

Editorial

A research agenda for patient safety

Patient safety is a global problem that calls for global solutions. In this issue, Didier Pittet and Sir Liam Donaldson present the strategy of the World Alliance on Patient Safety, led by the World Health Organization [1]. Six action areas are presented, one of which is research on patient safety. The necessity of patient safety research is echoed by another wide-reaching organization, the Council of Europe, in a recommendation on the management of quality and safety in health care soon to be issued to its member states. Everyone seems to agree on the principle, but what type of research should we be doing? Let us consider some of the options.

In-depth studies of errors, mishaps, and patient safety incidents

These studies apply rigorous investigation methods, variants of ‘root cause analysis’, to a variety of health care incidents. Their purpose is to learn as much as possible about the complex causal chains that lead to incidents. Typically, such studies are qualitative and do not attempt to measure frequencies of events. The validity and reproducibility of such investigations are questionable [2] and should be established in a variety of contexts. Even the underlying conceptual models of incident occurrence are interpreted inconsistently [3]. Which incidents are reported and which are not is another issue worthy of exploration.

Epidemiologic studies of incidents and errors

Such studies estimate frequencies or incidence rates of patient safety incidents, health care-related complications, and appropriate practices of care, using methods that minimize bias and allow accurate measurement. So far, such studies have been conducted mostly in hospitals but should be done across the spectrum of care—from outpatient care to rehabilitation. Currently, such epidemiologic studies are hampered by the lack of consensus definitions of various types of events [4]. The development of a consensus taxonomy of patient safety incidents—another priority of the World Alliance—should much improve the situation [5]. Other methodological issues include the selection of the unit of analysis (Is it the patient? a patient care episode? a health care provider? a person-time unit at risk?), and the choice of the most cost-effective sources of valid data.

Identification of risk factors for patient safety events

Analytic studies, whether prospective studies, case-control studies, or ecologic analyses, should seek to identify risk factors for the occurrence of patient safety events. Such studies have built the foundation of prevention activities for a variety of public health problems. The risk factors that deserve consideration include patient characteristics but also characteristics of the health care providers, teams, and organizations.

Research on human factors

The old saying ‘to err is human’ is certainly true but does not tell the whole story. Another defining characteristic of humans is their ability to work reliably in hectic circumstances. We need research to understand in what situations people are most prone to errors or violations. In particular, how do contextual factors, such as a ‘culture of safety’, the physical environment, or regulatory mechanisms, influence people’s behaviour? We need to understand a lot better the feasibility of optimal patient care given the time pressures and other resource constraints that are prevalent in hospitals. And more research is needed about teamwork, particularly multi-disciplinary teamwork. This line of research should draw on experimental psychology, ergonomics, and anthropology, in addition to more traditional epidemiologic studies.

Patient involvement in safety

Involving patients and their families in patient safety activities is another priority of the World Alliance [1]. A potential role for patients is to alert health care staff about possible errors, related to personal identification problems, allergies and comorbid conditions, or basic precautions, such as hand washing. But in what circumstances is it fair to burden patients with responsibility over their own safety? In what cultural contexts will a patient remind his doctor to wash her hands? Other ways of involving patients in safety include allowing patients to file incident reports, questioning patients about mishaps or near misses, seeking patients’ input into the safe design of health care processes, and including patient representatives in hospital governance. More research is needed on all these options.

Development of patient safety indicators

Accurate measurement, regular monitoring, and benchmarking are key activities for progress in patient safety, as for other aspects of quality improvement in health care. Proposals of sets of patient safety indicators have been made by several organizations [6,7], yet the ascertainment of the reliability, validity, sensitivity to change, and interpretability of indicators remains an important area for research. Because the documentation of undesirable events is typically poor—sweeping unpleasant stuff under the carpet is human, too—measurement of patient safety is particularly challenging, as are concerns about data quality.

Simulation—in silico and in vivo

Simple problems call for simple solutions, but the health care system often behaves in ways that are complex, non-linear, uncertain, and quasi-chaotic. In such situations, computer-based simulation may be a powerful tool. An example is

discrete event modelling, which can be used to estimate the probabilities of stochastic events (including adverse events) as a function of various interconnected inputs (such as hospital resources). Such methods have not been used sufficiently in patient safety research.

Although a computer can model what may happen over the long run in a complex system, real-life simulation can help understand human behaviour. Replicas of operating rooms, delivery rooms, pharmacies, or intensive care units can be built so that various aspects of human behaviour, from individual performance to team crisis management, can be recorded and manipulated experimentally. The same real-life models can also be used for training of health care professionals. These approaches are gaining in popularity.

Evaluation of interventions to improve safety

Finally, a crucial domain of research on patient safety is the evaluation of interventions that aim to improve safety in

Table 1 Recent examples of studies on patient safety

Analyses of patient safety incidents	In-depth analysis identified system weaknesses that contributed to eight accidents in health care [8] A study of more than 2000 adverse events in Australia described the most common types of contributing factors and of responses to these events [9]
Epidemiologic studies	A chart review conducted in a national sample of Canadian hospitals estimated that adverse events occurred in 7.5% of hospitalizations [10] Older hospitalized patients had a higher rate of adverse events than younger patients [11]
Risk factors for incidents	A study of drug administration errors identified several risk factors, including the type of drug, unusual route of administration, and administration by a non-registered nurse [12] Direct observation of doctors and questionnaire data explored personal factors and workplace conditions associated with compliance with appropriate hand hygiene [13]
Human factors research	A reduction of working hours for residents in intensive care reduced the frequency of medication errors and of diagnostic errors [14] Interviews with doctors who committed drug prescription errors explored the psychological mechanisms that led to the occurrence of errors [15]
Patient involvement in safety	About 50% of former inpatients reported an undesirable event during their hospitalization, whether a medical complication, an interpersonal problem, or a process-related problem [16] Providing hospitalized patients with their medications list and with drug safety information led to a small decrease in adverse drug events [17]
Validation of patient safety indicators	Unplanned admissions to intensive care within 24 hours of a procedure were associated with incidents or near-misses, and with higher mortality rates [18] The occurrence of patient safety events captured by AHRQ indicators was associated with longer hospital stays, higher costs, and higher mortality rates in Veterans Affairs hospital [19]
Simulation	A discrete-event simulation model was used to explore factors related to the occurrence of medication errors [20] A simulated operating room was built to facilitate the training of surgeons and of operating teams [21]
Evaluation of interventions	The presence of a pharmacist on rounds at an intensive care unit was associated with a decreased rate of adverse drug events [22] An education program did not improve residents' attitudes and behaviours related to incident reporting [23]

real-life health care settings. Remarkably little evidence exists today regarding the impact of several routinely recommended interventions, including incident reporting and analysis. In absence of evidence, the best course of action is debatable: should we do it anyway because it makes sense, or should we abstain? What is not debatable is the need to gather the relevant evidence so as to settle the question, at least whenever the stakes are sufficiently high. Of particular interest are studies that assess the effectiveness of educational interventions to increase the awareness of health care staff about patient safety and managerial interventions to heighten the 'culture of safety' in hospitals.

Conclusion

Some examples of recent research projects in each of these areas appear in Table 1. There are many others that are not mentioned, and also other interesting domains of research not discussed in this editorial, and other ways of slicing the patient safety research pie. This is a rich field of research that offers exciting opportunities to researchers of many disciplines. The impetus to patient safety research that will be given by the World Alliance and other governing bodies is a welcome development.

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