Netherlands
The Journal of Medicine

EDITORIAL

Clinical incidents and risk prevention

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INTRODUCTION

Over the past two decades a series of medical disasters have created public concern. One of the most widely disputed and analysed scandals was the one that took place at the Bristol Royal Infirmary, usually referred to as 'the Bristol case'. This tragedy is thought to have at least doubled the mortality rate in young children after paediatric cardiac surgery for over more than a decade.[1]

Much has been made of the way in which the principal actors (two paediatric cardiac surgeons) and their medical and managerial colleagues initially denied the situation and failed to recognise that their clinical activities had and were placing lives at risk.[2]

Unfortunately the Bristol case was not just an isolated incident. Since the inception of the National Health Service (NHS) in the UK in the 1970s, more than 30 NHS public inquiries had been conducted up to 2001 to address catastrophic failures in patient care and this number is rapidly increasing.[3]

And things do not only go wrong in the UK. Most countries in Europe and important regulatory bodies in the US and Australia report on problems in the field of patient safety.[4-6]

Also the Netherlands has its share of failures. Recent interventions and analyses of hospital misconduct undertaken by the Inspectorate in the Netherlands (the cardiothoracic surgeons at the Radboud University Medical Centre in Nijmegen, the surgeons at the Maas Hospital in Boxmeer and the Intensive Care doctors at the St Jans Hospital in Weert) show communication failure and deficits in teamwork were important determinants of harm,[7] a finding that is affirmed by investigations elsewhere.[8] For example, a survey in the Netherlands showed that overt conflicts between medical specialists threaten the quality of patient care in at least one third of the hospital departments.[9]

What can medical specialists learn from these cases? First, take a close look at your practice, your department and your own hospital. Are you sure this could not happen to you? Second, if you feel or think that everything is safe, do you have the numbers available to confirm that you are indeed safe?

In this editorial, I will address the subject of patient safety, with a focus towards the hospital setting. What are the most important types of medically unsafe practices that may confront us? Do we know how often they occur and the consequences? Do we know how to prevent them? What is the evidence to support these preventive activities? How can we measure and monitor progress?

PATIENT SAFETY ON THE AGENDA

Eight years ago, the Institute of Medicine (IOM) called for a national US effort to make American health care safer.[10] They reported that as many as 98,000 patients die annually due to medical errors. Ever since, patient safety has become a hot topic for journalists, health care managers and concerned citizens, but much less so for health care professionals. They are primarily concerned about being blamed, punished and suspended.[11]

Instead they should take the lead in medical error prevention and promote a culture of safety. So let us see what is known about error and preventive actions.

THE FIGURES

The epidemiology of accidents in health care is well known. The prevalence of iatrogenic harm in hospitalised patients ranges between 3.7 to almost 16%.[12,13] Besides the burden placed on patients and their relatives, the knowledge that half of these events are preventable and the enormous costs of dealing with the resulting injury seriously challenges the health care system. The IOM report estimated that 17 billion US dollars of direct health care costs annually are related to medical injuries. In patients involved in medical complications the mean hospital stay has more than doubled (up to a mean of 14 days) while the costs have tripled.[14]

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DYSFUNCTIONING

Apart from the rather constant numbers of complications that seem to be related to Western health care delivery, disaster medicine resulting from serious misconduct may occur. Disasters may become visible by, for example, a high incidence of complaints from patients, high reporting of incidents by health care providers or high complication or death rates from registrations. These reporting systems are not very sensitive, as history shows. Usually it takes a long time before the disaster is recognised, and even longer before the problems are taken seriously and tackled. The Bristol Royal Infirmary tragedy already mentioned is exemplar.[15] Recently, systems to detect and 'treat' dysfunctioning doctors have been developed,[16] and are gradually being introduced in the US and UK. It is probably even more difficult to detect group dysfunctioning or conflicts among medical specialists, as doctors usually have a group code to try to keep the problems among themselves.

IT MAY HAPPEN TO ANY OF US

In the past ten years, medical errors are repeatedly occurring in hospitals all over the world. These can no longer be considered incidents, but seem part of common practice. Numerous studies increasingly show that between 30 and 50% of patients do not receive the optimal care they deserve.[17] It is only a matter of time before over-, under- or misuse leads to error that is reported or detected.

THE RESPONSE

What must be done within the health care system, by the health care professionals and by management? What actions can make your health care safe?

SAFETY PLANS AND SYSTEMS

As a result of the IOM report, only a few US hospitals did not take any action.[18] A survey in 2004 showed that while 74% of American hospitals reported full implementation of a patient safety plan, just under 9% reported no plan at all. The area of surgery showed the greatest level of patient safety systems. What was surprising was the low level (34%) of fully implemented computerised physician order entry systems for medication. *Table 1* shows an overview of systems developed and used in US hospitals.

Most hospitals in Western Europe are currently introducing all manner of risk management activities and systems. An example is the critical incident reporting about (near) misses that has been introduced in almost all the hospitals in the US and UK.

Table 1. *Patient safety systems*

Variables
Plans, policies and programmes
• Patient safety committee
• Patient safety officer
• Patient safety programme budget
• Significant adverse events reported to patients/families
• Trend analyses conducted on incidents
• Process redesigns monitored for effectiveness
• Written patient safety plan as part of quality improvement plan and developed on safety assessment results
• Root cause analysis after (near) miss, with actions taken based on the analysis and findings
• American Hospital Association self-assessment documents used
Leadership and environment
• Adverse event actual/potential assessed
Data and computerisation
• Clinical codes from medical records used to monitor patient safety
• Quality improvement programme that monitors injuries and adverse events using discharge data
Surgery
• Preanaesthesia patient assessment and anaesthesia plan
• All preprocedure diagnostic studies included in chart prior to surgery
• Primary surgeon verbally confirms side for operation, limb and/or site marked with witness
• Identification of equipment malfunction
• Surgery technical performance errors
Medications
• Full-time pharmacist on staff
• Nonpharmacists have access to medication after hours when no pharmacist is available
• Safety measures for look-alike drugs
• Safety measures for sound-alike drugs
• Safety measures for spelled-alike drugs

A critical look at these systems shows great variations in what is reported and how the data are being used.[19] No research has proven its effectiveness in health care[20] although the reporting and the actions based on it have successfully reduced the number of aviation incidents[21] and accidents in other types of industries.

One of the problems is the poor level of reporting.[22] The blame and shame culture and the fear for litigation, dismissal and suspension that pervades our medical system frustrates the implementation of such a critical incident reporting.[23-25] Anonymous reporting to an independent body at a regional (or national) level may encourage reporting;[26] however, on the one hand it may lead to irresponsible accusations and on the other may overlook local problems. Safe reporting, which means that the reporter cannot be legally accused on the basis of his own report, seems the solution but reporting incidents is not enough. Only proper investigation leading to appropriate preventive action seems worthwhile. Unfortunately the evidence on the best and most cost-effective methods stops here and intuition takes over.

SAFETY MANAGEMENT SYSTEMS

Managers and commercial firms have taken the lead and try to persuade hospitals to take over their (often time-

consuming or costly) system or method. No results are available yet from properly designed studies of all these systems. So all actions may be classified as premature, although a sense of urgency forces hospital management to take some kind of action, even if no evidence is available. Systems used include the widely introduced systematic analysis of severe reported events by root cause analysis.[27] Root cause analysis follows a highly structured process of triage questions throughout the health care system, tracing some fundamental problems over a series of events. It is time consuming, retrospective in nature and simplifies events. Therefore, the American National Centre for Patient Safety developed a more proactive method (HFMEA; Healthcare Failure Method and Effect Analysis) for the functioning of a process delivered by a multidisciplinary team. Nonetheless, HFMEA is also time consuming while it is not known whether its deployment really prevents unsafe care.

A SAFETY CULTURE

In accordance with high-risk industries it is recommended that health care organisations should regularly assess their 'safety culture'. Safety culture is considered the product of individual and group values, attitudes, perceptions, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation's safety management. From this definition it is already clear that a safety climate will be difficult to measure, an opinion secured by a systematic review that showed the weaknesses of measurement instruments.[28] And if a valid and reliable instrument can be designed in the future, the next problem will be which strategy should be used for improvement.

PRACTICE VERSUS SYSTEMS

So let us get out of management language and systems and return to the quality of patient care itself. What practices will most endanger patients and what practices will most improve safety?

After the IOM report the US president ordered a government-led wide feasibility study, which directed governmental agencies to implement the recommendations. As a consequence the Agency for Health Care Research (AHRQ) determined a list of 'best practices' for all clinicians, with the evidence level included.[29]

Three problem areas emerged as the most important health care issues occurring most frequently with a high strength of evidence to support them:

1. Anticoagulation therapy to prevent deep venous thrombosis (the number one rating).
2. Antibiotic prophylaxis to prevent surgical infections.
3. Use of pressure-relieving materials to prevent pressure ulcers.

The use of perioperative β-adrenoceptor blockers in cardiac patients, maximum sterile barriers (with antibiotic or impregnated or sterile silver alloy-coated catheters and if indicated ultrasound guidance) during catheter insertion, informed consent procedures from patients, the prevention of ventilator-associated pneumonia by continuous aspiration of subglottic aspirations (CASS) with semi-recumbent positioning all have a high level of evidence. Patient self-management using home monitoring devices during chronic long-term anticoagulant therapy and various nutritional strategies in (abdominal) surgery patients (with selective decontamination of the digestive tract), computer monitoring of adverse drug events (due to analgesics, potassium, antibiotics, heparin), information delivery if transfer of the patient is indicated and adequate pain management also showed a high strength of evidence.

Management of falls, postoperative pain, delirium and contrast-related renal failure are recommended with a medium strength of evidence.

Although they lacked sufficient rigorous evidence of efficacy unit dosing, the introduction of a computerised physician order entry (CPOE) and bar coding were placed in the top category for improvement. This was followed by localising specific surgical and other procedures to high-volume centres, improved hand washing compliance and clinical pharmacist consultation services, all with a medium strength of evidence.

The recommendation to introduce CPOE, bar coding and pharmacist consultation is probably due to the high frequency of medication error in the Boston Medical Practice Study.[30]

Overlooking the recommendations, technical approaches prevail. These technical advances are probably easy to study, while system errors or easy practical solutions have received little research funding. Simple practical 'common sense' solutions are not mentioned because they have not been studied in randomised controlled trials.[31]

Examples of these common sense solutions are the removal of concentrated potassium chloride from nursing units, unit dosing instead of bulk dosing, the requirement of duplicate independent calculating and reading when intravenous drugs are prepared and administered, and educating patients about accurate use of their medications. Leape *et al.*[31] plead for a combination of evidence-based solutions with a common sense approach, to be tested later on, and accepted practices from other industries.

KNOWLEDGE FOUNDED ON MEASUREMENT

One key barrier for progress is the paucity of proven safety measures in the literature. To identify problems and to demonstrate improvement over time robust measures

should be available. In the early 1990s, Iezzoni *et al.*[32] developed a Complication Screening Programme to screen systematically for quality gaps, using administrative data. Soon after, the Agency for Healthcare Research and Quality (AHRQ) developed a similar set.[33]
In the lately 1990s, hospitals in the State of New York started using measurements extracted from discharge records.[34]

AUTOPSY

Discussion on the results of autopsy is the oldest tool and still the gold standard to evaluate medical accuracy in diagnostics and therapeutics. After the ancient Greeks, who used it to study human anatomy, autopsy became common practice in Europe during the Renaissance and was gradually linked to diseases and an evaluation of clinical handling. Unfortunately autopsy rates are steadily falling as most clinicians are convinced that the new imaging techniques such as computerised tomography, magnetic resonance imaging and positron emission tomography scanning, which can also be combined with functional studies, offer clinicians all the critical information needed and seem to have made pathological examinations after death unnecessary.[35]
Over and over it has been shown that this impression is wrong. For example Aalten *et al.* recently showed that in nearly 40% of autopsies in geriatric patients, major discrepancies were seen between clinical diagnosis and autopsy findings. These findings stress the important role of autopsy as a quality instrument to detect diagnostic errors.[36]

SCREENING OF MEDICAL RECORDS

Record review is one of the primary methods to assess the incidence of adverse events. This method is time consuming, its reliability depends on the training and experience of the (independent) assessors and the accuracy and completeness of the patient records. Yet it has provided a more complete indication of the incidence of adverse events than other reporting systems.[37] A new modular review form is suggested, which makes it possible to benchmark the results.[38]

COMPLICATION REGISTRATION

Having information regarding unwarranted results of diagnosis or treatment provides the information to develop interventions to prevent them. Such a complication registration should be supplemented by a statistical analysis to identify preventable high frequency complications and contributing factors. During the structured discussion meeting that follows, a redesign of the process that influenced the event and a literature search regarding the evidence of improvement measures are important.[39]

SAFETY INDICATORS

Recently the AHRQ promulgated a set of patient safety indicators (available at: http://www.qualityindicators.ahrq.gov). The Institute for Health Care Improvement developed trigger tools for measurement of harm.[40] A similar indicator tool has been developed for preventable drug-related morbidity in general practice.[41] To design reliable indicators for unsafety these indicators should fulfil the criteria of a solid diagnostic instrument. Safety indicators should be valid, reliable and feasible.[42] Future research will show whether the proposed safety indicators comply with these requirements.[43]
Table 2 gives an overview of the safety indicators as measured in 430,552 US patients, registered in the Veterans Administration. The precise definitions of the numerator and the denominator can be found in the report by McDonnald *et al.*[44]

BEST PRACTICES

Yet, why all these time-consuming registrations? The epidemiology of incidents is well known and the success of the method depends on the conclusions and the subsequent measures taken.
Some warn that too much effort is being devoted to measures of injury rather than implementing known methods that reduce injury, because it is argued that the amount of knowledge about how medical care can be made safer is already so comprehensive that these strategies should be implemented now.[45] For example standardised, electronic guideline-driven dosage protocols in high-risk medication areas have already been proven effective in diabetes,[46] and in anticoagulant care.[47]
The Joint Commission on Accreditation of Health Care Organisations has a very informative and practical website (http://www.jointcommission.org) with a site dedicated to patient safety. It contains the 14 US 2006 national patient safety goals. These are related to patient identification, medication and surgery safety, prevention of infections, falls and pressure ulcers, communication and patient involvement. Their website presents facts, questions asked, practical and simple advice, implementation strategies and background and teaching information. So it is possible to start now, without a great burden on personnel or resources.

A PRACTICAL APPROACH

If you feel you should start now, a practical approach is advisable. Let each medical speciality in a hospital select its five topics regarding medical error from literature by using three criteria (prevalence, resulting damage and preventability). Next construct or take over two process

Table 2. *Rates of patient safety indicator (PSI) events in VA* data#*

		Numerator	Denominator	PSI
1	Complications of anaesthesia	55	97,482	0.56
2	Death in low mortality DRGs	178	55,079	3.23
3	Decubitus ulcer	3207	208,097	15.41
4	Failure to rescue	3316	21,318	155.55
5	Foreign body left in during procedure	73	430,536	0.17
6	Iatrogenic pneumothorax	469	402,185	1.17
7	Infection due to medical care	817	345,442	2.37
8	Postoperative hip fracture	81	71,053	1.14
9	Postoperative haemorrhage or haematoma	315	97,479	3.23
10	Postoperative physiological and metabolic derangements	77	40,788	1.89
11	Postoperative respiratory failure	107	31,207	3.43
12	Postoperative pulmonary embolism or deep vein thrombosis	1262	97,231	13.00
13	Postoperative sepsis	106	17,283	6.13
14	Postoperative wound dehiscence	129	20,115	6.41
15	Technical difficulty with procedure	1216	430,524	2.82
16	Transfusion reaction	3	430,536	0.007

***VA = Veterans Administration. DRG = diagnosis-related groups. #Data extracted from Jonantgen, et al.[33]**

indicators and one outcome indicator connected with the topic. Measure the results and give feedback in a comparative way[48] after case-mix correction. Let the responsible person or group comment on the results if these deviate more than two standard deviations (SDs) below average. Subsequently, let the group be peer-reviewed by the best national, regional or local performers regarding this issue. With their advice an improvement plan is formulated and feedback is given on the formulated targets within an agreed time frame.
This looks simple, cheap and attractive for care providers. Is it better or more cost-effective than the managerial plans? Let's find out.

CONCLUSION

In conclusion the research agenda in this area is clear. There is a need for much more quantitative research comparing the several approaches that are now being introduced because of the sense of urgency. Comparative studies in high incident areas such as in surgery, obstetrics or the medication process are warranted. The prevention of iatrogenic harm is a research priority, not only for doctors, allied health professions or nurses, but also to their patients and society. The failure to carry out such research is a disgrace to all of us.

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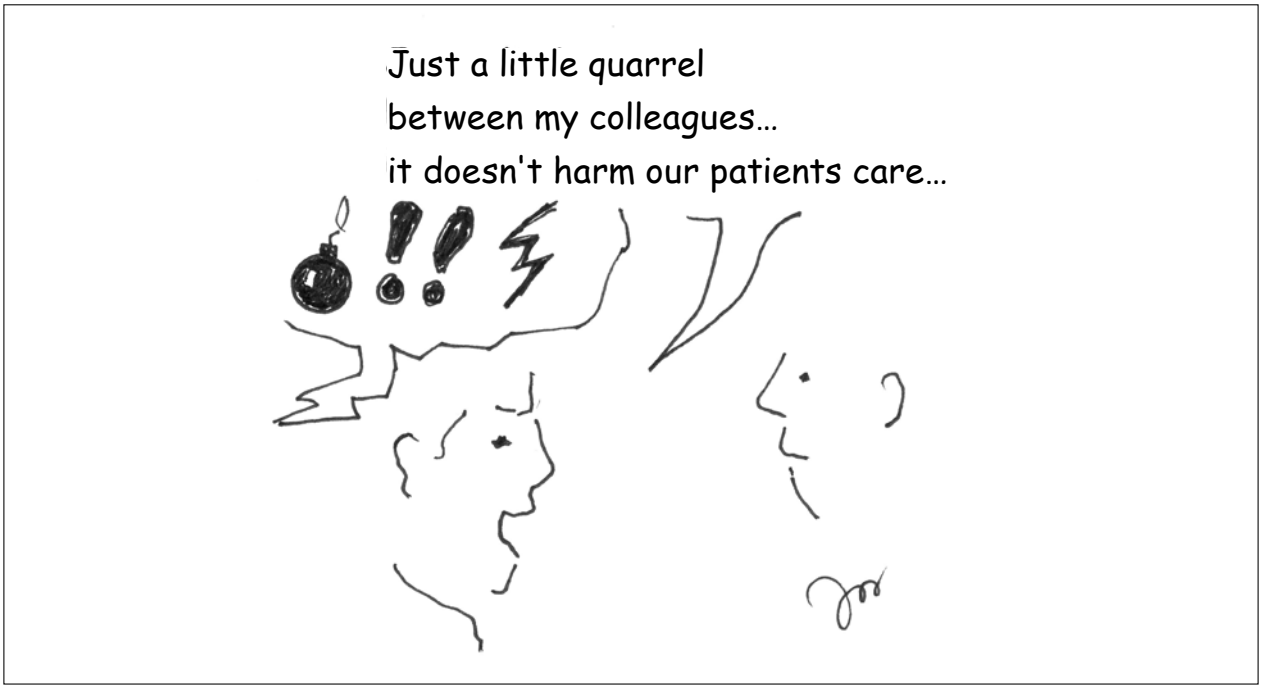

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