REVIEW ARTICLE

Patient Safety and Error Management

What Causes Adverse Events and How Can They Be Prevented?

Barbara Hoffmann, Julia Rohe

SUMMARY

Background: Even in industrialized countries, health care is not as safe as it should be. The term "patient safety" denotes the non-occurrence of adverse events and the presence of measures to prevent them.

Methods: The literature was selectively reviewed to obtain information on the epidemiology and causes of preventable adverse events (PAE), as well as on measures that can increase patient safety.

Results: Preventable adverse events occur in Germany both in the hospital and in outpatient settings, although their precise frequency is currently a disputed matter. PAE should be analyzed systematically. They are caused both by active errors and by latent failures that are inherent in components of the health care system.

Conclusion: Three main strategies should be pursued to improve patient safety. A safety management system involving error reporting, learning from errors, and the fair exchange of information should be established in hospitals and in doctors' outpatient practices. An error management system should be implemented in which critical incidents are identified, reported, and analyzed so that similar events can be prevented, and measures for the prevention of critical incidents and errors should also be implemented and evaluated. Finally, whenever preventable adverse events do occur, the persons involved should take action to prevent further harm to the patient and other involved individuals.

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Even in industrialized countries, health care is not as safe as it should be. However, this problem has only been identified in recent years as a problem that is inherent in modern healthcare systems. In the 1970 and 1980s, a drastic rise in court actions for treatment errors in the United States forced health care providers to tackle the problem (1).

The Harvard Medical Practice Study (2, 3) and a study conducted in Colorado and Utah (4) investigated systematically how often patients were harmed by medical treatment in hospitals. Both studies form the basis of the report on the quality of US health care that was commissioned by the Institute of Medicine (5). For the first time, the public was made aware that modern health care can have negative as well as positive effects. Many industrialized countries subsequently conducted similar studies (6, 7) and set up institutions whose objective it is to improve patient safety—among others, the National Patient Safety Agency (NPSA) in the United Kingdom and the German Coalition for Patient Safety (Aktionsbündnis Patientensicherheit, APS) in Germany.

The public is interested in the subject. A 2005 survey conducted by the European Union showed that 72% of Germans and 78% of EU citizens regard medical errors as an important problem. 29% of Germans included in the survey expressed concern that they themselves might be affected by a medical error (8).

This review article provides an explanatory introduction into the topic of patient safety, focusing on the causes and contributing factors of medical errors, and introducing measures to prevent such errors. The authors assessed relevant scientific articles published since 1990 and discuss national and international activities.

Definition of adverse events and errors

Patient safety is defined as the "absence of adverse events" (5). In the international context, this definition of patient safety is often extended and, in addition to the non-occurrence of adverse events and the activities involved in preventing these, it includes adherence to quality standards and access to healthcare services. *Table 1* lists the most important terms used in this context.

Adverse events are all harms occurring in the patient care setting that are not due to the underlying illness itself. They include unavoidable side effects associated with diagnostic or therapeutic approaches—such as

hair loss after chemotherapy—and preventable adverse events (PAE) that are caused by erroneous actions—for example, allergic exanthema after administration of penicillin in spite of a patient's known penicillin äallergy.

Patient safety in inpatient care

Hospitals are complex working organizations. Different professional groups and skilled employees are involved in the direct and indirect care of patients. Patients receive treatment simultaneously from representatives from different disciplines or organizational areas. In many areas, work can be organized only as shift work so as to be able to provide services 24/7. These activities require numerous planning and communication processes in order to guarantee rapid and safe service delivery across numerous interfaces. Diagnosis and treatment are often associated with a high risk for complications that may give rise to severe sequelae, especially in vulnerable patients such as neonates, infants, and very old or critically ill patients.

Hand hygiene and medication safety have been identified as important problem areas (9). Complex hospital structures in particular may negatively affect medication therapy.

- Errors occur mostly during the prescription, preparation, and administration of medical drugs (10).
- Errors are often due to mistaking patient or procedures, miscalculation, writing mistakes, reading mistakes, mishearing, or reaching for the wrong substance.

There are also other problematic areas:

- Patient information may go missing at the interface of one treating department to the next; necessary treatments may thus be disrupted or continued in an erroneous manner.
- Patients and/or procedures are mixed up; one patient may be given another's medication or undergo an inappropriate examination (e2).
- Patients are often passive "consumers" of health care; they do not participate actively or cannot react because of their illness.

The studies from New York (2, 3) and Utah/Colorado (4) found after retrospective patient chart review that 3.7% of patients (New York) and 2.9% of patients (Utah/Colorado) had experienced adverse events in hospital. 58% and 53% of these events were categorized as avoidable.

For Germany, a study such as the Harvard Medical Practice Study is thus far lacking. However, the order of magnitude of the data collected in the US was confirmed in Australia and the United Kingdom (6, 7). A systematic review of 151 international studies of the German Coalition for Patient Safety (APS) showed rates of preventable adverse events of 0.1% to 10% (11). The wide range can be explained with the variance of the studies, with different data collection methods and study sizes, and underlines that the unequivocal identification of PAE presents methodological problems. On the basis of a subgroup analysis of the studies,

TABLE 1

Overview of terms

Term used	Explanation
Adverse event (AE)	A harmful event that is due to the treatment rather than the disease; it may be preventable or non-preventable
Preventable adverse event (PAE)	An adverse event that is preventable *[1]
Critical incident	An event that might result in an adverse event or clearly increases the probability of an adverse event
Error	An action or omission that entails deviating from the plan, following a wrong plan, or no plan. Whether harm arises from this is irrelevant for the definition of an error
Near miss	An error without harm that could have resulted in harm

*[1] "Preventability" applies when an error has caused the event
Source: German Coalition for Patient Safety (e1)

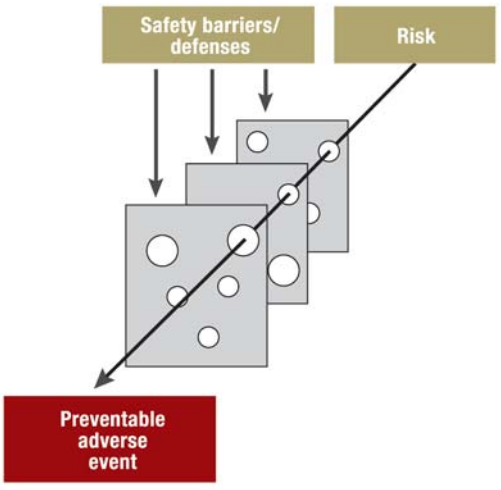
TABLE 2

Systematic analysis of cases and contributing factors, adapted from (e6)

Contributing factor	Explanation
Patient factors	Illness; social, physical, or psychological conditions; relationship between patient and outpatient practice/hospital; language; articulateness; personality
Task factors	How the process is structured; are protocols/standards available?
Individual (staff) factors	Knowledge, skills, education/training, stress levels, health, motivation
Team factors	Verbal and written communication, team structure, supervision, seeking help
Work/environment factors	Staffing levels, staff qualifications, work stress, design, availability and servicing of equipment and devices, environmental conditions, noise, distractions
Organizational and management factors	Resources, restrictions, structure of practice (single-handed or group practice) or structure of hospital, existence of and handling of rules, regulations, safety culture, and priorities
Institutional context	Financial situation/funding of the organization, requirements imposed by the liability insurers, legal/statutory requirements (quality management)
Safety barriers/ defenses	Existing, reliable, and known? Might the safety barriers have prevented the event?

Swiss cheese model, some gaps are due to active human failures, others to latent human failures, modified from (e5)

FIGURE 1



BOX 1

Patient safety culture

The way in which an outpatient practice, a hospital, or any other organization in the healthcare setting deals with the topic of patient safety is known as patient safety culture. Safety culture encompasses an underlying pattern of shared values, convictions, and course of action in an organization.

James Reason describes a person approach and a resultant safety culture ("blame culture") that concentrates on individual failures of persons at the sharp end. He distinguishes from this a system approach in which—on the basis of acceptance of human fallibility—errors are regarded as consequences of system failures rather than as consequences of individual attributes (e5).

An organizational psychological model (e7) differentiates between 5 levels of organizational maturity of safety culture: In a pathological safety culture (level 1), patient safety is regarded only hesitantly; when critical evens occur the main focus is on identifying guilty parties and sanctioning those, and learning from critical events does not happen. A reactive safety culture (level 2) is reflected in the fact that an organization acts only once a critical event occurs. In a calculative safety culture (level 3), mainly external requirements are met—for example, the introduction of quality and risk management. In a proactive safety culture (level 4), measures are in place to improve patient safety, even though no critical events have occurred. And the most evolved safety culture, the generative safety culture (level 5), patient safety constitutes an integral component of the working lives of everyone in the organization.

the German Coalition for Patient Safety estimates a death rate due to PAE among hospital patients in Germany of 0.1%. In 17 million hospital patients in Germany, this equates to 17 000 deaths a year.

Patient safety in outpatient care

Most patients worldwide receive outpatient care by their general practitioner. The following aspects require special attention—in contrast to inpatient care:

- Patients often consult their general practitioner at an early stage of disease when symptoms may be non-specific. The risk of overlooking severe, life threatening illnesses may be increased as a result. A high proportion of alleged treatment errors in general practice relates to diagnostic errors (12). However, this does not permit the conclusion that diagnostic errors really are the most common errors in this setting.
- Monitoring an outpatient's treatment and state of health is more difficult than in hospital. The result may be that adverse events are not recognized or recognized too late.
- Adherence and patient information is much more crucial to therapeutic success (13).
- Patients may simultaneously receive care from other service providers that are usually based at a distance (medical specialists, pharmacists, nursing care services, or physiotherapists). There is no common patient file; the communication barriers are higher because no institutionalized pathways exist for such collaborations.

Little information exists about adverse events or preventable adverse events in general practice, and drawing conclusions from inpatient data is problematic owing to the differences described above. A review of 11 studies with different definitions of events and data collection methods calculated a rate of 5 to 80 events per 100 000 consultations, in which patients were harmed or may have been harmed (14). An Australian study asked a representative sample of 86 general practitioners to report anonymously critical incidents from their practice for 12 months. The result was a rate of about 2 reported events per 1000 consultations per year (15).

Controversial discussion

Since the report "To err is human..." (5) was published, a controversy has surrounded the actual frequency of PAE in health care (e3). In view of the methodological problems in collecting all preventable adverse events reliably and completely, conclusive data about the epidemiology should not be expected any time soon.

Another reason for this state of affairs is because of the difficulties in judging whether an event was preventable. This assessment always includes the observer's subjective opinion. Any data collection method—whether studying patient files, voluntary reporting, observation, or cases handled by the arbitration boards—represents only a certain section of all PAE and will therefore always estimate different incidence rates (16). Only a fraction of the patients who

experience an adverse event in the context of their health care actually go to court (e4). The result is a difference between the actual number of treatment errors and the number counted on the basis of relevant malpractice claims.

Causes of preventable adverse events

James Reason, an expert in errors and the causes thereof, thinks that in any PAE, active as well as latent human failures play a part (17): Active failure relates to unsafe actions such as mistakes and violations, which may be committed by nursing staff or doctors, for example. These persons are involved in direct patient care, and their actions may affect patients immediately and directly.

Latent failures result from decisions made at the senior management level of the organization—for example, as a result of cost effective but user unfriendly devices, or because of a lack of resources or an unfavorable architectural environment. Negative effects owing to latent failures do not become visible immediately but favor the occurrence of active errors. The interaction between these two components was illustrated by using the "Swiss cheese" model (*Figure 1*).

A risk can result in a PAE if the safety barriers have such weaknesses that they can be broken down simultaneously. Gaps in the safety barriers arise from active and latent failures as well as because of contributing factors *(Table 2*).

The way in which errors have been dealt with by the healthcare system so far follows the traditional, person oriented angle and does not improve patient safety (18). If doctors or nursing staff commit errors they are personally blamed, disciplined, penalized, or at least instructed to "pay more attention" *(Box 1*). This does not take into consideration that the failures of an individual person are often at least partially caused by safety gaps in the system and that it is therefore only a question of time until another person is confronted with the same error *(Box 1*) (e5).

Measures to increase patient safety

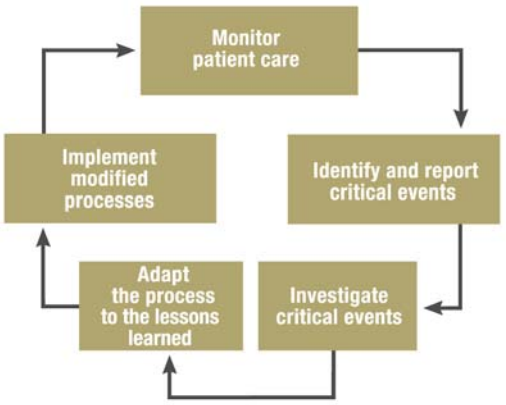
General measures

Reflecting and improving the safety culture is a fundamental step towards a reporting culture that is characterized by fairness and learning (19), in primary as well as secondary care. Crucial steps in this direction include the abolition of hierarchies, improving communication, inclusion of all participating professional groups, and active learning from critical incidents.

In re-engineering processes, the following aspects should be considered:

- Processes should be designed to be simple and should be standardized (e8). The less attention and memory input are required to perform a task, the fewer mistakes are made as a result.
- Patients should be included: Informed patients can draw attention to errors early on in the process and thus help prevent such errors and recover more easily from adverse events (e9).

FIGURE 2



The learning loop consists of 5 components: monitoring patient care, identifying and reporting critical events, investigating/examining critical events, adapting processes on the basis of the lessons learned, implementing learning outcomes and repeated monitoring, re-starting the cycle all over.

BOX 2

Error reporting systems in medicine

Error reporting or critical incident reporting systems (CIRS) collect information about critical events. They provide the basis for analyzing critical events as regards causes and prevention strategies and the dissemination of these events among the relevant professional groups and institutions in the healthcare setting, with a view to improving quality of care and patient safety by means of implementing the insights thus gained. The intention is to promote an open, learning patient safety culture.

Error reporting systems as internal systems may be accessible only to the staff of a particular hospital—and are already established in some hospitals—or, via the internet, to all service providers—for example www.jeder-fehler-zaehlt.de, the error reporting and learning system for general practitioners in Germany (e12).

Error reporting systems do not only serve the purpose of collecting data but the idea is that the knowledge and insights gained from analyzing these data will be reflected back to the users. Feedback methods include publication or internal feedback of error reports, analysis of causes, and prevention methods.

Other publicly accessible, internet based error reporting systems in Germany are:

- CIRSmedical Deutschland (www.cirsmedical.de)
- In anesthesiology and intensive care medicine, the patient safety optimization system PaSOS-ains (www.pasos-ains.de/index.html)
- In preclinical emergency medicine: www.cirs-notfallmedizin.de/home.html
- In nursing care: www.kritische-ereignisse.de

BOX 3

Systematic analysis of critical incidents and adverse events in medical practice

The strategy for analysis consists of the following steps:

Identifying and documenting critical incidents

Critical incidents may be noticed in daily clinical practice, but less serious events may often be rapidly forgotten. All team members should have the option of documenting events immediately.

Collating all relevant information

All important information and documentation relating to an event should be compiled. This includes questioning all those present, questioning treating physicians and staff from other healthcare professions, and studying the patient's file.

Team meeting

The event should be analyzed jointly—that is, a team meeting should include all practice staff; it should be strictly confidential, and it should seek answers to the following questions:

- What has happened?
- Why has it happened?
- What can be changed in order to prevent similar events in the future?

Firstly, the precise chronology of the event should be presented. Then the unsafe actions within the event can be identified. Unsafe actions are actions or omissions that cause the delivered health care to deviate from its usual "safety corridor." Examples include:

- Not seeking help when it is needed, or
- Lacking control of an ampoule before an injection.

Subsequently, the team should identify the factors that have contributed to the development of the event. The overview from *Table 2* can be used for this purpose. Then those contributing factors are identified that can be modified so as to prevent similar events in future. The necessary changes within the practice are decided, and a decision is made as to who should be responsible for their implementation.

Implementing, monitoring, evaluating modified processes

At a certain point in time a discussion should be had about whether the implemented measures have improved patient safety. If needed, routines and processes will have to be adapted further.

The course of action described here was developed by the Institute for General Practice at the University of Frankfurt/Main on the basis of methods used internationally in hospitals, which in turn go back to root cause analysis (RCA). Root cause analytic techniques were originally developed to analyze major incidents in industry—for example, in the nuclear power setting.

- Checklists should be used (20).
- Software should be used in combination with electronic patient files, which can serve as reminders, provide memory support, and stimulate attention by, for example, reminding doctors to control laboratory measurements in the course of monitoring pharmacotherapy (e10).

Many general and specific measures have already been used in a similar way in high risk industry branches.

Identifying and reporting errors

Error management starts with uncovering critical incidents *(Figure 2)*. The following methods are available to achieve this.

Information from healthcare professionals—such as nursing staff, medical staff, and doctors—can be gleaned from:

- Error reporting systems *(Box 2)* and clinical case conferences where adverse events are discussed.

Information from patients and their relatives can be obtained from:

- Patients' complaints and symptoms
- Allegations of treatment errors such as are available from assessment committees and arbitration boards of the medical associations or health insurers
- Patient surveys (e13).

Routine data are suitable for identifying:

- Defined triggers for medication errors, for example. Thrombocytopenia below 50 000 thrombocytes/µL may be interpreted as an adverse event associated, for example, with methotrexate (e14).
- Quality indicators such as are collected, for example, in the context of external comparative quality assurance by the German Federal Office for Quality Assurance (Bundesgeschäftsstelle Qualitätssicherung, BQS) *(Figure 2, Box 2)*.

All methods have gaps in capturing data (21). As routine data only documented events can be identified; reporting systems can capture only actively reported events, and alleged treatment errors can be discussed only if they are claimed by patients.

Systematic analysis of critical and adverse events

In order to learn from mistakes it is necessary to analyze events systematically. This enables the detection especially of latent failures. In the Anglo-American setting, different methods have been developed to analyze critical incidents in hospitals (22, e15, e6). The Institute for General Practice at the University of Frankfurt/Main has developed a method to analyze critical incidents in doctors' outpatient surgeries in a systematic fashion *(Boxes 3, 4; Table 2)*.

Specific measures

We present a selection of measures to prevent specific PAE that are recommended by patients' organizations:

- Medication reconciliation denotes a process of updating the patient's medication list (23). It is updated

continually after each new prescription or referral, especially when the patient moves between hospital care and outpatient care or is transferred within the hospital. After the comparisons were introduced, the rate of incorrect medication schedules was reduced by 90% (e16) and the rate of medication errors by 40% (e17).

- Safe identification of patients is an important measure in preventing errors as a result of mistaking patients, procedures, and body sites (e18). The German Coalition for Patient Safety has issued a recommendation that includes using wristbands bearing the patient's name, date of birth, and ID number, and which advises identifying the patient before each diagnostic or therapeutic measure and during transport and transfer. Patients should be actively identified; they should be prompted to say their name rather than be asked: "Are you Mr/Ms XY?" (e19).
- The World Health Organization (WHO) recommends repeating back and reading back to ensure safe communication: Verbal or written instructions are repeated orally by the person in charge of performing the task, in order to ensure that the instruction was understood correctly. A standardized template for the hand-over of critically ill patients—such as the SBAR scheme (situation, background, assessment, recommendation)—should be used to ensure that important information is available and is passed on in a reliable manner. This includes the patient's current situation, the clinical background, the explanation of the problem, and the recommended treatment (e20).
- The Surgical Safety Checklist, whose use is called for by the WHO, reduced the complication rate after surgical procedures in a multinational study by 4 percentage points as a result of jointly setting out a checklist comprising all the steps from initiating anesthesia to the end of the operation (24).

Measures after an adverse event

The most important aim after an adverse event has occurred is to prevent further harm. A sympathetic and honest explanation to the patient and their relatives helps to build trust ("We are sorry!") and is not to be understood as an admission of guilt (e21). According to §105 of the German law on insurance contracts (Versicherungsvertragsgesetz), acknowledgement of the claim of a third party by the insured is not problematic because it does not absolve insurers from liability (e22). Patients should be told what has happened. They have the right to know the medical sequelae of the event and to receive support.

In order to cope emotionally with an event it is important for all parties that the causes are analyzed honestly and stringently, and that the patient is reassured in a confidence inspiring manner that the hospital or practice will learn from the mistake (25).

BOX 4

An adverse event in general practice, and analysis of results

What has happened?

A patient aged over 90 years had received his flu jab in a group practice a month earlier and was due to receive the third dose of the early-summer meningo-encephalitis (FSME) vaccination. The jab was planned to be administered by myself (practice partner) because the patient's regular doctor was absent. The practice computer showed under "control dates" the third planned FSME dose for October, with a corresponding note in the diary; additionally a post-it note on the patient's record card. The flu vaccination had been documented as diagnosis but had not been recorded in the patient's vaccination record, because he had not had this with him at the time. Since no flu jab had been documented in the vaccination record, the patient received an additional flu dose. The notes in the computer and on the patient's paper file remained unnoticed.

What was the result?

The patient received a second flu jab within a month of the first one. The originally planned FSME vaccination had to be caught up.

Analysis:

Unsafe actions in this event included:

- Omission of "retrospective" documentation of the given flu jab in the vaccination record
- No direct communication with the patient
- The patient's file was not checked for any instructions or notes

Contributing factors for these unsafe actions include:

- The patient was not personally known to the treating physician (patient factor)
- Divergent documentation habits among the partners in the group practice (task factor)
- Lacking standard procedure for documentation in patient's vaccination record (task factor)
- Usual dissemination of information within the practice (oral, no checking of patient file) (team factor)
- The practice team expects an elderly patient to have a flu jab in the autumn; the indication for FSME vaccination is rather unusual (individual/staff factor)

Measure to prevent similar events:

- No vaccination should be administered without a vaccination record, at least retrospective documentation should be requested (use the comment function in the practice software)
- Ask the patient for the purpose of their practice visit at the time
- Check practice partner's prescription before administering the vaccine
- Uniform documentation of vaccinations

*Reported at www.jeder-fehler-zaehlt.de

Outlook

The fact that patient safety is at risk in the healthcare setting is widely acknowledged as a problem, including in Germany. International and national initiatives have been implemented, for example, by the German Coalition for Patient Safety and its partners. These include the "Aktion Saubere Hände" (Germany's clean hands campaign) and the measures for the prevention of medication errors, which are supported by Germany's Federal Ministry of Health. In addition, the German Agency for Quality in Medicine—a joint institution of the German Medical Association and the National Association of Statutory Health Insurance Physicians—is working on a bundle of measures to improve patient safety (e23).

There are many unanswered questions that require further studies. These include the causes of active and latent human failures, the influence of the patient safety culture on safe behavior, and the effectiveness of strategies to prevent adverse events. The real challenge lies in changing the safety culture in the long term since rapid results are not to be expected.

KEY MESSAGES

- Patients are harmed not only by their illness but additionally and to a substantial degree by the healthcare system itself. This phenomenon has been observed in all countries, including industrialized countries.
- The causes of preventable adverse events include active errors in direct patient care as well as latent failures that are due to decisions made at the management level.
- The systematic analysis of critical incidents—preventable adverse events and near misses—is an essential ingredient in error management.
- Dealing with critical incidents should evolve into an open reporting, learning, and fair safety culture.
- Some measures already exist that improve patient safety—for example, the Surgical Safety Checklist and medication reconciliation. These include all professional groups in the healthcare setting as well as the patients.

Conflict of interest statement
The authors declare that no conflict of interest exists according to the guidelines of the International Committee of Medical Journal Editors.

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