CORRESPONDENCE

Patient Safety and Error Management—What Causes Adverse Events and How Can They Be Prevented?

by Dr. med. Barbara Hoffmann, Dr. med. Julia Rohe in volume 6/2010

Active Support

Since education and training are always crucial for a successful implementation, I wish to add two topics that are important for the introduction of a safety culture:

Between the submission and publication dates of the article, the German Medical Association published a concept for further medical education relating to patient safety for doctors; one of the collaborators was Dr Rohe, one of the article's authors. The concept is eminently suitable for introducing and further developing a safety culture in a hospital. The CME concept serves the purpose of qualifying medical personnel within the increasingly complex subject that is medicine.

Since patient safety has to be anchored in medical professionals' minds from medical school onwards, the World Health Organization—also in 2009—devised a similar educational concept for medical students. The intention is to introduce this at medical schools worldwide and thus sensitize future doctors to issues of patient safety early on in their careers.

It is not enough to demand patient safety, but doctors have to be supported actively in order to be armed with modern methods to rise to modern challenges. At Magdeburg University Medical Center, the CME concept patient safety is offered by default to all doctors working there, free of charge.

At the same time it is important to sensitize future generations of students to the topic. The medical faculty at Otto-von-Guericke-University at Magdeburg is therefore one of the first medical schools to offer its students a patient safety training course from this summer semester, which follows the concept established by WHO.

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Experiences With Checklists

Since the Institute of Medicine's initiative "TO err is human," efforts have been ongoing to establish a new error culture within medicine. In addition to the patients, generations of doctors who have grown up within the "blame culture" are sure to welcome this.

I miss in the article a more concrete discussion of the known causes of human error. WHO in this context names two factors that have the biggest influence on human susceptibility to errors: fatigue and stress (1). It remains to be seen whether introducing checklists will help, as is explained "without any additional expenditure in terms of time and costs" (2). We remind readers of the experiences when a "simple checklist" was introduced to help reduce the number of infections associated with central venous catheters and intensive care wards. The media liked the idea of a "simple" checklist. In reality, however, the implementation was onerous in terms of time and human resources (3).

The actual underlying problem, that the "limits of what's tolerable" (4) has been reached for hospital doctors, is being completely ignored at the sociopolitical level.

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Ordering Errors Were Identified

On the basis of a selective literature review, Hoffmann et al. report on the epidemiology and etiology of avoidable serious adverse events. Their excellent review article clarifies that 70–80% of the population regard medical errors as an important issue, and 29% are worried that in case they contract an illness they might be subject to treatment errors themselves. Retrospective

analyses have shown that 4% of treated inpatients do experience adverse events, of which at least half are avoidable. It is of interest that the estimated death rate due to avoidable errors of 0.1% seems low; however, in view of 17 million inpatients, this corresponds to 17 000 deaths per year. The authors regret that studies investigating this issue are lacking in Germany; albeit these studies do exist for highly complex and potentially toxic medications, namely chemotherapies.

We assessed 22 216 chemotherapeutic orders for 2337 patients receiving chemotherapeutic treatment in our department from 1/2005 to 12/2006 in regard to their correctness and identified 3.8% ordering errors (1). Of these 3792 ordering errors, 99.9% were corrected and successfully avoided by our quality control management and did not get passed on to the patient. This error rate confirms a publication from Boston (2), which also described a 4% error rate for ordered chemotherapeutic regimens, of which merely 45% were avoided. Assuming that each serious medication error incurs follow-up costs owing to complications of € 1000, then 3792 chemotherapeutic errors would result in costs of € 3,792,000. Implementing our clinical service system helped to reduce these assumed costs by a factor of 1264. Our clinical service system, a quality control management team, is comprised of physicians, pharmacists and an additional medical technician. This medical technician monitors all chemotherapy orders and uses 25% of her time to check 50–100 orders of chemotherapeutic regimens per day. The additional staff cost per chemotherapeutic order accounts for 1€.

Our data confirm and add to the article by Hoffmann et al., emphasizing that dealing transparently with errors to support avoidance of severe adverse events is indispensable for safe medication. Our results were enthusiastically discussed by the Frankfurter Allgemeine Zeitung under the heading “Kontrolle zahlt sich aus [control pays off]” (3), and our achievements in safe patient medication care was awarded first prize of the Quality Award from the Freiburg University Medical School Center in 2009

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Transparency was created

The authors mention the error reporting system CIRS-medical Germany, the patient safety optimization system (PaSOS) used in anesthesiology, and two further error reporting systems used in preclinical emergency medicine and geriatric care. No mention was made of the assessors’ Medical Error Reporting System (MERS), which was developed by Germany’s arbitration and review boards.

These institutions check whether a patient was subjected to treatment errors and whether a causal relation exists with the reported health problem. Decisions made by arbitration boards will be shared with the patient, the doctor’s or hospital’s professional indemnity insurers, and the reviewer consulted by the arbitration board.

MERS has shown that in 2008, in 2090 out of 7133 cases of arbitration, errors were noted—including deficiencies in how risk was communicated. The results are presented to the public every year by the German Medical Association in collaboration with the arbitration boards. The results are in the public domain (www.bundesaerztekammer.de, www.schlichtungsstelle.de).

Publication of the results creates transparency about error related health problems in Germany. Medical problem areas are identified on a statistically sound basis. The arbitration boards publish the results regularly in their medical journals. Doctors and lawyers in the arbitration boards give presentations about the results gained by using MERS. The boards thus make a valuable contribution to error prevention and increasing patient safety. The work of the arbitration boards and MERS should not be omitted from an article on patient safety and error management.

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Cooperation of All Participating Groups

The authors do not mention the action plan for drug safety in their report of German activities. In the context of the 1. Deutscher Kongress für Patientensicher-

heit bei medikamentöser Therapie 2005 [Germany's 1st congress for patient safety in the context of medication treatment in 2005], the topic of drug safety was picked up by Germany's Federal Ministry of Health; the subsequent action plan 2008/09 for drug safety improvement in Germany initiated a continuous process for the improvement of patient safety in the context of medical drugs, which is carried jointly by politicians and doctors. The aim is close cooperation in analyzing the causes among the groups involved in the medication process; the declared objective is to develop risk minimization strategies. In March 2008, the Drug Commission of the German Medical Association instituted a coordination group consisting of representatives from patients' organizations, pharmacists' associations, doctors, the federal health ministry, and the German Coalition for Patient Safety; the objective is to implement and further develop the action plan. In addition to numerous research projects, an information leaflet for patients (www.ap-amts.de) and other information services have been developed—for example, the information page of Berlin's pharmacovigilance center for embryo toxicology (Pharmakovigilanz und Beratungszentrum für Embryonaltoxikologie).

The continuation of the action plan—decided in the meantime—is for 2010–12. New aspects have been included—for example, the implementation of drug safety in medical quality assurance and the strengthened cooperation between doctors and pharmacists to improve drug safety. The results and further development of the action plan drug safety were presented to the public at the third congress for patient safety in the context of medication treatment in Berlin in 2010 (www.kongress-patientensicherheit.de).

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In Reply:

The readers' responses underline the relevance of patient safety and the need for quick as well as more detailed information on the subject. We thank our correspondents for their comments and additions, which bring to attention important studies and projects aiming to improve patient safety in Germany.

Professor Schaffartzik and attorney Neu note the omission of the arbitration boards' Medical Error Reporting System (MERS) from the list of incident reporting systems. However, the arbitration boards' MERS is a registry of malpractice claims, not an incident reporting system in the actual sense. As shown in our article, such reporting systems receive their reports from the service providers themselves (staff at hospitals, practices, or nursing institutions). They include near-misses, errors, critical events, and harm events. By contrast, the MERS includes cases of suspected or actual treatment errors that resulted in actual harm to the patient in every case (the very reason why the patient involved the arbitration board). Such cases are evaluated by the arbitration boards' staff on the basis of the available files (for example, expert opinions) and then entered into the MERS database, which, consequently, enables different analyses to incident reporting systems.

Incident reporting systems use primarily information from insiders within the organization in the healthcare system that is not documented; a treatment error registry analyses data that are documented in patients' files. A registry such as the MERS does offer an additional window into the system (1)—albeit one with a different perspective—and thus enables important insights into adverse events and their causes.

Dr Tönneßen thankfully mentions the German Medical Association's CME concept "patient safety" (2) and introduces the exemplary activities embarked on at Magdeburg university medical center and medical faculty. We wish to mention a new working group focusing on education and training within the German Coalition for Patient Safety, which will dedicate itself entirely to this subject while keeping a broad focus on all healthcare and allied professions (3).

Professor Engelhardt et al mention the exemplary adverse event prevention project at Freiburg University Medical Center and show just how manifold patient safety activities in Germany are.

Professor Müller-Oerlinghausen and Dr Aly complain about the lack of detail about the action plan drug safety. The federal health ministry's action plan did not find its way into our review article because of our particular focus on the causes and contributing factors of medical errors and the necessary restriction on naming only a few measures to prevent errors.

Professor Hanisch comments that the article does not focus in a concrete manner on the known causes of human error. He explicitly names fatigue and stress as the factors that the WHO considers as having the greatest influence on error proneness. We wholeheartedly agree that these factors are important in terms of negative outcomes. Fatigue, stress, and time pressures have a potentially devastating effect on patient safety in hospitals and practices, all the more if occurring in problematic institutions in terms of organization, communication, education, and supervision. In view of the

current working conditions at some hospitals that we are aware of, we do not think that checklists can be implemented without a higher expenditure in terms of time (4), but we wish to emphasize their importance (5), which is also due to the fact that clinical actions are transparent for all parties involved and is communicated as such (6).

Staff shortages, however, do not fundamentally prevent all attempts to achieve greater patient safety. They may support the development of innovative ideas and concepts and increase patient safety. This should not be done at the expense of the staff, however. The resources that are necessary to improve patient safety should unfailingly be applied for and should be granted.

In the 10 years since "To err is human," Germany has introduced various measures to improve patient safety. This review article and resulting correspondence have shown that we are taking the right steps towards a learning healthcare system, to learning organizations that will tackle the question: what are we actually doing, and what positive and negative effects does it have?

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