observe the development of quality labels leading to financial recognition or mandate for services. However, these labels or accreditations cover exclusively a particular area of specialisation or address a particular aspect of care. Hospitals tend to prefer these isolated solutions to an overall quality management system, even more under economic pressure. In the era of increasing economic health care crises, one major challenge lies in the maintenance of a good balance between expenditure and benefits of the quality accreditation process.

These issues have to be addressed within a policy framework that aims to optimise the quality of care in the Swiss health care system. In particular, incentives for quality management should be reconsidered with a perspective on the whole health care system.

Testimonial of an accredited institution

Joachim Koppenberg[8]

Since 1996, our hospital has pursued its quality management with the help of the peer review method and was audited for the first time in 1998 by VQG, the preceding organization of SanaCERT Suisse. Since 2001 our institution has been regularly and consistently audited and successfully (re-)accredited several times by the subsequent SanaCERT Suisse foundation. Under the umbrella of the Health Centre "Unterengadin", since 2007 the following institutions have been working closely together within the framework of integrated regional health care in the spirit of "everything from a single source": a public hospital, accident and emergency services, home care service, an advice centre for nursing and care, a rehabilitation clinic, a nursing home, three residential care groups and a wellness bath. The Health Centre "Unterengadin" operates a joint quality management system and was accredited as the first health care network in Switzerland in 2014, following a successful re-accreditation in 2018.

The reasons for committing to the peer review method in general and for collaborating with the SanaCERT Suisse Foundation in particular for almost 20 years in the field of quality assurance are manifold.

The principle of peer review is ideal for organisations with a high degree of expertise and diversity with usually no trivial and straightforward solutions. Hence, we appreciate the conversation from expert to expert for the real understanding of the sections to be audited, leading to a much higher acceptance for the audit among our experts than verification by non-specialists, a circumstance that is especially in medicine of great importance.

In medicine, still tending to be dominated by hierarchies, it is seldom only a question of the right profession, but also of the auditor's position (chief or leading physician, nursing service manager or nursing expert and CEO or hospital director). Both aspects play a vital role to overcome the first important barrier of professional competence for an open, appreciative and ultimately target-oriented expert discussion at eye level among colleagues. While this procedure has often been perceived as too "soft" and facts and figures were preferred, in the German-speaking countries peer review as a dynamic procedure has fortunately experienced a renaissance in the health care system in recent years.

Furthermore, the quality standards by SanaCERT Suisse are based on the clinically relevant core processes of care and require to demonstrate consistently improving steps in the Plan-Do-Check-Act cycle with verifiable key figures. Many patient's path-oriented standards imply cross-departmental solutions within an institution and in some cases even cross-company solutions.

---

[8] Chairman of the Board of Management of the Health Centre "Unterengadin" and Chief Physician for Anaesthesiology, Pain Therapy and Rescue Medicine, Ospidal Scuol; peer for SanaCERT Suisse since 2005.

Those solutions are developed in standard groups, which are preferably being composed inter-disciplinary and interprofessional, a fact which represents another major advantage. The collaborators concerned up front are directly involved in the process of development and implementation. During the most active periods, in addition to professional quality managers up to one third of all health professionals have been directly involved in quality assurance in our institution. This, in turn, leads to a high level of acceptance of the method and an understanding of quality assurance and thus to smooth integration in working life.

Thanks to our close collaboration with SanaCERT Suisse, our institution has been able to develop our quality of care noticeably and measurably over the past two decades. It can be stated that quality management has become an integral part of our organizational DNA thanks to SanaCERT Suisse. But SanaCERT Suisse has also continued to evolve over the years, by regularly developing new standards and updating existing with our contribution as an accredited institution. This allows us to incorporate the practical point of view into the standards. And as already mentioned, SanaCERT Suisse proved to be open for providing a solution for accrediting our whole network. SanaCERT Suisse is thus demonstrating impressively that it is flexible, needs oriented, not only having the right feeling for the needs of the complex and changing health care market, but actively meets these needs.

As I have the privilege of acting as peer for SanaCERT Suisse, auditing other health care facilities, I see even underlying effects. I am always fascinated and deeply impressed to see how other institutions solve similar problems in their own special manner. The consistent implementation of the peer review idea allows to unfold its full impact: While we receive valuable suggestions and hints for improvement by esteemed colleagues at the audits, I can also regularly share my professional competence and experience during my visits with peers - and learn from the best. This kind of 2nd order learning results in another Plan-Do-Check-Act cycle that might not be explicitly recognised at a first glance.

Recommendations for the development of Quality and Safety in Swiss Healthcare

Based on our experience we suggest four main aspects to be considered for the development of quality and safety in Swiss healthcare.

- Process modelling and optimized structures are important promoters for a continuous quality improvement. Therefore, health care facilities should be encouraged to provide evidence for the continuous development of the corresponding processes and structures in addition to measuring quality indicators.
- Health care facilities vary considerably in size, mandate for services, cantonal demands and other conditions. Hence there also is a difference in the appropriate method for quality improvement. It is therefore important, that the authorities define a range of suitable options on different accreditation or certification methods the health care facilities can choose from.
- Health care facilities providing evidence of a functioning quality management should get some kind of reward or recognition. To avoid misallocation of resources, e.g. by favouring island solutions, an overall quality management system covering all essential areas, focusing on patient-centred care and asking for cross-departmental and interprofessional collaboration should be preferred.

- On a national level the selection and method of collecting the quality indicators should be harmonised and coordinated with international guidelines. This makes a meaningful comparison (benchmark) possible and shows where quality improvement would have the greatest impact in the health care system.

Development instead of a standstill: accreditation for medical practices

This is a contribution to the Swiss National Report on Quality and Safety in Healthcare

Martin Hošek, Ph.D.
Deputy Managing Director, Head of Research and Development, EQUAM Foundation

Paula Bezzola, MPH
Managing Director, EQUAM Foundation

.
Date of Submission: 22nd January 2019

Abstract

The accreditation of medical practices promotes the development dynamics of the businesses and contributes to an improvement in the work conditions of health professionals. Moreover, it also contributes to an increase in cost efficiency. In Switzerland, there are currently no regulatory requirements regarding accreditation. Accordingly, this has led to it having a niche status. Approximately 10 per cent of the primary care providers in Switzerland work in medical practices that have an EQUAM practice certificate.

Two longitudinal studies on the effectiveness of practice accreditation conducted by the European Praxis Assessment (EPA) have consistently found that practices that have EPA accreditation, which was also applied by the EQUAM Foundation between 2004-2017, are better structured and push ahead with quality development in their businesses. They do so to a greater extent than non-accredited practices.

Although accreditation alone is no guarantee of quality, it makes proper medical services considerably more likely through compliance with appropriate criteria. In addition, the practices promote a culture in which constant quality development and improvement is rooted.

The aims and history of EQUAM

The EQUAM Foundation has devoted itself since its founding in 1999 to the accreditation of outpatient healthcare facilities, and medical practices in particular. The Foundation has its roots in the environment of integrated care. Most accredited practices are members of doctor networks. But even independent practices choose to earn accreditation.

In the early years of the Foundation, mainly the doctor networks became accredited. From 2004, the accreditation of primary care practices according to the standards of the European Practice Assessment (EPA) was added[1]. Since 2018, the EQUAM foundation has accredited primary care practices according to its own guidelines[2]. These guidelines were developed by the EQUAM Foundation together with Swiss experts from practice and research based on the EPA standards and other internationally recognised programmes. Thus, the EQUAM Foundation guidelines were always and still are specifically adapted to the everyday reality of medical practices.

In addition to accreditation of primary care practices, the EQUAM Foundation also offers accreditation for specialist practices, radiology institutes and accreditation of integrated care for doctor networks. Physicians can also receive accreditation for treatment quality. The latter has an even greater focus than practice accreditation on the medical treatment itself. Based on certain patient groups, the implementation of evidence-based treatment guidelines is reviewed. Accreditation for treatment quality is currently implemented for the area "medical safety" and the diagnosis groups "arterial hypertension", "diabetes mellitus" and "coronary heart disease".

A change in practice culture to turn a practice into a learning organisation is and remains the most important goal of EQUAM accreditation for medical practices. The offering of a framework of content and the possibility to compare one's achievement of standards through benchmarks with other practices are only partial steps on this path. Achieving good results naturally also requires structures and processes that correspond to the requirements of practices.

Preparing for the primary care accreditation audit requires on average 25 hours of work for a physician or a medical practice assistant. This is manageable even for a small practice, and even more so for larger group practices. The precise effort required depends on how many criteria a practice already meets before the audit and how well organised it is. With the exception of minimum criteria, the EQUAM accreditation does not require all criteria to be met from the beginning. This means that the practice can set priorities aligned with its background situation and individual needs so that it can further develop step by step.

As at the end of 2017, a total of 254 practices comprising 611 doctors were accredited by EQUAM. Most of these were primary care practices, with the exception of seven specialist doctors and two paediatrics practices. Excluding the latter, calculations indicate that as at the end of 2017, of the 5,918 physicians[3] with a specialist certification in general and internal medicine who practice medicine in the outpatient care sector in Switzerland, approximately ten per cent work in an EQUAM accredited practice.

Benefits of accreditation
In an often quoted review article on the hurdles to implementation of integrated care in the US, Berwick et. al. 2008 postulated that improvements in healthcare must pursue three aims: the improvement of patient satisfaction, better health amongst the population and a reduction in healthcare costs[4]. Bodenheimer and Sinsky (2014) supplemented these three aims with a fourth: the improvement of work conditions for healthcare professionals. In particular, the authors focus on a decrease both in dissatisfaction with the career and the likelihood of a burnout[5]. It is also known that a work environment adapted to task performance and the system, as well as processes aligned with the aims, increase patient safety[6].

The aims listed are identical with those of EQUAM Foundation's practice accreditation[7]. But to what extent are these aims being met?

In Switzerland, there are no regulatory requirements that prescribe accreditation. As a result, there is a lack of incentives to see added value in it. The decision in favour of accreditation thus lies with the service providers, their networks and the corresponding business organisations. The cantonal health authorities only mandate or recommend accreditation as part of their supervisory duty in exceptional cases. Thus, unlike in other countries as, for instance, Denmark[8], in Switzerland it is rare for the requirement of accreditation to be stipulated by a state authority. However, there is sufficient justification here for a practice to earn accreditation.

The fulfilment of requirements for accreditation supports practice management and its staff in business operations and organisation. It initiates and promotes the development dynamics of the businesses and contributes to an improvement in the work conditions for health professionals.

With the offer of a framework of content through the accreditation process and the fulfilment of requirements, including the definition of development goals, the practice sets itself on a path to becoming a dynamic, learning organisation. It can then better react to new challenges and is better able to deal with existing requirements.

By fulfilling certain criteria and achieving the associated increase in effectiveness, cost efficiency in the practice as well as the treatment processes overall also improve. This is achieved thanks to better coordination of treatment with other service providers and the avoidance of complications or unnecessary services. Some health insurers honour this with additional compensation if the practice in question belongs to a network.

Critiques of accreditation

Relatively high staff costs for the accreditation process with little added value is often criticised. It is argued that accreditation is useless because it is not directly geared toward an improvement in treatment results, but quality is rather defined solely based on fixed processes and structures instead of developing these further.

Criticism of accreditation in the healthcare sector occasionally also arises from the fact that quality certificates at the beginning of the second half of the 20th century were originally developed for industrial production processes within the scope of quality management. This side argues that service companies, which includes medical practices, are structured differently and that in rendering interaction-based services, the individual components must take and maintain precedence over standardized processes.

As much as this objection is to be taken into account in creating standards according to which medical facilities can be accredited, it cannot be denied that medical practices are organised business entities that, if better organised, are better able to complete their tasks. So, for example, rooms must be suited to their intended purpose, equipment and devices serviced, medicines stored professionally, patient safety ensured, hygiene guaranteed and operations and communications made suitable for staff and the performance of services. Accordingly, some principles of traditional quality management also apply to medical practices.

The key difference between the manufacturing of industrial products and the rendering of services in the healthcare sector is that industrial processes must be completely identical. In healthcare however, a great variance in basic conditions and individual needs and wishes of the patients necessitates a large degree of flexibility in the processes. Modern practice accreditation – such as that of the EQUAM Foundation – takes full account of this fact.

A further point of contention regards the selection and assessment of criteria and the issue of what is actually relevant to the definition of quality. There is inevitably the need to limit the number of criteria to be used when developing accreditation programmes. Based on what is known, these criteria should be fundamental and it should be possible to assess the criteria with a reasonable effort. For the efficiency of accreditation programmes, it is crucial that insights from research and practice are applied in the selection of criteria and variables. Moreover, the criteria must be formulated in such a way that various organisational structures and possible methods can be taken into account to address the culture and situation of the practice. The recommendations for accreditation of the Swiss Academy for Medical Sciences (SAMW)[9] and the requirements of the Swiss Accreditation Office (SAS) are also taken into account in the development of the EQUAM programmes. These guidelines include, for example, training and education of the auditors and independence of the accrediting body.

Sometimes however, despite criteria that have been selected with the utmost diligence, the review of these criteria by an external body is perceived by physicians as an unreasonable demand or even as an insult. In these cases, the additional knowledge from quality management and regarding patient safety is not deemed by physicians to be beneficial for medical work or quality, which in turn highlights the importance of the affected managers' view of quality management and the importance of leadership[10]. This applies to the management of medical practices and doctor networks alike. Practices where the implementation of quality criteria in day-to-day work is supported and modelled by management, see a further professionalization and increase in quality as well as greater satisfaction amongst staff and patients.

How this is dealt with is of vital importance to the result of the business activities of medical practices. A well organised company renders better services. This is also confirmed by effectiveness studies on accreditation in medical practices as is shown in the section below.

Evidence and effect
While objections were raised in a British publication in 2012 that the evidence basis on effectiveness, cost efficiency and suitability of the accreditation of practices is considered to be relatively limited[11], it was also pointed out that the information regarding the effectiveness of EPA accreditation used by the EQUAM Foundation between 2004-2017, represents a notable exception.

A longitudinal study from 2011 with a comparison group of 102 practices each makes clear that the performance of accredited medical practices has significantly improved during the course of the three years between accreditation dates with regard to the analysis of critical events, quality development and policy as well as complaint management. The accreditation result was better overall for the intervention group at the second time of measurement than for the comparison group that had not yet been accredited at that time in the study[12].

In 2015, a Swiss longitudinal study was conducted amongst 45 primary care practices that had been accredited by the EQUAM Foundation according to EPA standards, confirming the benefit of practice accreditation in supporting ongoing development of practices. The data used for the assessment was taken from practices that each received accreditation according to EPA standards three times in intervals of three years. Significant improvements were noted in the areas of quality and safety, as well as information and quality per se. The total score of the overall 129 indicators improved considerably between the measurement dates[13].

A randomised case-control study on the effect of accreditation on a patient level with a total of 1,252 practices, is currently underway in Denmark, where accreditation of primary care practices has been mandatory since 2016[14]. The results of this comprehensive study, which is representative of the Danish healthcare system, is highly anticipated.

Key recommendations
As shown above, there are many arguments in favour of practice accreditation. Thus,

favourable conditions for practice accreditation to leave the status of a niche product that it has had until now in Switzerland, and spread wider should be built. Considering a legislation that makes practice accreditation mandatory should be amongst them.

In order to be accepted, the criteria for practice accreditation must address the culture and the organizational needs of the practice. Therefore, the key success factor for the development of accreditation programmes – be they voluntary or mandatory - is certainly the involvement of practice experts in the development process.

Especially – but not only – larger group practices should consider the benefits of a practice accreditation in terms of organizational development and business organization.

Conclusion

Although accreditation alone is no guarantee of quality, it makes proper medical services considerably more likely through compliance with appropriate requirements. Above all, it enables practices to promote a culture that is rooted in constant quality development and improvement.

Compared with Denmark, for example, where practice accreditation has been mandatory since 2016[9], in Switzerland, accreditation of medical practices is still a niche status after nearly 20 years despite its success. This relative success is due to its direct benefits and not in least to the reward of their cost efficiency by some health insurers in the area of integrated care.

Specific regulatory requirements regarding practice accreditation or proposed legislation in this direction are currently not underway in Swiss healthcare policy. This is surprising. Accreditation of medical practices significantly contributes to making services in outpatient care effective, appropriate and economical, thus implementing the requirements of Article 32 of the Health Insurance Act. For the outpatient sector in particular, accreditation by means of an audit conducted by an external specialist is a suitable measure for creating transparency and allowing for an independent review of practice data. This is not the case for quality programmes based exclusively on self-declaration.

Accreditation requires a certain amount of costs and effort that is certainly easier to manage for larger practices than for smaller ones. At the same time, larger practices often need to make processes more efficient through structuring and ongoing quality development. It remains to be seen whether the current trend towards more group practices will also lead more practices to decide in favour of accreditation and subsequent further development processes.

Conflicts of interest

The authors declare that they have no competing interests.

[1] Eisenring C, Hess K. Wirtschaftlichkeit und Qualität der Arztpraxis. Neuchâtel: Schweizerisches Gesundheitsobservatorium OBSAN; 2004.

[2] EQUAM Foundation. Primary care practice – Accredited quality [Internet]. EQUAM; 2018 Available from: https://www.equam.ch/wp-content/uploads/2018/07/Programmbeschrieb-Grundversorger-d-V0.2.pdf

[3] Interactive query tool on FMH statistics [Internet]. FMH; 2018 Available from: https://www.fmh.ch/services/statistik/aerztestatistik.html

[4] Berwick DM, Nolan TW, Whittington J. The Triple Aim: Care, Health, And Cost. Health Aff. 2008;27(3):759–69.

[5] Bodenheimer Thomas M, Sinsky Christine, MD2 3. From Triple to Quadruple Aim: Care of the Patient Requires Care of the Provider. Ann Fam Med. 2014;12:573–6.

[6] St.Pierre M, Hofinger G. Human Factors und Patientensicherheit in der Akutmedizin (3rd edition). Berlin: Springer-Verlag; 2014.

[7] EQUAM stands for "Externe Qualitätsförderung in der Medizin" (external quality improvement in medicine).

[8] Pedersen LB, Andersen MKK, Jensen UT, Waldorff FB, Jacobsen CB. Can external interventions crowd in intrinsic motivation? A cluster randomised field experiment on mandatory accreditation of general practice in Denmark. Soc Sci Med. 2018;

[9] SAMW, Accreditation in a Medical Context, SAMW Recommendations, 2011.

[10] Zimring C, Augenbroe GL, Malone EB, Sadler BL.Implementing healthcare excellence: the vital role of the CEO in evidence-based design. HERD 2008;1(3):7-21.

[11] Lester HE, Eriksson T, Dijkstra R, Martinson K, Tomasik T, Sparrow N. Practice accreditation : the European perspective. Br J Gen Pract. 2012;(May):390–2.

[12] Szecsenyi J, Campbell S, Broge B, Laux G, Willms S, Wensing M, et al. Effectiveness of a quality-improvement program in improving management of primary care practices. Can Med Assoc J. 2011;

[13] Goetz K, Hess S, Jossen M, Huber F, Rosemann T, Brodowski M, et al. Does a quality management system improve quality in primary care practices in Switzerland? A longitudinal study. Open [Internet]. 2015;5:7443. Available from: http://dx.doi.org/10.1136/bmjopen-2014-007443

[14] Andersen MK, Pedersen LB, Siersma V, Bro F, Reventlow S, Søndergaard J, et al. Accreditation in general practice in Denmark : study protocol for a cluster-randomized controlled trial. 2017;1–9.

Swiss National Report on Quality and Safety in Healthcare

Contribution by the Swiss Nurses Association to the Swiss National Report on Quality and Safety in Healthcare.

Approved by the ASI Board on 18.01.2019

Abstract

The Swiss Nurses Association (ASI) has prepared a short report as a contribution to a Swiss national report on quality and safety in healthcare, with a nursing care perspective and focus.

In Switzerland, a part of healthcare quality is regulated via the Federal Health Insurance Act (LAMal) and via the Federal Act on the Electronic Patient Record (LDEP). The healthcare education system is regulated via the Medical Profession Act, the Health Care Professions Act (LPSan) and the Federal Act on Vocational and Professional Education and Training (VPETA).

At national level, several organisations focus on the development of quality of care. For example the Swiss National Association for Quality Development in Hospitals and Clinics (ANQ) or the national foundation Patient Safety Switzerland. The Swiss Academy of Medical Sciences (SAMS) acts as a bridge builder between science and society and produces recommendations and ethical guidelines for the healthcare sector.

Additionally, the FIT-Nursing Care platform, the BEST Institute, the Cochrane Institute–Switzerland, the country's university institutes of nursing science, its universities of applied sciences (HES) and the Careum Foundation all promote the development and use of evidence-based practice (EBP). With regards to Switzerland's quality of care, the results of ongoing studies such as ProQuaS, Intercare, Match[RN], SHURP and RESPONS are eagerly awaited.

Via their guidelines and recommendations, associations of different health professions, interest groups or health leagues (e. g. the Swiss leagues for Alzheimer's disease or for palliative care) can all have a beneficial effect on the quality and safety of healthcare. These organisations have the ability to depoliticise debates and bypass Switzerland's regional diversity by advocating the use of best practices nationally.

Finally, solid research shows that the nurse-to-patient ratio as well as motivation and education of nurses have a major impact on patient safety and the quality of care. The WHO *Global Strategy on Human Resources for Health: Workforce 2030*, adopted at the World Health Assembly in May 2016, articulates one of its objectives around the linkage between investments in the health workforce and "improvements in health outcomes, social welfare, employment creation and economic growth", arguing that the investment in human resources for health can triple the results in terms of improved health outcomes, global health security and economic growth(1).

ASI's contribution to the "Swiss National Report on Quality and Safety in Healthcare Report" provides a vision that places nursing care at the very heart of the efforts to improve healthcare quality and safety. After examining issues concerning the safety, quality and effectiveness of care in Switzerland, it will discuss significant interventions, key factors for success and obstacles to improving quality and patient safety. Finally, it will highlight specificities of the Swiss healthcare environment which facilitate or hinder the development of quality and patient safety.

Conflicts of interest

The ASI hereby declares that it has no conflicts of interest with regards to this report.

Schweizer Berufsverband der Pflegefachfrauen und Pflegefachmänner
Association suisse des infirmières et infirmiers
Associazione svizzera infermiere e infermieri
Associaziun svizra da las tgirunzas e dals tgirunzs

1. What is known about the safety, quality and efficiency of care in Switzerland?

The current situation in Switzerland

<u>Federal Laws and strategies</u>

The services referred to in articles 25–31 of the Federal Act on Health Insurance (LAMal)(2) shall be effective, appropriate and economic. Efficacy shall be proven by scientific methods. The efficacy, expediency and efficiency of the benefits shall be reviewed periodically.

The government's overall strategy "Health 2020" aims to maintain quality of life, increase equal opportunities, raise the quality of care and improve transparency. National strategies such as the "National Dementia Strategy 2014–2019"(6) are contributing to the implementation of the overall national strategy. Usually the Federal Office of Public Health (FOPH) and the Swiss Conference of the Cantonal Ministers of Public Health (CMPH) collaborate with experts and expert organizations in the field. Some of the national strategies are underfinanced and therefore don't always have the expected impact.

Similarly, the Federal Act on the Electronic Patient Record (LDEP) obliges hospitals and nursing homes to start using electronic patient records by 2020 and 2022 respectively(3). In 2014, the Interprofessional Working Group on Electronic Patient Records (IPAG) was constituted in order to prepare for the introduction of the LDEP. IPAG's papers on cybermedicine(4) and on electronic patient transfer reports(5) now form the basis for document exchange formats guaranteeing interoperability and are integrated into the LDEP's rules of application. These reports reveal the needs expressed by the different professions concerned and will help to ensure higher quality electronic patient records.

A Federal Law on Prevention and Health Promotion(7) as well as the creation of a Swiss Institute for Quality Healthcare were in discussion but they never saw the light of day. The Swiss Nurses Association (ASI) strongly supported both plans. Following these projects, which have not been pursued any further, the creation of a Quality Network was discussed. The current status of this project is not known to ASI.

<u>Activities by associations</u>

Several organisations operating at the national level also put the emphasis on patient safety and quality, for instance the Swiss National Association for Quality Development in Hospitals and Clinics (ANQ)(8), the Swiss Academy for Quality in Medicine (ASQM)(9) and the Foundation Patient Safety Switzerland(10). The Swiss Academy of Medical Sciences (SAMS) acts as a bridge builder between science and society and produces recommendations and ethical guidelines for the healthcare sector.

<u>Nursing personnel</u>

A dramatic shortage of Registered Nurses (RNs) and high fluctuation of the nursing personnel put the safety, quality and effectiveness of care(11,12) at risk. This results in hospital readmissions, medical complications and even avoidable medical errors(13).

Some examples of the challenges concerning fluctuation and shortages of health personnel include
- the increasing complexity of work tasks combined with a reduction in the length of stays(13),
- the intensification of work(11,14),

- the multiplication of administrative tasks,
- a number of challenges around nurse migration and international recruitment(15).

Evidence shows that in addition to the numbers of healthcare professionals the skills- and grade-mix in hospitals, nursing homes and other healthcare organisations have a major impact on patient safety, as well as on quality and effectiveness of patient care. Apart from the information about efficiency and quality indicators, information about nurse-to-patient-ratios, fluctuation and employee satisfaction needs to be reflected in any system of stewardship of the health system, as they are central for good health outcomes(16).

A focus on nursing care

The Swiss Nurses Association (ASI)

The ASI leads different approaches aiming at developing and ensuring quality in nursing care:

- In 2017, the ASI and its allies submitted a federal popular initiative entitled "For a strong nursing care"(17), after having collected 120,000 signatures in eight months. The initiative's objectives are to ensure a good quality nursing care for all in Switzerland, to implement effective measures against the shortage of nursing personnel and to upgrade the profession's status.
- The ASI is part of the international "Nursing Now Campaign"(18) launched by the World Health Organisation (WHO) and the International Council of Nurses (ICN),
- Nursing Now(18,19), a three-year global campaign (2018-2020), aims to improve health by raising the profile and status of nurses worldwide.
- The ASI publishes brochures/information directly or indirectly linked to the quality of nursing care, such as:
  o Les soins infirmiers en suisse – Perspectives 2020(16),
  o Ethics and Nursing Practice(20),
  o Report on the Quality of Nursing Care in Switzerland(21),
  o The Strategic Missions of Freelance Nurses(22),
  o Brochure on Documenting Care(23),
  o Diverse ethical position papers(24).

Education system

The state ensures the quality of education, in particular by accrediting the study programmes run by universities and a system of quality assurance for other education institutions in healthcare based on the following national laws:

- the Federal Act on Vocational and Professional Education and Training (VPETA)(25) which covers secondary level vocational education and colleges of higher education (ES),
- the Health Care Professions Act (LPSan)(26) which includes the regulation of education and professional practice of health professions educated in Universities of Applied Sciences (HES).
- the Federal Act on Funding and Coordination of the Swiss Higher Education Sector (HEdA)(27) which provides the legal basis for medical universities.

Institutions promoting quality in nursing care

The subject of the quality of care is also covered by the FIT-Nursing Care platform(28), the BEST Institute(29), the institute Cochrane Switzerland(30), the country's university institutes of nursing sciences, its Universities of Applied Sciences (HES) and the Careum Foundation(31). All these organisations promote the development of the use of

evidence-based practice (EBP) by issuing good practice guidelines which enable healthcare professionals to integrate the latest research results into their daily practice. For example, FIT-Nursing Care(28) is a Swiss-German platform which provides direct access to the results of international research projects on nursing care that have been evaluated by experts. In French-speaking Switzerland, the BEST Institute(29), which is certified by the Joanna Briggs Institute (JBI), is active in the development of evidence-based nursing care practice while the institute Cochrane Switzerland(30) in Lausanne is internationally recognised.

Measurements and Indicators

There is no sufficient number of nurse sensitive indicators. Some information concerning the quality of nursing care, providing points of comparison at the international level, can be found in the measurements of the ANQ (e. g. falls and pressure ulcers among children and adults or surgical site infections).
The "Swiss Care Excellence Certificate" (SCEC)(32), a system of quality management developed by Concret SA in collaboration with the Universities of Applied Science of Bern and Winterthur, includes indicators which render the quality of nursing care visible and manageable.

Research studies

There are currently few studies on the efficiency and quality of nursing care. The domains of homecare and psychiatric care are particularly under-researched.

National and international studies, however, have demonstrated the positive repercussions on the quality of care given to patients and on their safety if nurses spend more time caring for patients and if the number of nurses in care teams is increased. Indeed, each 10% reduction in the proportion of nursing per patient staff has been associated with an 11% increase in the risk of death(33).

Therefore economic analyses indicate that an increase in nursing personnel improves the quality of care while reducing the risk of complications or death as well as reducing the duration of hospital stays and the risks of readmission(33).

Conclusion: Increasing the number of nursing staff will improve the quality of the healthcare system and lower its costs(33)**.**

Switzerland

There is limited stewardship concerning quality and safety improvement at national level. Plans to set up a national institute for health and care excellence were not supported by main stakeholders. Different associations and other players are, in a more or less coordinated manner, active in this field. However, there are various interventions and measures in Switzerland in order to improve the quality and safety of care:

- The **Federal Statistical Office**(34) the national centre for public statistics produces and disseminates key statistical information showing the current status and trends, for instance in fields "health of the population, diseases and the health system", including data concerning health personnel. They also carry out comprehensive analysis and devise indicator systems. This office fulfils the requirements for safe data collection and its publications should be a key element for the stewardship of the Swiss health system.
- As part of its mission to ensure the rights of and respect for patients, the **Foundation Patient Safety Switzerland** created the platform Critical Incident Reporting System platform (CIRS) and Critical Incident Reporting & Reacting NETwork (CIRRNET)(35). This structures help to develop new recommendations and to distribute "quick-alert" warnings(36), thus ensuring a culture of safe care, quality and interprofessional co-operation(35).
- The **Alliance Peer Review CH** consisting of the FMH (Swiss Medical Association), Swiss Nurse Leaders (nursing directors association) and H+ (Swiss Hospitals) promotes uniform and interprofessional peer review based on routine data. The Quality Medicine Initiative (IQM) was introduced to Switzerland from Germany in 2014–15 and adopted as standard in 2016. A similar procedure is being designed for psychiatric care(37).
- The **Swiss Medical Board**(38) is an association bringing together various Swiss institutes and organisations. Its goal is to make the best possible use of the healthcare system's resources in order to provide patients with an optimal quality of care.
- **Swissnoso**(39) is Switzerland's national infection prevention alliance, representing the key stakeholders in infection control making recommendations and collaborating with the Swiss Office of Public Health.
- Healthcare centres can search for accreditation, for example as "Comprehensive Cancer Centres" by the Swiss League Against Cancer, in order to demonstrate their high quality.
- Smarter medicine(40) aims to reduce healthcare costs by identifying any superfluous medical measures.

Nursing care

Like in the general system at national level, there is little stewardship and overall coordination concerning quality and safety improvements in nursing care. There is room for improvement concerning value based care and nurse-sensitive indicators. Some key elements of current activities and developments are described below.

Education

The integration of nursing education into the national education system represents a major improvement. Previously, the 26 cantons were responsible and had delegated the regulation of nursing education to the Swiss Red Cross. The education of nurses in Switzerland is now part of Switzerland's tertiary educational level A, within the Bologna

system, including bachelor's degrees (Universities of Applied Sciences, HES), master's degrees and PhDs in nursing sciences. About two thirds of the Swiss nurses have a tertiary educational level B with diplomas from colleges of higher education (ES)(41). A newly created apprenticeship for healthcare assistants yields around 4000 certificates a year.

Skills and grade-mix

Another element of importance is the proportion of registered nurses (RNs)per patient (nurse-patient ratio). A higher ratio of nurses per patient can be associated with better results and outcomes for patients and nurses whereas a reduction in qualified nursing staff and their replacement by care assistants or auxiliaries increases the number of cases of avoidable death, lowers the quality of patient management and patient safety and worsens the shortage of nursing personnel(42).

Furthermore, numerous studies and meta-analyses have demonstrated that for chronic illnesses, the results of patient management by specialised nurses are at least equivalent to those of patient management by physicians. This was also confirmed by a systematic review carried out by the University of Zurich's Institute of Primary Care(43).

Certifying nursing care quality

Currently, Concret's Swiss Care Excellence Certificate is the only quality certification procedure for nursing care. The certification cycle allows expert appraisals and evaluations as well as certifications in a variety of institutions. As a result, direct improvements are being implemented in those institutions(32).

The quality of nursing care and the ANQ(8)

The quality of nursing care influences the results of the ANQ's national quality indicators and measurements. There are, however, few publications about nursing centred interventions to improve quality and safety.

Research studies

Several research studies, such as ProQuaS(44), INTERCARE(45), Match[RN](46), SHURP(47) and Respons and Respons-Fam(48), will provide results concerning quality.

Schweizer Berufsverband der Pflegefachfrauen und Pflegefachmänner
Association suisse des infirmières et infirmiers
Associazione svizzera infermiere e infermieri
Associaziun svizra da las tgirunzas e dals tgirunzs

3. What are the results and what is known about their sustainability?

Switzerland

ANQ's measurements help to raise awareness among managers, nurses and other health professionals in leadership positions concerning the quality of care, thus setting off a learning process that aims at improvements(49).

Curaviva, the national association of care home directors, was mandated by the Federal Office of Public Health to develop quality indicators (QI) for long-term inpatient care (50). The ASI regrets the absence of clinical governance, that no nurses' organisation was involved in the development of the QI and that key decisions were made by managers.

ASI is involved in the development of indicators on home based care with the Resident Assessment Instrument (RAI)(51). Spitex Schweiz has the leadership in this project.

The measures mentioned do not always necessarily lead to interventions or allow organisations to intervene on their own. In consequence, there is currently no available overview of all these diverse interventions and their outcome. From a scientific point of view, there is limited evidence concerning the results and the sustainability of the different approaches. There are no mandatory certification processes (e. g. International Organization for Standardization (ISO); norms for total quality management and magnet hospitals). No institution exists, like the National Institute for Health and Care Excellence (NICE) in the United Kingdom, which establishes clinical standards for health and social services applicable across the whole country(52).

Nursing care

The ASI collaborates with the different partners mentioned under question 2, e. g. with Swissnoso on training workshops on the prevention of infection.

However, the ASI does not have precise information on the results of interventions on safety, quality and effectiveness of care.

Schweizer Berufsverband der Pflegefachfrauen und Pflegefachmänner
Association suisse des infirmières et infirmiers
Associazione svizzera infermiere e infermieri
Associaziun svizra da las tgirunzas e dals tgirunzs

4. What are the key factors of the success of these interventions?

Switzerland

One key factor is the definition of the right interventions for specific settings and their standardised use across the country. Switzerland is a country with the means to achieve good quality, e. g. to invest in highly qualified and well-trained healthcare personnel. Furthermore, the Swiss Medical Board aims to reduce unnecessary interventions and save costs(38). Finally, the new Health Care Professions Act (LPSan)(26) provides a necessary and very precise framework for professional practice and education.

Nursing care

Quality concept

The ASI, in collaboration with one of its specialised associations, Curacasa, is responsible for freelance nurses. This includes a responsibility for the quality of the services independent nurses provide. The quality programme(53) contains a training session on quality standards and an annual quality refresher-day as well as a self-evaluation and an external evaluation of quality, carried out by Curacasa and Concret. The result is a whitelist of freelance nursing personnel who fulfil the quality criteria set out by the ASI and Curacasa.

Professional competencies

Another factor of success is e-log(54), a platform created jointly by the ASI and the Swiss Federation of Anaesthetist Nurses. The platform allows nurses to prove their professional competencies with the aid of an electronic curriculum vitae. The e-log diary and the e-log points system certify the quality of the training nurses participate in. E-log is a response to the requirements of the LAMal and a very important tool for the documentation of continuous professional development (CPD). With the Health Personnel Professional Act there will soon be a legal basis in place to make the CPD mandatory (2019 or 2020).

Switzerland

The Swiss Confederation and the cantons have put forward ideas about achieving quality, but without specifying neither precise indicators of success nor evaluation programmes to be used. And there is little money available for financing the proposed measures.

For instance, there is competition between hospitals which can lead to lowering base rates for making more profit. As a consequence the number of health professionals might be reduced and skilled workers replaced by les skilled persons with lower salaries. The fragmentation of responsibilities for healthcare services and the shifts in staffing are obstacles to the development of quality.

Nursing care

The main obstacles and challenges nursing care is facing are:
- the lack of personnel,
- poor working conditions,
- low salaries (compared with other professions in Switzerland, with similar education)
- limited possibilities of reconciling professional and private live,
- low nursing staff retention(17,55).

6. What are the specificities of Switzerland's environment that facilitate or hinder these interventions?

The Swiss decentralised healthcare system has advantages and disadvantages. Firstly, the diversity of healthcare policies in Switzerland is a hindrance when it comes to applying a national decision linked to the quality of care in every canton. Cantonal pilot projects are sometimes easier to carry out than national projects which are far more complex. Empirically, by way of example, Quafipa(56), in the canton of Fribourg, had positive results. Projects should also be developed with close regard to the needs of a canton's population: the needs of the populations of the canton of Obwalden (rural environment) or the canton of Berne (urban environment) are not necessarily identical. The fact that the care services offered can be adapted to the population's need favours a democratic control (through Switzerland's highly devolved cantonal and communal direct democracy system).

Prevention, health promotion and the prevention of natural catastrophes or pandemics(57) are mainly dealt with at the national level. These types of interventions are complex to manage because directives must be applied across Switzerland's 26 cantons. In case of emergencies measures can be made compulsory.

The intertwined tasks of the Swiss Confederation, its cantons and communes make it extremely complex to implement potentially successful interventions to improve quality and safety in the field of public health. A further obstacle is the multiplicity of actors in the domain of the quality of care, which makes it extremely difficult to coordinate e. g. the care for patients suffering from chronic illnesses.

In addition to this, certain actors and political parties would prefer the entire healthcare system to be controlled by the market. This does not always lead to efficiency and carries the risk that significant amounts of financial resources (taxes and mandatory health insurance payments) destined for care go to private companies (hospitals, nursing homes, industries) and their shareholders(58,59).

Finally, the recommendations made by professional associations, interest groups and health leagues (ASI, Alzheimer's Switzerland, Palliativ.ch, etc.) can have beneficial effects. These organisations depoliticise debates and they can bypass Switzerland's regional diversity by advocating the systematic use of best practices across the country. It would be important to encourage the cantons to refer to these best practices in their own legislation.

7. Recommendations

The Swiss Nurses Association recommends the following:

- To create an overview of all the diverse organisations and activities and to describe if and how they influence quality and safety in health care.
- To create a national institute for patient safety and quality in healthcare, like the National Institute for Health and Care Excellence (NICE) in the United Kingdom, which establishes clinical standards for health and social services applicable across the whole country(52). If this is not feasible politically an extra parliamentarian commission for patient safety and quality of care could be an alternative.
- To collect enough of the right data on structure and performance of the different settings. Data analysis and publication should be carried out by the Federal Statistical Office.
- To define and formulate indicators and measurements with both parties concerned: professionals and patients.

Specific recommendations concerning patients:
- Besides the measurement of outputs and outcomes there is a need to further develop and consider the measurement of the quality of life. Patient reported outcome measures (PROMS) and patient reported experience measures (PREMS) are developed and systematically measured in Switzerland.

Specific recommendations concerning nurses:
- With 90 000 active nurses, this professional group is the biggest among health care and nursing care providers. For good stewardship of the health system more information about nursing care, e. g. nurse sensitive indicators, needs to be collected and evaluated.
- The Swiss Confederation and the cantons are committed to ensuring enough nurses per patient as well as to providing motivated and well educated nursing personnel, as these factors have a major impact on patient safety and the quality of care. The WHO *Global Strategy on Human Resources for Health: Workforce 2030*, adopted at the World Health Assembly in May 2016, articulates one of its objectives around the linkage between investments in the health workforce and "improvements in health outcomes, social welfare, employment creation and economic growth", arguing that the investment in human resources for health can triple the results in terms of improved health outcomes, global health security and economic growth(1).

Schweizer Berufsverband der Pflegefachfrauen und Pflegefachmänner
Association suisse des infirmières et infirmiers
Associazione svizzera infermiere e infermieri
Associaziun svizra da las tgirunzas e dals tgirunzs

8. Literature

1. Cometto G, Campbell J. Investing in human resources for health: beyond health outcomes. Human Resources for Health. 2016 Dec;14(1). [accessed 19 Dec 2018] Available from: http://human-resources-health.biomedcentral.com/articles/10.1186/s12960-016-0147-2

2. Loi fédérale sur l'assurance-maladie. 832.10 Mar 18, 1994. [accessed 3 Oct 2018] Available from: https://www.admin.ch/opc/fr/classified-compilation/19940073/index.html

3. eHealth Suisse. Questions et réponses concernant la LDEP. 2018. [accessed 8 Feb 2018] Available from: https://www.e-health-suisse.ch/fr/mise-en-oeuvre-communautes/mise-en-oeuvre/questions-et-reponses.html

4. eHealth Suisse. Formats d'échange pour le Dossier de cybermédication. 2018. [accessed 6 Nov 2018] Available from: https://www.e-health-suisse.ch/fr/technique-semantique/interoperabilite-semantique/formats-dechange/formats-dechange-existants.html

5. IPAG. eTOC / Rapport électronique de transfert. 2018. [accessed 6 Nov 2018] Available from: https://www.e-health-suisse.ch/fr/technique-semantique/interoperabilite-semantique/formats-dechange/formats-dechange-en-planification.html

6. OFSP O fédéral de la santé publique. Stratégie nationale en matière de démences 2014-2019. 2018. [accessed 8 Jan 2019] Available from: https://www.bag.admin.ch/bag/fr/home/strategie-und-politik/nationale-gesundheitsstrategien/nationale-demenzstrategie.html

7. Projet de Loi fédérale sur la prévention et la promotion de la santé. 09.076 Sep 27, 2012. [accessed 31 Oct 2018] Available from: https://www.admin.ch/opc/fr/classified-compilation/20073110/index.html

8. ANQ. Association nationale pour le développement de la qualité dans les hôpitaux et les cliniques. 2018. [accessed 31 Oct 2018] Available from: http://www.anq.ch/fr/anq/

9. FMH. Académie suisse pour la qualité en médecine. 2018. [accessed 8 Nov 2018] Available from: http://www.fmh.ch/fr/asqm/projets_relatifs_qualite.html

10. Sécurité des patients suisse. Home. 2018. [accessed 31 Oct 2018] Available from: https://www.securitedespatients.ch/

11. Benallah S, Domin J-P. Réforme de l'hôpital. Quels enjeux en termes de travail et de santé des personnels ? La Revue de l'Ires. 2017;91–92(1):155. doi: 10.3917/rdli.091.0155

12. Buchan J, Shaffer FA, Catton H. Policy Brief: Nurse Retention. 2018. [accessed 21 Nov 2018] Available from: https://www.icn.ch/sites/default/files/inline-files/2018_ICNM%20Nurse%20retention.pdf#page=11&zoom=auto,-130,476

13. Blanc A-L, Fumeaux T, Stirneman J, Bonnabry P, Schaad N. Réadmissions hospitalières : problématique actuelle et perspectives. Rev Med Suisse. 2017;13(544–545):117–20.

14. Dhaini SR, Denhaerynck K, Bachnick S, Schwendimann R, Schubert M, De Geest S, et al. Work schedule flexibility is associated with emotional exhaustion among registered nurses in Swiss hospitals: A cross-sectional study. International Journal of Nursing Studies. 2018 Jun; 82:99–105. doi: 10.1016/j.ijnurstu.2018.03.019

15. Schilliger S. 'Polinnen sind günstig und fürsorglich' - Ethnische und geschlechtliche Segregation des Arbeitsmarktes für 24h-Betreuung. TANGRAM. Commission fédérale contre le racisme. 2018 21; (p.68–71). [accessed 31 Oct 2018] Available from: https://www.ekr.admin.ch/pdf/Tangram_29.pdf

16. ASI-SBK. Les soins infirmiers en suisse – perspectives 2020. Berne: SBK-ASI; 2011. Available from: https://www.sbk.ch/fr/sujets-infirmiers/perspectives-2020.html

17. ASI-SBK. Initiative populaire pour des soins infirmiers forts. Initiative populaire pour des soins infirmiers forts. 2018. [accessed 31 Oct 2018] Available from: http://www.pour-des-soins-infirmiers-forts.ch/

18. WHO. Nursing Now Campaign. WHO. 2018. [accessed 31 Oct 2018] Available from: http://www.who.int/hrh/news/2018/nursing_now_campaign/en/

19. Nursing Now. Nursing Now. 2018. [accessed 21 Dec 2018] Available from: https://www.nursingnow.org/launch/

20. ASI-SBK. L'éthique et la pratique infirmière. ASI-SBK. Bern: ASI-SBK; 2013. [accessed 31 Oct 2018] Available from: https://www.sbk.ch/fr/sujets-infirmiers/ethique.html

21. ASI-SBK. Rapport sur la qualité des soins infirmiers. ASI-SBK; 2017. [accessed 31 Oct 2018] Available from: https://www.sbk.ch/fr/sujets-infirmiers/qualite-des-soins.html

22. ASI-SBK. Mission stratégique des infirmières et infirmiers indépendants. ASI-SBK; 2018. [accessed 31 Oct 2018] Available from: https://www.sbk.ch/fr/boutique-en-ligne/publications-de-lasi.html

23. ASI-SBK. Documenter les soins. ASI-SBK; 2019. Available from: https://www.sbk.ch/fr/boutique-en-ligne/publications-de-lasi.html

24. ASI-SBK. Publications sur les questions éthiques. 2018. [accessed 30 Aug 2018] Available from: https://www.sbk.ch/fr/sujets-infirmiers/ethique.html

25. Loi fédérale sur la formation professionnelle. 412.10 Dec 13, 2002. [accessed 21 Nov 2018] Available from: https://www.admin.ch/opc/fr/classified-compilation/20001860/index.html

26. Loi fédérale sur les professions de la santé LPSan. 15.077 2015. [accessed 21 Nov 2018] Available from: https://www.bag.admin.ch/bag/fr/home/berufe-im-gesundheitswesen/gesundheitsberufe-der-tertiaerstufe/bundesgesetz-ueber-die-gesundheitsberufe.html

27. Loi sur l'encouragement et la coordination des hautes écoles, LEHE. Dec 12, 2018. [accessed 12 Dec 2018] Available from: https://www.admin.ch/opc/fr/classified-compilation/20070429/index.html

28. FIT-Nursing Care. Home - FIT-Nursing Care. 2018. [accessed 31 Oct 2018] Available from: https://www.fit-care.ch/home

29. BEST. BEST | Bureau d'Echange des Savoirs pour des pratiques exemplaires de soins. 2018. [accessed 31 Oct 2018] Available from: http://www.best-sante.ch/

30. Cochrane Suisse. Trusted evidence. Informed decisions. Better health. Enter terms. 2018. [accessed 8 Nov 2018] Available from: https://swiss.cochrane.org/

31. Careum. Careum Forschung - Careum Stiftung. 2018. [accessed 8 Nov 2018] Available from: https://www.careum.ch/forschung

32. Concret SA. Swiss Care Excellence Certificate (SCEC). 2018. [accessed 31 Oct 2018] Available from: http://www.concret-ag.ch/

33. ASI-SBK. Proportion d'infirmières et infirmiers – répercussions sur la qualité et l'économicité. ASI-SBK; 2018. [accessed 8 Nov 2018] Available from: https://www.sbk.ch/

34. Federal Statistical Office. The Swiss Federal Statistical Office. 2018. [accessed 8 Jan 2019] Available from: https://www.bfs.admin.ch/bfs/en/home/bfs/bundesamt-statistik.html

35. Sécurité des patients suisse. CIRRNET – Critical Incident Reporting & Reacting NETwork. 2018. [accessed 2 Oct 2018] Available from: https://www.cirrnet.ch/index.asp?PID=7025&Lang=fr

36. Sécurité des patients Suisse. Quick-Alerts. 2018. [accessed 6 Nov 2018] Available from: https://www.securitedespatients.ch/actualite/quick-alert/

37. H+. Peer Review interprofessionnel. 2018. [accessed 1 Nov 2018] Available from: https://www.hplus.ch/fr/qualite/peerreviewsinterprofessionnels/

38. Swiss medical board. Home. 2018. [accessed 1 Nov 2018] Available from: https://www.swissmedicalboard.ch/index.php?id=1&L=1

39. Swissnoso. Que fait Swissnoso ? 2018. [accessed 1 Nov 2018] Available from: https://www.swissnoso.ch/fr/

40. Société Suisse de médecine interne générale. Smarter medicine. 2018. [accessed 1 Nov 2018] Available from: http://www.smartermedicine.ch/fr/page-daccueil.html

41. State Secretariat for Education, Research and Innovation. Swiss Education System. 2018. [accessed 8 Nov 2018] Available from: https://www.sbfi.admin.ch/sbfi/en/home/bildung/bildungsraum-schweiz/das-duale-system.html

42. Aiken LH, Sloane D, Griffiths P, Rafferty AM, Bruyneel L, McHugh M, et al. Nursing skill mix in European hospitals: cross-sectional study of the association with mortality, patient ratings, and quality of care. BMJ Quality & Safety. 2017 Jul;26(7):559–68. doi: 10.1136/bmjqs-2016-005567

43. Martínez-González NA, Tandjung R, Djalali S, Huber-Geismann F, Markun S, Rosemann T. Effects of Physician-Nurse Substitution on Clinical Parameters: A Systematic Review and Meta-Analysis. Baradaran HR, editor. PLoS ONE. 2014 Feb 24;9(2):e89181. doi: 10.1371/journal.pone.0089181

44. Franziska Zúñiga. ProQuaS | Pflegewissenschaft - Nursing Science (INS). 2018. [accessed 8 Nov 2018] Available from: https://nursing.unibas.ch/de/forschungsprojekte/forschung/forschung/proquas/

45. Simon M, Zúñiga F. INTERCARE | Pflegewissenschaft - Nursing Science (INS). [accessed 8 Nov 2018] Available from: https://nursing.unibas.ch/de/forschungsprojekte/forschung/forschung/intercare/

46. Instituts für Pflegewissenschaft, der Universität Basel. MatchRN Study on the changes in structures, processes and results of nursing care in Swiss acute care hospitals. 2018. [accessed 12 Dec 2018] Available from: https://matchrn.unibas.ch/en/

47. Institut für Pflegewissenschaft, der Universität Basel. Swiss Nursing Homes Human Resources Project (SHURP). 2018. [accessed 12 Dec 2018] Available from: https://shurp.unibas.ch/

48. BFH. Bern University of Applied Sciences: Health: Forschung: RESPONS. 2018. [accessed 12 Dec 2018] Available from: https://www.gesundheit.bfh.ch/en/research/nursing/projects/respons.html

49. ANQ. Enquête de satisfaction des patients ANQ. ANQ; 2017. [accessed 21 Nov 2018] Available from: https://www.anq.ch/wp-content/uploads/2018/02/ANQ_Satisfaction-patients_Concept.pdf

50. CURAVIVA Suisse. Indicateurs de qualité médicaux. 2018. [accessed 6 Nov 2018] Available from: https://www.curaviva.ch/Infos-specialisees/Dossiers-thematiques/Indicateurs-de-qualite-medicaux/oGarWL4u/PQBbv/

51. Association fribourgeoise d'aide et soins à domicile. Information AFAS et Spitex CH sur le RAI-HC et InterRai. 2018. [accessed 21 Nov 2018] Available from: https://www.aide-soins-fribourg.ch/files/1G54BRF/info_rai_hc_interrai_14_mars_2018_v_de_f_14032018.pdf

52. NICE. NICE, the National Institute for Health and Care Excellence. NICE. 2018. [accessed 21 Nov 2018] Available from: https://www.nice.org.uk/

53. Curacasa. Curacasa: programme qualité. CURACASA. 2018. [accessed 6 Nov 2018] Available from: http://www.curacasa.ch/français/programme-qualité/

54. ASI-SBK. Bienvenue sur le site de e-log! 2018. [accessed 1 Nov 2018] Available from: https://www.e-log.ch/fr/

55. SSP VPOD. Pétition: «Qualité des soins plutôt que rentabilité!». SSP VPOD. 2018. [accessed 21 Nov 2018] Available from: https://ssp-vpod.ch/themes/sante/

56. AFIPA. QUAFIPA: la démarche qualité des EMS fribourgeois. 2018. [accessed 8 Nov 2018] Available from: http://www.afipa-vfa.ch/projets-de-lafipa/qualite

57. Loi fédérale sur la lutte contre les maladies transmissibles de l'homme. Sep 28, 2012. [accessed 21 Nov 2018] Available from: https://www.admin.ch/opc/de/classified-compilation/20071012/index.html

58. Furger M, Burri A. Altersheim: das lukrative Geschäft mit Senioren - und wer den Preis dafür bezahlt. NZZ am Sonntag. 2018. [accessed 29 Nov 2018] Available from: https://nzzas.nzz.ch/hintergrund/altersheim-das-lukrative-geschaeft-mit-senioren-und-wer-den-preis-dafuer-bezahlt-ld.1437465

59. Furger M, Burri A. Wer kassiert ihre Rente? Zürcher Zeitung AG. 2018 Nov 18; (p.20–2).

9. Glossary

Abbreviations	Terms
ANQ	Swiss National Association for Quality Development in Hospitals and Clinics
ASI	Association suisse des infirmières et infirmiers / Swiss Nurses Association
CIRRNET	Critical Incident Reporting & Reacting NETwork
CIRS	Critical Incident Reporting System
EBP	Evidence-based practice
ES	Ecoles supérieures/Colleges of higher education
FOPH	Federal Office of Public Health
FMH	Foederatio Medicorum Helveticorum/Swiss Medical Association
H+	Les Hôpitaux de Suisse/Swiss Hospitals
HES	Hautes Ecoles Supérieures/University of Applied Sciences
Intercare	Nurse-led models of care in Swiss nursing homes: improving INTERprofessional CARE for better resident outcomes
ICN	International Council of Nurses
IPAG	Interprofessional Working Group on Electronic Patient Records
IQM	Quality Medicine Initiative
ISO	International Organization for Standardization
JBI	Joanna Briggs Institute
LAMal	Loi fédérale sur l'assurance-maladie/Federal Health Insurance Act
LDEP	Loi fédérale sur le dossier électronique du patient/Federal Act on the Electronic Patient Record
LEHE	Loi sur l'encouragement et la coordination des hautes écoles/Federal Act on Funding and Coordination of the Swiss Higher Education Sector
LPSan	Loi fédérale sur les professions de la santé/Health Care Professions Act
Match^{RN}	Study on the changes in structures, processes and results of nursing care in Swiss acute care hospitals
Nice	National Institute for Health and Care Excellence
QI	Quality indicators
QUAFIPA	Fribourg Association of Institutions for Older Adults' Quality Management Approach
ProQuaS	Development and Piloting of a multilevel Intervention to improve Pain Management in Swiss Nursing Homes
RAI	Resident Assessment Instrument
RESPONS	Residents' Perspectives of Living in Nursing Homes in Switzerland
RESPONS-FAM	Residents' Perspectives of Living in Nursing Homes in Switzerland-Family
SAMS	Swiss Academy for Quality in Medicine
SCEC	Swiss Care Excellence Certificate
SHURP	Swiss Nursing Homes Human Resources Project
VPETA	Federal Act on Vocational and Professional Education and Training
WHO	World Health Organization

Swiss National Report on Quality and Safety in Healthcare

Invited contribution on the state of quality and safety in Swiss Healthcare

Short report from The Swiss Society of Clinical Pharmacology and Toxicology

**The Contribution of Clinical Pharmacologists and Toxicologists
to Improve Medication Safety**

Prof. Dr. Alessandro Ceschi, M.D., FEAPCCT

FMH Board certified Clinical Pharmacology and Toxicology
FMH Board certified General Internal Medicine

February 26, 2019

Abstract:

Clinical pharmacology and toxicology deals with the study of drugs in humans and has a focus on the application of pharmacological principles and methods in the real world. Working for the quality and safety of drug prescription represents a core raison d'être of this discipline among the medical specialties.

Medication errors unfortunately still happen worldwide, and Switzerland is no exception, and are a leading cause of injury, disability, death and avoidable harm globally.

This report focuses on the multiple activities, interventions, and initiatives of clinical pharmacologists and toxicologists to address the frequency and impact of medication errors and improve drug safety; the goal can be summarized by "to treat the right patient, with the right drug, using the right dose, by the right route, and at the right time".

Some of these examples are the active involvement in patient care by providing recommendations to improve pharmacotherapy, the contribution to the development, integration and implementation of computerized physician order entry and clinical decision support systems, the significant contributions to pharmacovigilance, services and counselling to personalize drug therapy by pharmacogenetic tests and therapeutic drug monitoring, initiatives to optimize drug treatment and avoid unnecessary medications, contributions to drug and therapeutic committees, and educational interventions and activities related to teaching and research.

Reasons why the role of clinical pharmacologists and toxicologists will continue to gain importance are presented, and six concrete recommendations to improve medication safety in Switzerland are provided: 1) enhance collaboration, 2) facilitate research, 3) promote teaching, 4) create a national coordinating body, 5) clearer commitment to a national strategy and priority, 6) preserve the national pharmacovigilance system.

The work of clinical pharmacologists and toxicologists and their contribution to improve medication safety

Introduction
Clinical pharmacology and toxicology deals with the study of drugs in humans and has a focus on the application of pharmacological principles and methods in the real world. Working for the quality and safety of drug prescription represents a core raison d'être of this discipline among the medical specialities.

Current situation
A very comprehensive and detailed summary of the current state of medication safety in Switzerland, including a critical appraisal of the specificities of the Swiss Healthcare environment, the improvement interventions that have taken place and their results, was recently published by authors from the Swiss Patient Safety Foundation (Fishman et al., Bundesgesundheitsbl.). For this reason, the present report will directly focus on initiatives and activities of clinical pharmacologists and toxicologists to improve drug safety without summarizing again the current state of the field.

Critical steps in medication safety
Clinical pharmacologists and toxicologists contribute significantly to drug safety and the reduction of medication errors and related harm in a multitude of ways, with interventions to prevent adverse drug events at both provider- and system-level, that can be summarized by the goal to "treat the right patient, with the right drug, using the right dose, by the right route, and at the right time", according to "The Five Rights of Medication Administration" of the Institute for Healthcare Improvement.
The relevance of these critical steps in medication safety has already been recognized some decades ago, as Alphonse Chapanis studied medication-related errors in a 1100-bed hospital and identified seven sources of such errors potentially leading to patient harm: "medicine omitted, or given to the wrong patient, at the wrong dose, as an unintended extra dose, by the wrong route, at the wrong time, or as the wrong drug entirely". These errors unfortunately still happen worldwide, and Switzerland is no exception, and are a leading cause of injury and avoidable harm globally. This is the reason why the World Health Organization has launched on March 29, 2017, at the second Global Summit of Health Ministers on Patient Safety in Bonn, Germany, the Third Global Patient Safety Challenge Medication Without Harm, which has the goal to reduce the level of severe, avoidable harm related to medications by 50% over 5 years, globally. Two Swiss clinical pharmacologists and toxicologists from the Swiss Society of Clinical Pharmacology and Toxicology (SSCPT) have an active role in this Challenge, with the author of this report acting as expert.
Errors can occur at different stages of the medication use process, i.e. drug prescribing, transcribing, dispensing, administering and monitoring. The errors identified as such during the medication process may not represent the only problematic aspect of drug treatment. Actually, some prescription applied rigorously without any deviation may still prove definitely noxious to patients e.g. when the indication is questionable, when the information supporting prescription is flawed by unsatisfactory clinical studies, when elements governing drug choice and/or dosing decisions are suboptimal, when knowledge about adverse drug

reactions is missing, etc. The perimeter of potential issues regarding drug safety thus goes largely beyond the encounter of the patient with health professionals.

Activities, interventions and initiatives to improve medication safety

In the following paragraphs, the multiple interventions and contributions of clinical pharmacologists and toxicologists to address the frequency and impact of medication errors, and fight this serious source of avoidable harm, disability and death, will be briefly presented. It is however important to recognize and to underline that although multiple interventions and approaches have already been developed and deployed, yet their implementation is varied and this is mainly due to the fact that in Switzerland there are not enough clinical pharmacologists and toxicologists, who are mainly based in the five divisions of clinical pharmacology and toxicology in the university hospitals (of Zurich, Basel, Bern, Geneva, and Lausanne). A positive development was the creation in June 2015 of the Division of clinical pharmacology and toxicology in Lugano, which was subsequently followed by the opening of the Institute of Pharmacological Sciences of Southern Switzerland, which is serving all hospitals of the EOC hospital network and combines clinical pharmacology and toxicology, pharmacovigilance (regional pharmacovigilance centre), clinical pharmacy, pharmacoepidemiology, pharmacogenetics, hospital pharmacy and public pharmacy, and is offering support, consultancy and training to different hospital-based healthcare professionals and general practitioners from the region of southern Switzerland. Within this institute, clinical pharmacologists and toxicologists work closely together with clinical pharmacists and hospital pharmacists, and the cooperation is good and very effective. This is the first time in Switzerland that all these units are joined within the same institute and the hope is that others will follow, further promoting interprofessional collaboration to the benefit of safe pharmacotherapy for our patients.

Some important activities, interventions and initiatives of clinical pharmacologists and toxicologists to improve drug safety in Switzerland are:

- Involvement in patient care
  Active involvement in patient care as consultants, and in some cases by providing direct patient counselling and by participating on ward rounds, providing recommendations to improve pharmacotherapy in individual patients (provider-based approach as e.g. medication review and substituting, if possible, high-risk drugs, discontinuing unnecessary drugs (deprescribing), preventing and treating adverse drug reactions, preventing drug-drug interactions, adjusting dosing based on age and creatinine clearance, and addressing non-adherence).
- Computerized physician order entry and clinical decision support systems
  Contribution to the development and implementation of computerized physician order entry systems (CPOE) and integration and development of clinical decision support systems (CDSS).
- Contributions to pharmacovigilance
  Numerous activities related to pharmacovigilance, in close collaboration with the Swiss Agency for Therapeutic Products Swissmedic, including prevention, detection, diagnosis, evaluation with causality assessment and treatment of adverse drug

reactions, as the six regional pharmacovigilance centres of Switzerland are located within the Divisions of clinical pharmacology and toxicology.

- o It is worth mentioning that there have been some initiatives and innovative approaches in this field within the Divisions to increase the performance of the detection of adverse drug reactions, particularly in hospitals, and one of these has won the first national prize "Innovation Qualité", patient safety category, of the Swiss Academy for Quality in Medicine of the Swiss Medical Association in collaboration with the Swiss Patient Safety Foundation and supported by 22 important organizations, faculties and national academies of the healthcare sector.
- o Furthermore, the regional pharmacovigilance centres have a long-standing scientific track record in pharmacoepidemiological research with evaluation of safety signals from pharmacovigilance databases such as Vigibase®, the WHO global database of individual case safety reports. The centres have published numerous articles that report on important signals with an assessment of their impact based on such database analyses.

- Personalized pharmacotherapy, pharmacogenetics, and therapeutic drug monitoring
Services and counselling to personalize drug therapy (personalized medicine), including prescription and interpretation of pharmacogenetic tests, with the aim to prevent, or decrease, toxicity and increase efficacy. Related to laboratory tests, also the interpretation of drug concentrations (therapeutic drug monitoring) to adapt pharmacotherapy.

- Choosing wisely / Smarter medicine
The activities and interventions to optimize drug treatment, including avoiding unnecessary medications and paying attention to appropriateness, are well represented by some initiatives within the Choosing Wisely campaign/Smarter medicine, which are taking place in some regions of Switzerland. For example within the EOC hospital network in southern Switzerland, the approach has been based on data with a continuous transparent monitoring of new prescriptions; the focus has been placed initially on proton pump inhibitors and benzodiazepines, with very encouraging results, and now it is planned to include other medications as well.

- Drug and therapeutic committees
The substantial contribution to the activities of Drug and therapeutic committees, with, among other tasks, the definition of the hospital drug formulary and the elaboration of interventions and recommendations for rationale and safe drug prescribing.

- Educational activities and interventions
Educational activities and interventions for care teams, with a focus on physicians, on a range of topics related to medication safety and correct prescribing.

- Teaching
University teaching, at pre- and post-graduate level, in clinical pharmacology and toxicology including drug safety for medical, pharmacy and biology students.

- Research
Clinical research with different approaches and study designs, including pharmacoepidemiology, on issues related to drug safety. For example, a relevant

topic in drug safety is medication reconciliation - i.e. the process that identifies unintentional medication discrepancies, informs prescribing decisions, and prevents medication errors - which has been the subject of a national *Progress*! Programme. However, the evidence on the impact on patients' relevant outcomes is still inconclusive, and this was the rationale for starting the study *Parallel group randomized controlled trial to assess the impact of medication reconciliation at hospital admission on healthcare outcomes*, which is being performed in close collaboration between clinical pharmacology and toxicology, clinical pharmacy and hospital pharmacy.

Outlook

The special and important contributions of clinical pharmacologists and toxicologists for the well-being and safety of patients and the public have been summarized above. As the number of available medicines continues to increase, with biological therapies including immunotherapy, cell and gene therapies having a progressively more important and profound impact on contemporary therapeutics, the role of clinical pharmacologists and toxicologists will continue to gain importance. Related to drug safety, this is due to the fact that the safety and adverse effect profile of many of these new drugs is only partially known and also to some extent completely unusual compared to older drugs. Moreover, the impact of personalized medicine and pharmacogenetics is likely to further change the type and characteristics of therapeutics in the near future.

Recommendations

Enhance collaboration
As there are not enough clinical pharmacologists and toxicologist to fix all drug safety issues, the collaboration with other physicians trained in disciplines such as paediatrics, geriatrics, internal medicine, oncology and psychiatry, but also the interprofessional collaboration with both clinical and hospital pharmacists, as well as other health professionals such as nurses, becomes of vital importance. These colleagues carry out much important clinical pharmacological practice to the benefit of drug safety, and this should be promoted and further enhanced. In particular, the close and active collaboration between clinical pharmacologists and toxicologists and clinical pharmacists should be enabled and promoted, with the definition of clear duties and responsibilities based on competencies. This has been demonstrated to be possible and has proven very effective. The fear to lose power and influence is pointless and should be overcome as the competencies are complementary but not equal, and all these professional figures are needed and will have an important role to play in Swiss healthcare, in order address all remaining drug safety issues and finally increase patients' safety.

Facilitate research
Another very important point would be to guarantee adequate financial support for clinical pharmacological and toxicological research in Switzerland focussing on drug safety issues,

e.g. pharmacoepidemiology, with dedicated structured programmes such as, for example, the National Research Programmes (NRPs) of the Swiss National Science Foundation.

Promote teaching
The importance of the training in clinical pharmacology and toxicology, including drug safety and safe prescribing, both at pre- and post-graduate level, cannot be overstated and should be clearly realised by both medical and pharmacy faculties of all Swiss Universities. These principles should also be adequately included in the curriculum of other important health professionals such as nurses. Teaching should be uniform and ideally be based on "model" undergraduate core curricula in clinical pharmacology and toxicology, therapeutics and prescribing for students, such as those developed by IUPHAR and WHO, and also acknowledge the importance of interprofessionality.

Create a national coordinating body for medication safety
It would be of paramount importance to create a national coordinating body for drug safety initiatives in Switzerland, with a responsible person and with the involvement of all relevant stakeholders and institutions, so that the many useful and promising activities and interventions that are already taking place to different extents at hospital or regional (cantonal) level (e.g. implementation of medication reconciliation procedures, development and integration of CDSS), will gain on coordination, relevance and durability.

Clearer commitment to a national strategy and priority
A clearer commitment to a national strategy and priority, and to recognize the relevance of medication safety from the political leadership at a national level, and also from the Swiss Federal Office of Public Health, would be important and very welcomed. This will also be relevant in order to make good use of all the opportunities that will derive from the digitalization and the development of eHealth, with the widespread introduction of electronic patient records (elektronisches Patientendossier, EPD).

Preserve the national pharmacovigilance system
A relevant aspect of medication safety which is surely well organized and well functioning at a national level, with a good coordination with the cantonal and local level, is the Swiss pharmacovigilance system with the regional pharmacovigilance centres closely collaborating with Swissmedic. This system is regularly praised in the international context, and its high quality and efficacy is clearly recognized. It will be important to preserve this national pharmacovigilance system also in the years to come.

Author:

Prof. Dr. Alessandro Ceschi, M.D., FEAPCCT
FMH Board certified Clinical Pharmacology and Toxicology
FMH Board certified General Internal Medicine

Medical and Scientific Director, Institute of Pharmacological Sciences of Southern Switzerland
Head, Division of Clinical Pharmacology and Toxicology
President, Drug and Therapeutics Committee
Ente Ospedaliero Cantonale
Via Tesserete 46
CH - 6900 Lugano
Alessandro.Ceschi@eoc.ch
https://www.eoc.ch/Ospedali-e-Istituti/ISFSI/ISFSI.html

References:

- Fishman L, Brühwiler L, Schwappach D. Medikationssicherheit: Wo steht die Schweiz? Bundesgesundheitsbl 2018;61:1152-8.
- Donaldson LJ, Kelley ET, Dhingra-Kumar N, Kieny MP, Sheikh A. Medication Without Harm: WHO's Third Global Patient Safety Challenge. Lancet 2017;389:1680-1.
- Medication Errors: Technical Series on Safer Primary Care. Geneva: World Health Organization; 2016.
- Clinical pharmacology in research, teaching and health care: Considerations by IUPHAR, the International Union of Basic and Clinical Pharmacology. Birkett D, Brøsen K, Cascorbi I, Gustafsson LL, Maxwell S, Rago L, Rawlins M, Reidenberg M, Sjöqvist F, Smith T, Thuerman P, Walubo A, Orme M, Sjöqvist F. Basic Clin Pharmacol Toxicol 2010;107:531-59.
- Clinical pharmacology in health care, teaching and research. Rawlins MD. Brit J Clin Pharmacol 2013;75:1219-20.
- Ceschi A, Hitz P, Müller L, Kullak-UblickG, Piffaretti V (2018) Aktive elektronische Überwachung der unerwünschten Arzneimittelwirkungen bei hospitalisierten Patienten.
  https://www.fmh.ch/files/pdf20/Elektron._Ueberwachung_unerwuenschter_Arzneimittelwirkungen_Gewinner_Innovation_Qualite_2018.pdf