



ORIGINAL ARTICLE

## Roadmap for patient safety research: approaches and roadforks

DAG HOFLOSS & ELLEN DEILKÅS

Health Services Research Unit, Akershus University Hospital, Lørenskog, Norway

### Abstract

Patient safety improvement is a healthcare priority worldwide. Pioneer research reports include the 1984 Harvard Medical Practice Study, and the 1999 report “To err is human”. Patient safety research is expanding rapidly. Among the Scandinavian countries, Denmark is the patient safety improvement leader, and Norway is the laggard, having only recently institutionalized safety research and then having started with industrial safety research, and only recently having expanded into patient safety research. *Aims:* To produce a roadmap for patient safety research, indicating three main roadforks. Patient safety research can be conducted along a number of lines. To identify patient safety problems and come up with ideas for patient safety improvement one can investigate 1) particular cases of adverse events, 2) the design of healthcare delivery systems, or 3) the culture of the care-giving institutions. The study of safety culture can be subdivided into the study of organization culture in general (and in particular of leadership culture) and the study of patient safety culture. The article provides a number of references to existing instruments of patient safety research. *Methods:* Qualitative interpretation of the referenced literature. *Results:* Scrutinizing adverse events for errors is health care’s traditional way of improving patient safety. The idea of rethinking the design of care delivery systems has been accompanied by claims of modernity. The study of patient safety culture is the most recent approach. The three approaches are discussed in separate sub-chapters. *Conclusions:* **Although chronology suggests a developmental trend, the three approaches should not necessarily be seen as steps up the ladder of evolution. Each approach does have its merits.**

**Key Words:** *Adverse events, patient safety, safety culture, questionnaires*

### Introduction: The worldwide effort to improve patient safety

Some activities, like mountain climbing and bungee jumping, produce injuries and fatalities because they are inherently dangerous: relatively many of those involved have accidents. Other activities produce injuries and fatalities because they involve large numbers of people: the risk of having a car accident is small, but so many people drive cars. With its unique combination of scoring high on both factors, health care is, paradoxically, a particularly risky business: a very large number of people receive health care, and the risk of being hurt is disturbingly high [1]. Therefore, health authorities worldwide have recommended that health providers take active action to improve patient safety. Pioneering efforts include the (US) Institute of Medicine’s 1999 call

for building a safer healthcare system [2], the 2002 World Health Assembly’s resolution WHA55.18 urging countries to pay the greatest possible attention to patient safety [3], the 2004 World Health Organization’s (WHO) launching of the World Alliance for Patient Safety, and the 2005 passing of the (European Union) Luxembourg Declaration “Patient safety – making it happen” [4].

Systematic efforts to improve patient safety are being promoted in many countries. Most prominent among the countries which have taken nationally organized patient safety action are the USA, the UK, Canada, Australia, and Denmark. Internationally well-known institutions that are promoting patient safety include the (US/Global) Joint Commission International Center for Patient Safety, the (US) Agency for Healthcare Research and Quality

Correspondence: Dag Hofloss, Health Services Research Unit, Akershus University Hospital, PO Box 95, NO-1478 Lørenskog, Norway. E-mail: dag.hofloss@ahus.no

(Accepted 7 July 2008)

© 2008 the Nordic Societies of Public Health  
DOI: 10.1177/1403494808096168

(AHRQ), the (US) Institute for Healthcare Improvement (IHI), the (UK) National Center for Patient Safety (NCPS), the (UK) National Patient Safety Agency, the Canadian Patient Safety Institute, the Australian Commission on Safety and Quality in Health Care, the Australian Patient Safety Foundation, and the (DK) Society for Patient Safety. An overview is provided by Runciman et al. [1].

### **The growth in patient safety research**

Patient safety research is expanding rapidly. A March 2008 PubMed search for articles containing the words “patient safety” in the five 5-year periods from 1983 to 2007 returns these numbers: 74, 153, 278, 962 and 3631. Specifically designated scientific journals exist, e.g. *Quality & Safety in Health Care* (established in 1992 as *Quality in Health Care*, name updated in 2002), *Journal of Patient Safety*, and *Patient Safety and Quality Healthcare*. But research interest in patient safety is of course not limited to these articles and journals: any medical research article is dedicated to improving quality and safety in health care. What is new is neither the idea of patient safety nor the interest in it, it is the methodological approach.

### **Pioneer reports**

Among the first reports to create a stir over patient safety was the Medical Practice Study [5] of some 30,000 somatic hospitalizations in New York in 1984, showing “a substantial amount of injury to patients from medical management”. The subject was brought to the forefront of the public debate worldwide by the 1999 publication of the report “To err is human” [2] which estimated that each year 44,000 Americans, maybe as many as 98,000, died from medical errors – even the lowest of the two numbers made medical error the eighth most frequent cause of death in the USA, more common than traffic accidents (43,000 deaths) or cancer *mammae* (42,000).

The message has been reproduced in many countries. A joint Australian–American report [6] estimated that adverse medical events occurred in 16% of hospitalizations in Australia. High percentages have also been presented in the UK: 11% [7], and Denmark: 9% [8]. There are cross-national differences, which have attracted the attention of both healthcare providers and health services researchers. As parts of the differences are considered to reflect variations in definitions, recent comparative research initiatives include addressing

the problem of non-standardization of terminology [9].

### **Ways of doing patient safety research 1: Specific investigation of adverse event cases**

The literature on patient safety shows patient safety research to be conducted along several lines. One common approach is scrutinizing adverse events for provider error. Following standard aviation disaster practice, one may argue that every serious accident has its specific causes and deserves a separate “crash commission” to investigate what went wrong. Routine meetings – “Mortality and morbidity conferences” – may be institutionalized to look into such cases, or ad hoc commissions may be established to look into particularly bad cases, as in the case of the 1997–8 investigation of the deaths of 29 children at the Royal Bristol Infirmary [10,11] or generally looking into “sentinel events” [12], that is, accidents on a predetermined list of healthcare outcomes that should never occur, like a maternal death, or an object being left inside a surgical patient. Over the last few years, this kind of effort has come to be seen as passive, retroactive scapegoat-hunting, and other approaches have come to the forefront of research. One should not disregard the power of this “traditional” way of identifying possibilities for quality improvement. And it keeps developing. A recent trend in scrutinizing treatment mishaps is doing it from the patient’s perspective. The analysis of adverse events does no longer only mean having clinical experts looking into what went wrong, it also means studying it through the patient’s eyes. Contributions like Regenbogen et al.’s [13] remind us that malpractice claims analysis may provide important data for research on patterns of medical error. And in the wider perspective the WHO’s World Alliance for Patient Safety has initiated the “Patients for Patient Safety”: a global network of patients and consumer organizations who work in partnership with health professionals and policymakers across the world to identify safety problems in health care, design solutions and implement change.

### **Ways of doing patient safety research 2: Delivery system reviews**

Yet, the idea has gradually come to the forefront of patient safety research that errors should be seen as the effects of the healthcare delivery system they occurred in. More is to be gained by viewing adverse events as “a window on the system” than by seeing

them as person-driven or as effects of equipment breakdown. Thus, the Institute of Medicine holds the view that “the biggest challenge to moving toward a safer health system is changing the culture from one of blaming individuals for errors to one in which errors are treated (...) as opportunities to improve the system” [14]. As noted by many, every system is perfectly designed to get exactly the results it gets. Every traffic accident indisputably involves a person who might have acted differently. But some traffic systems have fewer accidents than others. Although each accident is mediated by identifiable actors, the actors may not be guilty of punishable carelessness. And even if they were, person-directed sanctions may not be the most effective way to prevent the adverse event from happening again. How does one eliminate the risk of cars crashing with trains? As patient safety advocate and former chairman of the Danish Medical Association Jesper Poulsen reminds us – not by warning drivers to look more carefully and punishing them more harshly for being careless, but by building roadbridges [15]. The same reasoning applies to healthcare systems and healthcare adverse events. Everybody can easily imagine circumstances under which things are more likely to go wrong, and from that insight follows the recognition that the performance of those who care for the patient at “the sharp end” of health care should be viewed in the context of the constraints established at healthcare’s “blunt end”. Poorly designed systems for delivering health care contain latent failures which may lie dormant for a long time until some unfortunate healthcare provider happens to trigger one [16]. An example is when an anaesthesiologist moves to observe the patient better, and inadvertently switches off his machine because his clothes pull the uncollared dip-switch into off-mode. An alternative approach to patient safety, therefore, is to focus on flaws in the design of the system, e.g. by collaring the dip-switch so that it cannot be turned off unintentionally.

As this more proactive approach does not feed only on the bad outcomes that actually occurred, but also on near-misses and potential dangers, the quality of the reporting system becomes even more important than in traditional patient safety research. To increase the chances that all relevant events will be reported and that constructive preventive action can be taken, a non-punitive approach to errors and near misses is strongly advocated [17,18].

To the extent that errors are system-driven, the patient safety job is to construct systems that make it more difficult to make mistakes and/or makes it easier to perform correctly. This “reliability science” [19] approach can produce important information

on risk factors, as shown e.g. by the contributions made by analysis methods like “Failure mode and effects analysis” [20,21], “Root cause analysis” [22,23] and “Probabilistic risk assessment” [24].

### **Ways of doing patient safety research 3: The study of organization culture**

A third option for studying adverse events is to focus on organization culture. Instead of employing the above socio-technical engineering techniques for patient safety analysis and improvement one may investigate healthcare organizations’ patient safety culture. Data from other industries where safety is an issue of critical importance have demonstrated that safe performance is a function of staff preoccupation with failure avoidance. Therefore, assessing staff safety attitudes is an important approach to improving safety [25–29].

Several influential organizations in health care point to the need to examine clinical staff attitudes about patient safety [30]: policy organizations and regulators (such as the WHO, the European Union, the (US) Joint Commission on Accreditation of Healthcare Organizations, and (the UK) National Patient Safety Agency), professional organizations (such as the American Hospital Organization), quality improvement organizations (such as the (US) National Quality Forum and the (US) Institute for Healthcare Improvement), and research agencies (such as the (US) Agency for Healthcare Research and Quality, and the (US) National Patient Safety Foundation). Safety culture improvement has been rated the most important of the 30 patient safety enhancing procedures selected by the (US) National Quality Forum [31]. The main argument for doing patient safety culture research is that one then starts in the correct end of the causal chain: a well-developed safety culture produces safe care – while programmes directed towards improving procedure safety often succeed in improving the targeted procedure, they may not produce an underlying culture of safety.

### **Patient safety culture, too, may be studied from various angles: Organizational culture in general or patient safety culture**

The next road fork is the choice between studying organizational culture in general (“well-led and integrated organizations are safer organizations”) and focusing more directly on patient safety culture. The first option argues that “Total quality management” does not only aim at better management, it is

also a leadership tool for improving care [32]. Many case studies and much anecdotal evidence suggest that healthcare performance depends on organizational culture in general [33]; a common observation is that information flow and error reporting is better where managers see themselves as coaches and not commanders. Also, the best NHS hospitals (the “high-star” hospitals) were less likely than others to be characterized as having traditional (“clan” or “hierarchical”) cultures [18].

Still, one may opt not to investigate organization culture in general, but to focus on those parts of it that are directly related to safety. A sceptical view has been presented by Guldenmund [34], who in his discussion of the theoretical foundation of safety culture research concluded that not much consensus has been reached on the consequences of safety culture for safety performance. He has also questioned the success of safety culture questionnaires in exposing the core of safety culture: the factors found tend to describe management and not the cultural basic assumptions of the organization [35]. Guldenmund, however, did not specifically address healthcare organizations and patient safety culture questionnaires. In health care, safety attitudes have been shown to vary within and between healthcare institutions, and units with more positive safety culture scores had fewer adverse events like medication errors and blood-stream infection [36].

Patient safety culture can be studied quantitatively by surveys or qualitatively by anthropological/ethnographic methods – with a “middle category” consisting of questionnaires constructed to function as guidelines for reflective dialogue in staff groups, like the “Strategies for Leadership: an Organizational Approach to Patient Safety” (SLOAPS) [37], the Checklist for Assessing Institutional Resilience (CAIR) [38,39] and the Manchester Patient Safety Framework [40].

### **Patient safety survey instruments (questionnaires)**

If one decides to do quantitative surveys, a number of questionnaires exist, including the “Hospital Survey on Patient Safety Culture” (HSOPS) [41], the “Veterans’ Administration Patient Safety Culture Questionnaire” (VHA PSCQ) [42], the “Culture of Safety Survey” (CSS) [43] and the “Safety Attitudes Questionnaire” (SAQ) [30,36] – the latter also comes with an intervention programme package – safety education, staff identification of safety concerns, senior executive walk-round follow up of improvement efforts, documentation of efforts and effects,

dissemination of results and culture reassessment – which has been shown to improve patient safety culture and reduce the number of adverse events and also nurse turn-over [44]. Reviews of a number of quantitative safety culture survey instruments are presented by Colla et al. [45], and by Flin et al. [46].

Choosing an instrument may not boil down to answering the simplistic question “Which one is The Best?”. Colla et al. [45] have shown that not all existing instruments have been psychometrically tested, and they recommend preferring those that have been shown to be reliable by comprehensive and sound psychometric testing. But they also remind potential users to bear in mind that the selection of instrument should depend on the purpose of the investigation. Mannion et al. [18] conclude along the same line. Having discussed a large number of safety culture measurement instruments used in the UK, and noted that by far the most frequently used instrument in the NHS was the Manchester Patient Safety Framework, followed by the Safety Attitude Questionnaire and the Safety Climate Survey, they report as one of their key findings (Executive Summary, page 3) that “We identified seventy instruments and approaches (...) There is no such thing as an ‘ideal’ instrument or approach for cultural examination: an instrument that works well in one case may not work in another”.

### **Conclusion**

Patient safety research can be undertaken in several ways. Sometimes single-case investigation and training and/or warning are required: less-than-fully competent professionals do exist, and even experts are sometimes negligent or irresponsibly careless. Technological and procedural improvements are sometimes needed: medical equipment does break down, and some procedures are more prone to unnecessary adversities than others. System designs must be studied: some systems conceal more latent failures than others, and there, someone should think “Let me redesign this so no one can do that”. The patient safety culture of healthcare institutions should be studied: there are large safety culture variations across care-giving units, and those who score low on safety culture have more adverse events.

### *Sources of support*

One of the authors (ED) is funded by Health Region South-East, Norway. Additional project support provided by the Akershus University Hospital.

## References

- [1] Runciman B, Merry A, Walton M. Safety and ethics in healthcare. Aldershot: Ashgate; 2007.
- [2] Kohn LT, Corrigan JM, Donaldson MS, editors. To err is human. Washington, DC: Institute of Medicine, National Academy Press; 1999.
- [3] World Health Organization. Quality of care: patient safety. A55/13. Geneva: WHO; 23 March 2002.
- [4] The (EU) Luxembourg Declaration 5 April 2005 "Patient safety – making it happen" [www.ec.europa.eu/health/ph\\_overview/Documents/ev\\_20050405\\_rd01\\_en.pdf](http://www.ec.europa.eu/health/ph_overview/Documents/ev_20050405_rd01_en.pdf) (accessed 6 March 2008).
- [5] Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, et al. Incidence of adverse events in hospitalized patients. *N Engl J Med* 1991;324:370–6 (republished as "Classic Paper" in *Qual Saf Health Care* 2004;13:145–52).
- [6] Runciman WB, Webb RK, Helps SC, Thomas EJ, Sexton EJ, Studdert DM, et al. A comparison of iatrogenic injury studies in Australia and the USA. *Int J Qual Health Care* 2000;12(5):379–88.
- [7] Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ* 2001;322:517–19.
- [8] Schiøler T, Lipczak H, Pedersen BL, Mogensen TS, Bech KB, Stockmarr A, et al. Forekomsten af utilsigtede hændelser på sygehuse [Frequency of adverse events in hospitals]. *Ugeskrift for Læger [Journal of the Danish Medical Association]* 2001;163:5370–8.
- [9] Chang A, Schyve PM, Croteau RJ, O'Leary DS, Loeb JM. The JCAHO patient safety event taxonomy: a standardized terminology and classification schema for near misses and adverse events. *Int J Qual Health Care* 2005;17(2):95–105.
- [10] Treasure T. Lessons from the Bristol case. *BMJ* 1998;316:1685–6.
- [11] Kennedy I. Learning from Bristol. Public inquiry into children's heart surgery at the Bristol Royal Infirmary 1984–1995. London: The Stationery Office; 2001.
- [12] Rutstein DD, Berenberg W, Chalmers TC, Child CG 3<sup>rd</sup>, Fishman AP, Perrin AB. Measuring the quality of medical care. A clinical method. *N Engl J Med* 1976;294:582–8.
- [13] Regenbogen SE, Greenberg CC, Studdert DM, Lipsitz SR, Zinner MJ, Gawande AA. Patterns of technical error among surgical malpractice claims. An analysis of strategies to prevent injury to surgical patients. *Ann Surg* 2007;246(5):705–11.
- [14] Institute of Medicine. Crossing the quality chasm: a new health system for the 21<sup>st</sup> century. Washington, DC: National Academy Press; 2000.
- [15] Poulsen J. Ethvert system ... [Every system ...]. *Ugeskrift for Læger [Journal of the Danish Medical Association]* 2001;163:5327.
- [16] MacReady R. Second stories, sharp ends: dissecting medical errors. *Lancet* 2000;355:994.
- [17] Leape LL, Kabacell AI, Gandhi TK, Carver P, Nolan TW, Berwick DM. Reducing adverse drug events: lessons from a breakthrough series collaborative. *Jt Comm J Qual Improv* 2000;26(6):321–31.
- [18] Mannion R, Davies HTO, Marshall MN. Cultures for performance in health care. Maidenhead: Open University Press; 2005. p 212.
- [19] Resar RK. Making noncatastrophic health care processes reliable: learning to walk before running in creating high-reliability organizations. *Health Serv Res* 2006;41:1677–89.
- [20] Marx DA, Slonim AD. Assessing patient safety risk before the injury occurs. *Qual Saf Health Care* 2003;12(Suppl II):ii33–ii38.
- [21] Day S, Dalto K, Fox J, Allen A, Ilstrup S. Utilization of failure mode effects analysis in trauma patient registration. *Qual Manag Health Care* 2007;16(4):342–8.
- [22] Knudsen P, Herborg H, Mortensen AR, Knudsen M, Hellebek A. Preventing medication errors in community pharmacy: root-cause analysis of transcription errors. *Qual Saf Health Care* 2007;16(4):285–90.
- [23] National Patient Safety Agency. Incident investigation and root cause analysis toolkit. Available at <http://www.npsa.nhs.uk/patientsafety/improvingpatientsafety/rootcauseanalysis/> (accessed 6 March 2008).
- [24] Wreathall J, Nemeth C. Assessing risk: the role of probabilistic risk assessment (PRA) in patient safety improvement. *Qual Saf Health Care* 2004;13:206–12.
- [25] Reason JT. Managing the risks of organisational accidents. Aldershot: Ashgate; 1995.
- [26] Maurino DE, Reason JT, Johnston N, Lee RB. Beyond aviation human factors. Aldershot: Ashgate; 1995.
- [27] Vincent CA, Taylor-Adams S, Stanhope N. Framework for analyzing risk and safety in clinical medicine. *BMJ* 1998;316:1154–7.
- [28] Vella K, Goldfrad C, Rowan KJ, Bion J, Black N. Use of consensus development to establish national research priorities in critical care. *BMJ* 2000;320:976–80.
- [29] Pronovost PJ, Morlock L, Dorman T. Creating safe systems of ICU care. In: Vincent JL, editor. Yearbook of intensive care and emergency medicine. Berlin: Springer Verlag; 2001. p 695–708.
- [30] Sexton JB, Thomas EJ, Helmreich RL, Neilands TB, Towan K, Vella K, et al. Frontline assessments of healthcare culture: Safety attitudes questionnaire norms and psychometric properties. Technical Report 04-01. The University of Texas Center of Excellence for Patient Safety Research and Practice, 2004.
- [31] Sundhedsstyrelsen/Dansk selskab for patientsikkerhed [Directorate of Health/Danish Society for Patient Safety]: Specifikke patientsikkerhedsstandarder – udvalgte procedurer med forbedringspotentiale [Specific patient safety standards – selected procedures with a potential for improvement]. København: Sundhedsstyrelsen; 2005. p 5–8.
- [32] Øvretveit J. Integrated quality development in public healthcare. Oslo: Den norske lægeforening [The Norwegian Medical Association]; 1999.
- [33] Westrum R. A typology of organisational cultures. *Qual Saf Health Care* 2004;13(Suppl II):ii22–ii27.
- [34] Guldenmund FW. The nature of safety culture: a review of theory and research. *Saf Sci* 2000;34:215–57.
- [35] Guldenmund FW. The use of questionnaires in safety culture research – an evaluation. *Saf Sci* 2007;45:723–43.
- [36] 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 (electronic publication).
- [37] Questionnaire "Strategies for Leadership: an Organizational Approach to Patient Safety": Available at: <http://www.ihatoday.org/issues/safety/tools/vhatoofinal.pdf> (accessed 6 March 2008).
- [38] Carthey J, de Leval MR, Reason JT. Institutional resilience in health care systems. *Qual Health Care* 2001;10:29–32.
- [39] Institute for Healthcare Improvement. Checklist for assessing institutional resilience. Available at: <http://www.ihl.org/>

- IHI/Topics/PatientSafety/SafetyGeneral/Tools/ChecklistForAssessingInstitutionalResilience.htm (accessed 6 March 2008).
- [40] Questionnaire “Manchester Patient Safety Framework”: Available at: <http://www.npsa.nhs.uk/patientsafety/improvingpatientsafety/mapsaf/> (accessed 6 March 2008).
- [41] Sorra J, Nieva V. Psychometric analysis of the Hospital Survey on Patient Safety. Rockville, MD: Westat; 2003.
- [42] Burr M, Sorra J, Nieva VF, Famolaro T. Analysis of the Veterans’ Administration (VA) National Center for Patient Safety (NCPS) FY 2000 Patient Safety Questionnaire. Rockville, MD: Westat; 2002.
- [43] Weingart SN, Farbstein K, Davis RB, Phillips RS. Using a multihospital survey to examine the safety culture. *Jt Comm J Qual Saf* 2004;30:125–32.
- [44] Pronovost PJ, Weast B, Rosenstein B, Sexton JB, Holzmueller C, Paine L, et al. Implementing and validating a comprehensive unit-based safety program. *J Pat Safety* 2005;1:33–40.
- [45] Colla LB, Bracken AC, Kinney LM, Weeks WB. Measuring patient safety climate: a review of surveys. *Qual Saf Health Care* 2005;14:364–6.
- [46] Flin R, Burns C, Mearns K, Yule S, Robertson EM. Measuring safety climate in health care. *Qual Saf Health Care* 2006;15:109–15.