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Patient safety – who cares?

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Summary

Medical errors and adverse events are a serious threat to patients worldwide. In recent years methodologically sound studies have demonstrated that interventions exist, can be implemented and can have sustainable, measurable positive effects on patient safety.
Nonetheless, system-wide progress and adoption of safety practices is slow and evidence of improvements on the organisational and systems level is scarce and ambiguous. This paper reports on the Swiss Patient Safety Conference in 2011 and addresses emerging issues for patient safety and future challenges.

Key words*: patient safety; medical errors; adverse events*

Background

In November 2011, approximately 550 professionals attended the international conference "Patient safety – moving forward!" organised by the Swiss Patient Safety Foundation in Basel. The 2½-day programme included a preconference, 11 plenary talks and 24 parallel sessions designed as minicourses (abstracts are available at http://www.patientensicherheit.ch/dms/de/Kongress/Abstract-Band/Abstract-Band_final/Abstract-Band.pdf).
Participants had the opportunity to meet internationally acknowledged patient safety experts and to exchange knowledge and experiences with national and international researchers, practitioners, and health care executives. The talks and presentations covered the entire range of patient safety, from distinct clinical safety concerns and potential solutions, methodological approaches and measurement issues, to education in patient safety, legal aspects, public health strategies and political concepts. Besides well-known, but nevertheless urgent, matters such as medication safety and nosocomial infections, several emerging issues were discussed that have attracted increasing attention recently.

Diagnostic errors – terra incognita

Diagnosis is the centrepiece of medical care. If the diagnosis is wrong the treatment will not be right. Diagnostic errors include heuristics and biases in diagnostic reasoning, failure to order, perform, follow-up and interpret tests at the appropriate time, as well as errors in judgment and decision-making, such as choosing and initiating the right treatment. Research suggests that diagnostic errors pose a common and serious threat to patients. In the Dutch adverse event study based on chart review, adverse diagnostic events occurred in 0.4% of hospital admissions and represented 6.4% of all adverse events [1]. Autopsy studies reveal an error rate of 10–15% [2, 3]. In one of the earlier adverse event studies, the Harvard Medical Practice Study II, diagnostic errors accounted for 17% of preventable adverse events [4]. In a retrospective review of closed malpractice claims 59% involved diagnostic errors that harmed patients [5]. In physicians' self-reports of diagnostic errors, the latter occurred most frequently in the testing phase (failure to order, report, and follow-up laboratory results) (44%), followed by clinician assessment errors (failure to consider and overweighing competing diagnoses) (32%), history taking (10%), physical examination (10%), and referral or consultation errors and delays (3%) [6]. In a recent analysis of diagnostic errors involving internists, cognitive factors contributed to the diagnostic error in 74% of cases [7]. The most common cognitive problems involved faulty synthesis. Despite this evidence, diagnostic errors have lagged behind other concerns since the start of the safety field [8]. A number of causes may help to illuminate this finding: first, diagnostic errors are among the errors most embarrassing and unacceptable to the medical profession and are often perceived as a lack of clinical competence. Second, errors in diagnosis are hard to detect and identify. In outpatient care in particular, it may take months, if ever, until missed diagnoses are identified [9]. Third, a large proportion of diagnostic errors are due to flawed reasoning and overconfidence rather than technical failures, and there are no easy solutions to hand for these types of error [10, 11]. It is thus not surprising that a number of interventions have been suggested but few empirical studies have yet tested interventions to prevent diagnostic errors and their associated harm [12]. Electronic tracking of patients and implementation of computerised notification systems have been shown to reduce failures in follow-up of test results [12]. Nendaz and colleagues report that a case-based clinical reasoning seminar, designed to give students insight into cognitive features of their reasoning, improved aspects of diagnostic

competence [13]. However, effects on safety outcomes still need to be confirmed. Use of checklists to reduce diagnostic errors has also been recommended by experts in the field [14]. Clearly, considerable progress needs to be made in the understanding and prevention of diagnostic errors during the next decade.

Designing errors out of the clinical environment

A fundamental experience in ethnographic observation of care processes is that the clinical environment, be it a hospital, a medical office, or a nursing home, seems as if it has been designed to provoke errors. In many instances, cutting edge clinical care is provided with infrastructure and equipment that has not fundamentally changed in recent decades. Clinicians that are able figuratively to step back from their environment and look at it with fresh eyes are often overwhelmed by the many major and minor obstacles in everyday processes (and sometimes their triviality) that are like sand in the gearbox: a cable of a diagnostic device that is too short to allow for unrestricted movements; look-alike medication boxes; a walk-through room designated for patient handover; plasma bags whose bar code label is crumpled or covered in a thick layer of ice; non-IV equipment that is connectable with IV equipment; chemotherapy patient records that require the administering nurse to switch and scroll between landscape and portrait paper formats. Nurses and physicians share a wealth of experience as to how they struggle with their work environment, infrastructure, equipment and materials, and they frequently develop work-arounds and short-cuts to bypass these deficiencies. Sometimes with serious risks for patient safety.

Figure 1

The newly designed CareCentre infection control station, designed by the DOME project and manufactured by Bristol Maid™. © Bristol MaidTM 2011. Reprinted with kind permission.

While the relevance of human factors for the safety of technical devices has been recognised earlier [15], the importance of interior design of rooms, equipment and materials and work flow for patient safety on wards has long been ignored. However, recent research suggests that sometimes simple changes can have substantial effects on safety. For example, Birnbach and colleagues used simulation-based testing in real-size replications of proposed hospital architectural designs [16]. Physicians examined standardised patients in two hospital room replications that differed only by the placement of the alcohol-based hand-rub dispenser. The hand hygiene compliance rate was significantly higher when the dispenser was in clear view of the physicians as they observed the patient (54% sanitised their hands). Only 12% of physicians sanitised their hands when the dispenser was not in their visual field. This is only one example of how thoughtful design features, if properly evaluated and assessed, can make patient safety "easy" for clinicians in their everyday work.

At the Swiss conference, researchers presented results of the DOME project (***D****esigning* ***O****ut* ***M****edical* ***E****rror*, available at http://www.domeproject.org.uk) [17, 18]. The project aims to increase patient safety on surgical wards by developing equipment and products that fit the requirements

Figure 2

New trolley for bedside monitoring of vital signs with easy-clean design and improved cable management, designed by the DOME project. © The Helen Hamlyn Centre for Design, The Royal College of Art 2011. Reprinted with kind permission.

of healthcare processes and staff. In prior research five error-prone processes were identified and prioritised for action: hand disinfection, information handover, vital signs monitoring, isolation of infection, and medication delivery. The approach followed by DOME is groundbreaking in several respects: it is truly multidisciplinary and combines expertise from clinicians, safety experts, design specialists, psychologists, and ergonomists. Second, DOME is strongly devoted to research. The team used several methodological approaches to map care processes and understand the work-flow and requirements of health care workers' tasks. Interventions were designed for each of the error-prone processes and tested in a simulated ward environment in repeated evaluation and improvement cycles. Finally, the research team cooperates with manufacturers to ensure that safe designs are spread and produced en masse. DOME does thus not design nice-looking (but unusable) toys with no added value. Oliver Anderson and his colleagues from Imperial College London presented the outcomes of the DOME project at the Basel patient safety conference to an enthusiastic and excited reception from participants. One of the most powerful products is an all-in-one infection control station for the end of a patient's bed (fig. 1). The CareCentre is equipped with an alcohol gel dispenser, integrated gloves and aprons, a medication locker, a flat surface for writing, a folder holder, and a touch-free, infrared controlled bin. Infection prevention practices improved significantly with the new CareCenter (53% adherence with CareCentre vs. 16% adherence with control; unpublished data presented at the Basel conference). A new, easy-to-clean trolley was designed for measurement of vital signs at the bedside (fig. 2). Some of the new interventions are currently under investigation in clinical trials, such as a respiratory rate recorder for reliable and accurate manual measurement of vital signs at the bedside. DOME is a promising and innovative project, regarding both the approach to improvements in safety as well as the designed products.

Where have we gone so far and how do we know?

In recent years, methodologically sound studies have shown that improvements in patient safety are feasible and realistic.

Peter Pronovost and colleagues have developed and implemented an evidence-based multifaceted intervention to reduce the incidence of catheter-related bloodstream infections in intensive care units (ICUs) [19]. The programme consists of three core elements: translating evidence into practice at the bedside, improving culture and teamwork, and having a data collection system to monitor central catheter-associated bloodstream infections and other relevant measures [20]. In the initial study more than 100 ICUs in the US implemented specific procedures (hand washing, full-barrier precautions during the insertion of central venous catheters, cleaning the skin with chlorhexidine, avoiding the femoral site, and removing unnecessary catheters) and monitored the effects on infection rates. The median rate of catheter-related bloodstream infection decreased from 2.7 (mean 7.7) infections per 1000 catheter-days at baseline to 0 (mean 2.3) at 0 to 3 months after implementation of the study intervention and was sustained at 0 (mean 1.4) during 18 months' follow-up. The incidence-rate ratios decreased continuously from 0.62 (at 0 to 3 months after implementation) to 0.34 (at 16 to 18 months). In other words, patients' risk of acquiring catheter-related bloodstream infection decreased substantially by two thirds. In a retrospective comparative study the project also achieved significant decreases in inpatient mortality in the state of Michigan compared with the surrounding area [21].

In a multinational study Haynes and colleagues investigated the effects of the WHO surgical safety checklist [22]. This 19-item checklist is used at three stages in surgical care (before induction of anaesthesia, immediately before incision, and before the patient leaves the operating room). The checklist is completed by the surgical team and requires oral confirmation of the completion of essential steps in care provision, such as antibiotic prophylaxis, surgical site marking, and team time-out. Considerable improvements in mortality and morbidity were recorded in both low and high income countries, and in emergency operations in particular [23]. Comparable results have been obtained with similar surgical checklists such as the SURPASS tool [24]. A systematic review and meta-analysis estimated that with the use of WHO or SURPASS checklists the relative risk is 0.57 for surgical mortality and 0.63 for any inpatient complication [25]. A recent study confirmed the positive effects of the checklist on patient safety, but only in patients for whom the checklist was fully completed [26]. Patients did not benefit from partial completion or complete noncompliance with the checklist. At the Basel conference, several researchers and practitioners reported local experiences with the checklist.

Other examples of effective patient safety interventions include the large scale introduction of surgical team training to lower surgical mortality [27], a nurse-led programme which reduces medication error rates by implementation of six medication administration safety processes [28, 29], pharmacist-led medication reconciliation [30, 31], and use of information technology [32–34] (table 2). These success stories confirm that interventions exist, can be implemented and can have sustainable, measurable positive effects and make a difference in patient safety. But what have we achieved on the systems level since the US Institute of Medicine published their report "To Err is Human" in 2000 [35]? Has healthcare become safer? Have risks for the "average patient" seeking care significantly declined in recent years? Is it ultimately time to sit back, relax and bring in the harvest?

The evidence on this question is mixed and not as unambiguous and positive as one would hope after reviewing the evidence on successful interventions. On the organisational and systems level, improvements in safety are not easily achieved, and not even easily measured. For example, Landrigan et al. investigated temporal trends in rates of patient harm caused by medical care in North Carolina, a state with above average engagement in safety campaigns [36]. The researchers applied the *Institute for Healthcare Improvement*'s Global Trigger Tool for Measuring Adverse Events to patient records of patients discharged from 10 randomly selected hospitals between 2002

and 2007. They found harm to be persistently common and no significant decreases in the rate of harms over time. Rates of preventable harms and harms of greater severity also remained stable during the 6-year period. At the Swiss conference Maike Langelaan and colleagues reported the results of two adverse events studies based on chart review methodology conducted in hospitals in the Netherlands [37]. The first Dutch adverse event study conducted in 2004 [38] was followed by several patient safety campaigns and a second adverse event study in 2008. There was no significant decrease in preventable adverse events between the study periods. Charles Vincent presented similar data from France in his plenary talk [39].

Results from the UK "Safer Patients Initiative" (SPI1 and SPI2), a large scale safety improvement programme, are complex and ambivalent [40, 41]. Improvements in safety climate, practices and outcomes have been achieved in both control hospitals and hospitals that participated in SPI. However, only a few selective incremental effects of the initiative were detectable. In other words, improvements over time were observed on many safety items such as consumption of hand disinfectants and simultaneously decreasing rates of *Clostridium difficile* and methicillin resistant *Staphylococcus aureus*, but the difference in differences between control and SPI hospitals was not significant. Of 57 quantitative outcome measures, 24 favoured the SPI hospitals, 22 favoured the control hospitals and in 11 outcomes there was no difference at all [41]. One of the major explanations for the counterintuitive results of SPI2 was the spread of contemporaneous policy and professional forces in the control environment. During the study period of SPI other safety campaigns were underway and improvement activities accelerated in many hospitals. Rather than testing the effect of "treatment", SPI was thus more like evaluating "dose" and it can be concluded that the "dose" given in SPI was too small to achieve incremental effects compared to the control dose.

A number of lessons can be learned from the SPI experience: First, the programme directors and commissioners are to be congratulated on the efforts and resources expended on evaluation and the use of concurrent controls in particular. Without these controls the improvements over time observed in SPI hospitals would have been causally linked to SPI, and may have masked *how* improvements were achieved, making it even harder to generalise and transfer the approach to other settings. Second, improvement programmes should be designed and interventions should be selected on the basis of baseline data, i.e., actual safety targets. One problem with SPI was that hospitals were already performing to high standards and improvements are then hard to achieve and measure. Third, measurement and data quality control are crucial for any patient safety improvement project and have long been ignored as a key – and resource-intensive – force [42]. Fourth, the SP initiative may have been too diffuse and not well-grounded in theories of organisational change [43]. Interventions and measures need to be evidence-based, pilot-tested and accepted by clinicians. Different areas of patient safety probably need different theories of change, methods, interventions, and measures, but all should be based on "health care delivery" science [44]. The call for more science is justified in particular for large-scale improvement programmes for which we do not yet fully understand what works and why. Ex-post theorisation seems a valuable approach to increasing improvement programmes' generalisability and transferability to other settings [45].

Above all: accountability

One reason for the observation that system-wide progress in patient safety is slow is that compliance even with simple and inexpensive interventions such as hand disinfection remains low [36] and the penetration of evidence-based safety practices has been quite modest and often needs years of change [46]. It is surprising that this slow and fractious progress seems to be to some extent accepted by health policy leaders and clinicians, given the safety epidemic and the widespread perception of medical error in the general public. For example, in a recent citizen survey conducted in eleven high-income countries, one out of ten citizens reported medical or medication error [47]. However, this rate varied widely between countries (range: 5% in the UK, 11% in Switzerland, 13% in the US, 16% in Norway).

Table 1: Conference participants' backgrounds, results from the evaluation survey (n = 327).

Background characteristic	**n**	**(%)**
Female gender	184	57%
Educational background		
Medicine	93	28%
Nursing	114	35%
Pharmacy	20	6%
Quality/risk management	105	32%
Administration, economics, law	50	15%
Other	44	13%
Current workplace		
Hospital	229	70%
Nursing home	8	2%
Outpatient care	12	4%
Public administration	15	5%
Insurance business	4	1%
Consultancy	12	4%
Educational institute	23	7%
Other	38	12%

In many countries adoption of safe medication practices has been particularly slow and surveillance data of adverse drug events are generally lacking [46, 48]. Longo at al. report on a survey among all acute care hospitals in Missouri and Utah in 2002 and 2004 which assessed the development, implementation and spread of patient safety systems such as computerised test results, drug storage, administration and safety procedures, or handling of adverse event/error reporting. The results show that improvements have been achieved in many items over time, but are only modest at best. It is striking that in 2002 only 28% of hospitals had a patient safety programme budget. This figure rose to 39% in 2004 but is still disappointing. Clearly, great care must be taken to ensure that the public does not lose confidence in, and patience with, the health care system, and that the safety movement does not end up in circularities.

There are instances in which individual clinicians, providers, executives and directors, health care leaders, and health care system administrations *are* to be held accountable: for not investing in safety programmes, for not providing their staff with the necessary support and resources, for not teaching and instructing students and residents in the cornerstones of safety, for not implementing evidence-based safety standards, for not using hard edges, and, when all is said and done, for not disinfecting their hands. As Robert Wachter argues, (no) blame needs to be sensitively balanced with accountability [49].

At the Swiss conference, accountability, and sometimes lack thereof, was noticeable. It was noticeable and encouraging in each and every report of clinicians and other professionals that devote their time and efforts to promoting change in patient safety.

However, it was also noticeable in what was *not* present.

Our subjective impressions at the conference are confirmed by participant evaluation. Table 1 displays background characteristics of conference participants that responded to the electronic evaluation survey (60% response rate). One number in the table is eye-catching, and disturbing: the relatively low fraction of physicians among participants. The limited participation by physicians is not a matter of chance but seems to some extent symptomatic. One common concern of quality and risk managers when discussing opportunities for participation in safety projects or implementation of safety measures is: what can I do to get clinical staff involved? In fact, a major obstacle for any patient safety initiative is the motivation of physicians, and, to a lesser extent, nurses. Hours over hours are spent considering how evidence-based patient safety measures, like the surgical safety checklist or hand hygiene, can be made "tasteful", what clinicians need to adapt the recommended behaviours, and what incentives hospitals can implement to increase staff compliance. Indeed, sometimes it feels like "pushing an elephant up the stairs".

Why is this?

The vast majority of clinicians are involved in safety every day. Preventing harm to *individual* patients is central to most clinicians and belongs to the intrinsic motivation of health professionals. Ironically, the same clinicians are often reluctant to engage in system-wide safety initiatives. To many physicians, saving additional lives (through advanced therapy) seems psychologically more attractive than avoiding deaths through prevention of harm. It is much easier to enthuse surgeons about a new microinvasive device, or innovations such as fast-track surgery, than about the surgical safety checklist, team training, or structured handovers. Asked why he did not attend the Swiss Patient Conference, a senior consultant argued: *Yes, it's certainly interesting. But I do not have the time. Inspiration about patient safety would be a nice-to-have but keeping up with developments in my clinical area is more directly relevant because that is what is expected from me.* This statement reveals a fundamental misconception: that patient safety is something "additional" to clinical care provision. In the same way as the safety movement has long failed to embrace science, clinical medicine is still too often failing to embrace the patient safety agenda. The unavailability of safety data at the local level has been identified as a major barrier to clinician engagement in safety [48]. It is simply unacceptable that in many Swiss hospitals, clinicians do not have monitoring data about hand disinfection compliance rates at their department regularly available. Similarly, at most hospitals no data is available regarding medication safety, including safe administration practices, or diagnostic performance. It is hardly possible to engage clinicians in safety if you cannot even document the target.

In addition to the data availability problem, clinicians often underestimate the impact of human factors, system and process design, and communication on safety. The best surgeon in the theatre and the best physician on ward is no guarantee of safety if the handover between and across professions is unstructured, incomplete or erroneous. Put simply, safety is more than the sum of dedicated and safe-acting individuals.

From the various reports presented at the Swiss Patient Safety Conference it can be concluded that there is still a long way to go on the safety journey, but considerable improvements are achievable. Collaboration, expertise and engagement from clinicians, safety experts, health services researchers and psychologists is needed – the recent meeting in Basel proved that this community exists – and is growing.

Table 2: Examples of effective patient safety interventions.

Targeted patient safety problem	**Intervention**
Catheter-related bloodstream infections	Implementation of specific evidence-based procedures, improving culture and teamwork, and infection incidence monitoring [19]
Surgical mortality and morbidity	Surgical safety checklists [22, 24]
Surgical mortality	Team training [27]
Medication errors	Implementation of six medication administration safety processes [28, 29]
Adverse drug events	Pharmacist-led medication reconciliation [30, 31]
Medication errors / adverse drug events	Information technology, e.g. electronic prescribing [32–34]

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Figures (large format)

Figure 1

The newly designed CareCentre infection control station, designed by the DOME project and manufactured by Bristol Maid™. © Bristol MaidTM 201. Reprinted with kind permission.

Figure 2

New trolley for bedside monitoring of vital signs with easy-clean design and improved cable management, designed by the DOME project. © The Helen Hamlyn Centre for Design, The Royal College of Art 2011. Reprinted with kind permission.