

The Topic

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Patient Safety: What Is It All about?

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Abstract

Patient safety is a major concern in health care systems worldwide. Patients with serious conditions, multimorbidity, and with intense and fragmented health care utilization, like end-stage renal disease (ESRD) patients, are at increased risk for suffering adverse events. In this chapter, the fundamental terms and concepts of patient safety are introduced. Essential epidemiological data relating to the frequency of adverse events and medical errors are provided. The chapter reports important safety threats for ESRD patients and describes examples of key innovations which contribute to patient safety. Recommendations and risk reduction strategies to improve care of ESRD patients are presented.

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Recommendations to Improve Patient Safety

- Patients with end-stage renal disease (ESRD) are at increased risk for adverse events and medical errors.
- Important safety threats for ESRD patients are wrong site access surgery, infections of access site, needle infiltration, venous needle dislodgements, clotting, medication error (in particular dose omissions), and falls following hemodialysis.
- Staff noncompliance and failures to follow protocols and procedures are the main sources of errors and adverse events.
- Interdisciplinary 'safety teams' should be installed to assess and monitor risks and implement evidence-based risk reduction strategies.

Introduction

Patient safety is a major concern in health care systems worldwide and has gained increasing attention since the Institute of Medicine published its report *To Err Is Human* in 1999 [1]. Based on extrapolations of study data, this report estimated that approximately 44,000–98,000 Americans die annually due to adverse events in health care. Patients with serious conditions, multimorbidity, and with intense and fragmented health care utilization, like end-stage renal disease (ESRD) patients, are at increased risk for suffering adverse events. It is thus vital that clinicians caring for ESRD patients make patient safety a top priority and cooperate on safety with their colleagues within and across other clinical specialties inside and outside the hospital. In this chapter, we will introduce the fundamental terms and concepts of patient safety and present readers an overview of essential data. We describe examples of important innovations which contribute to patient safety and briefly discuss future needs and developments.

Terms and Definitions

In brief, *patient safety* refers to the absence of errors and preventable adverse events associated with health care. Interventions, activities and policies which reduce the frequency or consequences of preventable adverse events thus improve patient safety. This definition of patient safety introduces two important terms: adverse events, and medical errors. *Adverse events* have two major characteristics: a patient has been harmed and this harm was caused by the medical management rather than the underlying condition or progression of disease. The term adverse event describes that an unintended and undesirable outcome occurred; it does not necessarily involve error. An allergic reaction to a drug is a common adverse event. Clearly, we have an unintended injury, but as long as the allergy was unknown to care providers, no error occurred when the drug was prescribed or administered. *Medical error* is defined as the failure of a planned action to be completed as intended (error of execution) or the use of a wrong plan to achieve an aim (error of planning). Medical errors have the potential to cause undesirable outcomes but do not require a link to actual subsequent harm. In fact, the vast majority of errors do not result in iatrogenic injury. Prescribing a patient with known allergy penicillin because the information is overseen during prescribing is an error. But the error may be detected by the administering nurse before the error reaches the patient and thus harm can be avoided. Adverse events, i.e. harm, caused by error are – by definition – preventable and are

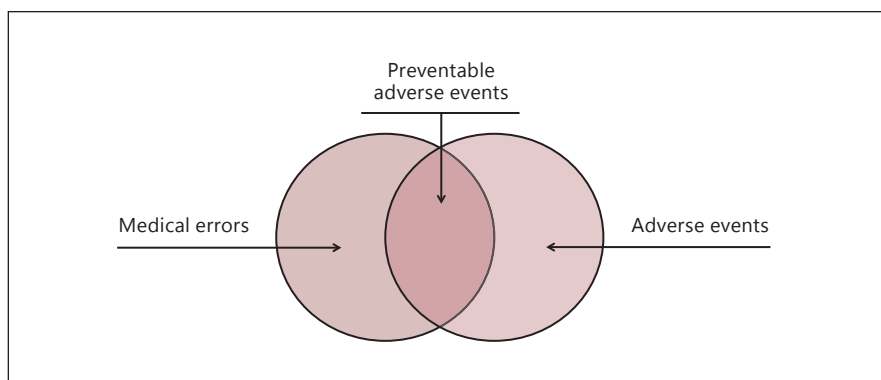


Fig. 1. Concept of medical errors, adverse events and preventable adverse events.

thus called ‘preventable adverse events’. A *preventable adverse event* is defined as harm resulting from error in medical management. Figure 1 conceptualizes the terms and how they are interconnected. Patient safety is mainly concerned with preventable adverse events.

Different classifications of error (sub)types emerged in the last years which are *not* mutually exclusive. All types of errors have in common that they are unintentional behaviors. Contrary, violation of rules describes intentional, willful behavior. Useful distinctions amongst errors are between slips/lapses and mistakes, errors at the sharp and at the blunt end, and errors of omission and commission. Slips and lapses are both skill-based errors, whereas mistakes are decision-making failures, for example, making a poor judgment. *Slips and lapses* are failures of schematic behavior and occur in familiar tasks which are conducted with little attention. Common causes of slips and lapses are fatigue or stress. In contrary, *mistakes* are failures in attentional behaviors requiring thought, analysis, planning or problem solving. Mistakes are often caused by lack of knowledge, experience or training. Typically, mistake happens when we do something wrong believing it to be right. Historically, mistakes have received much more attention than slips and lapses, though it is believed that the latter are much more frequent. Slips/lapses and mistakes require quite different treatments. For example, more or better education and supervision is a common and often appropriate ‘antidote’ to mistakes, but ineffective in the prevention of slips. Errors can occur at the sharp and at the blunt end. The former are often called ‘active failures’, whereas the latter are termed ‘latent conditions’. Errors at the sharp end describe actions committed by the person closest to the patient, whereas organizational failures and poor process design occur at the blunt end. Errors at the sharp end are easier to detect but are often only the last failure in

Table 1. Important terms and examples

Term	Example
Error	Passing incorrect information during hand-off Prescription of a drug to a patient with known allergy
Error subtypes	Forgetting hand disinfection before touching a patient's wound dressings Confusion of look-alike syringes
Slip/lapse	
Mistake	Choosing the wrong surgical technique Using the wrong formula to calculate a medication dose adjustment
Error of commission	Access not taped/bandaged appropriately after dialysis Heparin ordered when contraindicated
Error of omission	Failure to provide preoperative antibiotic prophylaxis Not ordering renal diet
Error at the blunt end (latent conditions)	Management decision to have the surgical count performed by only one technician (no double check) Equipment designed with poor display design making it hard to identify numbers
Error at the sharp end (active failures)	Unintentionally retained foreign objects in the body (e.g. surgical sponge) Error in programming an infusion pump
Adverse event	Allergic drug reaction Postoperative infection
Preventable adverse event	Wrong site surgery Allergic drug reaction to a drug in a patient with known allergy

the error chain and preceded by one or more latent failures at the blunt end. Finally, errors can be classified as acts of *commission* and acts of *omission*. Errors of commission describe 'doing something wrong', whereas errors of omission involve a failure to do required actions. Acts of commission are usually easier to recognize and thereby received much more attention, but errors of omission are more common. Table 1 presents some examples.

Health Care as a Risk: The Magnitude of the Safety Problem

Different methodological approaches exist to assess the frequency of adverse events or medical errors. The 'state of the art' methodology for assessing errors is observation and document analysis. With observation, health care profession-

als are 'shadowed' during their tasks, and any deviations from standards are recorded. This resource-intensive approach has been followed to estimate the frequency of medication errors in particular. Chedoe et al. [2] used ethnographic observation to detect medication preparation and administration errors on a neonatal intensive care unit. With an incidence of 49%, these errors were quite common. 0.3% medications contained severe and 26% moderate errors. A similar error rate (48%) was found by Taxis and Barber [3] when they observed errors in preparing and administering intravenous drugs in a German hospital. Document analysis has typically been used to detect physicians' prescription errors in written orders.

Contrary to errors, adverse events are usually not detectable by observation. The gold standard methodology for assessing the frequency of adverse events is retrospective record review with at least two stages. Patients' charts are usually screened for potential incidents by trained nurses (stage 1) and then reviewed by qualified expert physicians (stage 2). Physician reviewers also rate events in terms of preventability and severity. Numerous studies in different countries have been conducted using this approach in the last years. These studies revealed adverse event rates of 5–15% of all acute care hospital admissions [4–8]. Approximately 50% of events were deemed preventable [5]. Based on these studies, it has been estimated that ca. 0.1%, i.e. one out of 1,000, patients admitted to hospital will die due to preventable adverse events [4]. Hauck and Zhao [9] modelled the risk of adverse events based on administrative hospital episode data of more than 200,000 patients admitted to Australian hospitals. Based on these data, a hospital stay carries a 5.5% risk of an adverse drug reaction, 17.6% risk of infection, and 3.1% risk of ulcer for an average episode. In a recent retrospective record review analysis in 10 hospitals in North Carolina, reviewers found 25.1 harms per 100 patient admissions. Notably and despite all patient safety efforts, there was no significant change over time in the rate of harms during the past 5 years [10].

Some countries have also established mandatory reporting systems for 'never events'. These are serious events which are deemed as largely preventable and every health care system should strive for zero frequency. Examples of never events are wrong site surgery, wrong application route of chemotherapy agents, and mistakenly left instruments after surgery. In the UK, 762 of these never events occurred during 2009–2012 (<http://www.england.nhs.uk/ourwork/patientsafety/never-events/>). Such data help to monitor 'the tip of the iceberg' and to establish safety measures for the prevention of severe patient harm and death.

Patients and citizens have also been surveyed about their experiences with the safety of medical care. In the 'Commonwealth Fund's 2010 International Survey of the General Public's Views of their Health Care System's Performance', citizens of 11 countries were asked to report about medical errors [11]. Across

Table 2. Summary of important safety threats to ESRD patients

Wrong site access surgery (rare but serious)
Needle infiltration
Venous needle disconnections/dislodgements (rare but potentially dangerous)
Clotting in the hemodialysis circuit or lines
Medication errors, in particular omissions
Infection of access
Falls (following hemodialysis)

countries, medical error during the last 2 years was reported by 11% of patients but with marked differences between countries. Perceived poor care coordination was the single most important risk factor for reporting errors. Similar studies have been conducted to assess the frequency of infection during or after hospital stay or errors in chemotherapy treatment [12–14]. Despite the tragedy associated with all these incidents, medical errors also come at high financial cost. In a recent study, the annual cost of measurable medical errors with patient harm was estimated at USD 17.1 billion in 2008. Postoperative surgical infections were the most costly error and accounted for USD 3,364 million [15].

Specific Safety Threats for Patients on Hemodialysis

Though a large and increasing number of patients with ESRD undergo hemodialysis and the technology is well established, only limited data are available about the specific safety hazards associated with the treatment. As ESRD patients often suffer serious comorbidities and have intense and fragmented health care utilization with multiple providers involved and thus a high level of exposure, it is likely that these patients are at elevated risk for medical errors. Table 2 summarizes important safety threats to ESRD patients.

Like all surgical patients, patients undergoing vascular access surgery are at risk for wrong site surgery. Wrong site surgery, i.e. *wrong* site, *wrong* patient, or *wrong*-procedure surgery, is rare but is devastating and a true ‘never event’. Of the total of 375 reports of wrong site surgery the Pennsylvania Patient Safety Authority received during the years 2004–2010, 7 reports involved the wrong vascular access device [16]. Five of the cases indicated confusion between subcutaneous venous access ports and Hickman or Broviac intravenous catheters. One report indicated confusion between a dialysis catheter and an intended port and another confusion between a dialysis catheter and an intended arteriovenous fistula. The Authority concludes that insertion of the correct vascular ac-

cess device from among all the potential options appears to be the most common challenge involving insertion of devices.

There is no comprehensive study on the prevalence of adverse events or errors in hemodialysis, and the available data are heterogeneous and based on different methodologies.

The Pennsylvania Patient Safety Authority analyzed all reports of incidents involving hemodialysis administration submitted through the Authority's reporting system during a one-year period [17]. Among 526 reports submitted, 5.5% resulted in harm to the patients. Medication errors were the most frequent events (29% of all reports) and among them, the greatest fraction involved dose omissions. Heparin errors were also common (3% of all events reported). Other events reported included failure to follow protocol, procedure complications, falls, equipment failures, and clotting. There were 32 reports of needle infiltration (blood infiltration into the surrounding tissue due to accidental piercing of the back wall of the graft or fistula during insertion of the needle) and an equal number of needle disconnections, together representing 12% of all hemodialysis administration events submitted to the Authority.

Needle infiltration most commonly occurred during the needle insertion. Lee et al. [18] reported an annual rate of major fistula infiltration leading to further intervention of 5.2%. Venous needle dislodgement is a rare but potentially serious event in hemodialysis [19]. A survey among nephrology nurses revealed that 77% of nurses had seen at least one venous needle dislodgement in the past 5 years [20]. Every second of the participating nurses reported to be concerned about venous needle dislodgement often or very often. The American Nephrology Nurses Association for instance provides valuable material for education of staff and patients about risk factors and prevention of venous needle dislodgement (<https://www.annanurse.org/resources/venous-needle-dislodgement>).

Holley [21] conducted a study of adverse events and medical errors in four hemodialysis units. Incident data are based on reports by the units' clinical directors. Among nearly 65,000 dialysis treatments, 88 errors occurred (1 event/733 treatments). Infiltration of the hemodialysis access, clotting of the dialysis circuit and omitted medications were common problems. In a surveillance study of dialysis patients in Gran Canaria (Spain), the incidence rate of adverse events was 8.6/100 patient-months [22]. The rate was higher among patients with arteriovenous fistula (9.1/100 patient-months) compared to patients with permanent catheter (2.9/100 patient-months). The preventability of the events is unknown.

As has been outlined above, important information about safety hazards can also be obtained from professionals (physicians and nurses) and patients (fig. 2). Garrick et al. [23] report about the results from a survey among ESRD patients

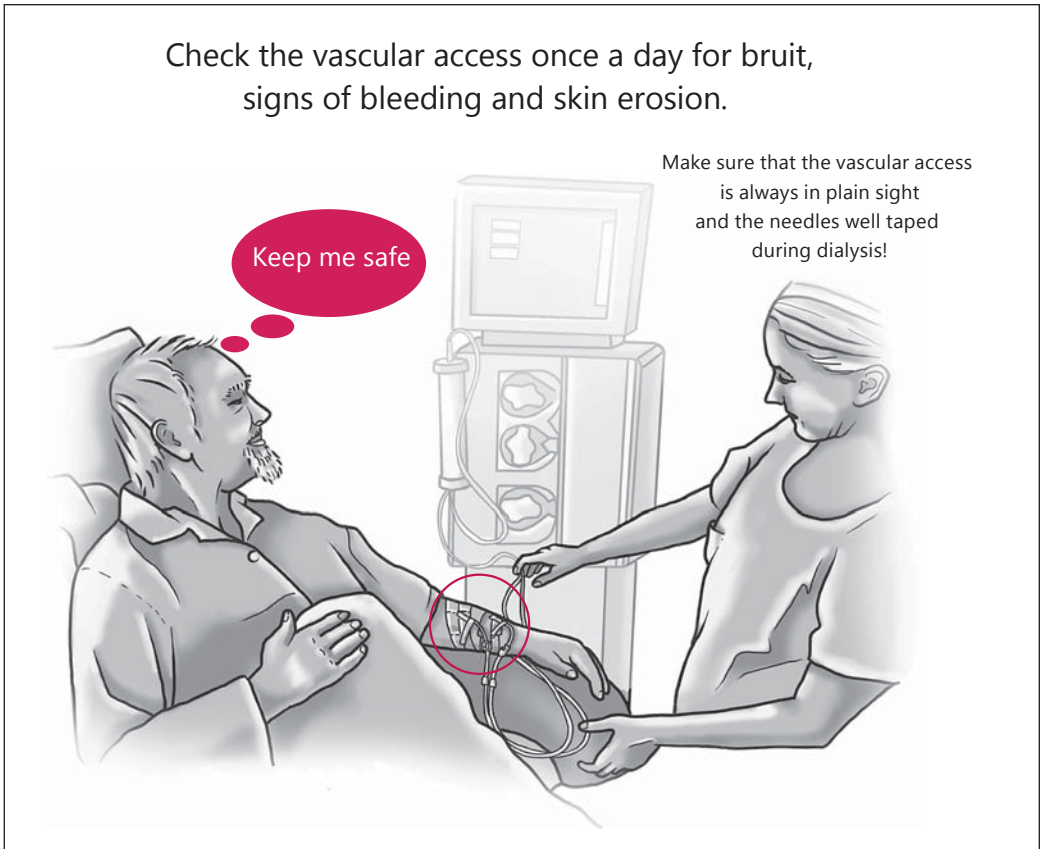


Fig. 2. Education posters for staff and patients may help to improve patient safety.

and professionals commissioned by the US Renal Physicians Association. In this survey study, 49% of patients reported to be worried about safety at least sometimes. 5% of patients reported falls at the dialysis center in the past 3 months. Almost half of patients indicated that the nurses or technicians inserting the needles for their dialysis treatments experience problems and 30% of patients indicated that staff tried more than twice to insert needles before getting assistance. Five specific threats to patient safety were identified from the survey among nurses and physicians: setting up an incorrect dialyzing solution prior to a dialysis session; patient falls following dialysis; medication omissions; staff failures to adhere to procedures (e.g. failure to take blood pressure), and staff non-compliance with hand disinfection or glove usage before touching a patient's access site. 55% of surveyed professionals attributed errors to staff failing to adhere to procedures.

Harel et al. [24] took a different yet highly important perspective in their study. They assessed how safe chronic dialysis patients are in hospital when admitted to surgical services, e.g. after fracture. They used retrospective chart review of patients receiving chronic hemodialysis and screened for safety lapses using a set of four predefined indicators. They detected 96 lapses in 38 patients. Failure to order an appropriate ‘renal diet’ was the most common problem, followed by inappropriate analgesic order, inappropriate intravenous fluid administration, and inappropriate antibiotic dosing. One adverse event directly attributable to these process errors was identified (volume overload). The authors also analyzed whether the problem was detected during hospitalization, by whom, and how long it took to be remediated. The majority of errors were detected by the consulting nephrology service. Inappropriate analgesia orders were only detected in 27% of cases during hospitalization. It took on average 2.5 days to detect that patients received the wrong diet. This study emphasizes that ESRD patients suffer risks not only associated with hemodialysis treatment, but also in the context of other, unrelated treatments. Obviously, general surgical units are often not sufficiently prepared to care for ESRD patients in their everyday routines.

Improving Systems – Improving Patient Safety

Recent research has demonstrated that sustainable improvements in patient safety are achievable. Well-recognized examples are a multifaceted intervention to reduce the incidence of catheter-related bloodstream infections and a surgical checklist to decrease adverse events and mortality in the operating room (OR) [25, 26]. The surgical safety checklist has proved effective in a broad range of surgical patient populations. In addition, the Pennsylvania Patient Safety Authority makes three specific recommendations for procedures involving the insertion of a device to prevent confusion during vascular access surgery [16]:

- (1) The specific device should be mentioned on the schedule, the consent, and the surgeon’s preoperative evaluation of the patient. This information should be checked for its presence and agreement with all the documents in the preoperative verification.
- (2) The specific device should be mentioned during the time-out.
- (3) The specific device should be called out when delivered onto the operative field.

Based on adverse event studies and reports, a number of specific risk reduction strategies for dialysis units have been recommended recently [17, 23]. These include for example:

- Independent double checks of i.v. heparin doses and infusions before dispensing
- Involvement of patients in their hemodialysis care and engagement to speak up if they note errors, observe rule violations
- Establishment of a policy to assess all hemodialysis patients for their risk of falling
- Monitoring and evaluation of infiltration problems that occurred to determine whether adjustments to cannulation techniques are necessary
- Systematic assessment of patients' risk for a serious venous needle dislodgement incident [20]
- Instruction of patients to keep all needle and blood line connections from being covered with blankets or other items so that staff can monitor the connections.

In the following chapters of this volume, experts present successful approaches and strategies to improve patient safety in vascular access patients. For example, Davidson et al. [pp. 97–106] discuss how team training and checklists can be used to improve safety in the OR, and Shemesh et al. [234–250] report about the important role of the hemodialysis patient in creating and maintaining safety.

From an organizational perspective, we suggest that every hemodialysis unit sets up an inclusive, interdisciplinary 'safety team' to assess and monitor risks at their specific environment. As a start of this safety team, patients and staff could be surveyed about risks, past incidents, violations of procedures and protocols and their perceptions of safety. Staff could be asked to report events to the hospital's critical incident reporting system. If such a system is not available, staff could complete a report form for every incident they observed (e.g. confusions or 'close calls'/near misses in the OR, missed medication dose, infection, clotting, fall, etc.) for a 4-week period. We also find it important that vascular access surgeons and hemodialysis clinicians and nurses have the opportunity to discuss their experiences of safety of care. This communication is often very restricted, irregular, and patient safety may be considerably improved if each involved specialty knows about the others' experiences, activities and concerns. Based on the individual unit's risk assessment, priorities for improvement can be set. The safety team could also serve as a connection to other units in the hospital which treat ESRD patients (e.g. general surgery) to ensure that safe care is provided outside the hemodialysis unit.

The following chapters provide valuable examples of important aspects of safe care for the vascular access patient. Many of the successful interventions focus on the performance of individuals. However, improvements at the systems level such as design of rooms, equipment and materials and work flow are often

much more promising and effective, in particular in the prevention of lapses and slips, but have much too long been ignored. For example, rather than relying on staff education about proper hand disinfection practices, design of wards, patient rooms and devices can be designed to make failure much less likely [27, 28]. Similarly, instead of relying on the education of staff to be aware of line misconnections, research is underway to design and test material that does not allow dangerous misconnections [29]. Hopefully, such efforts will benefit the safety of care of vascular access patients in the future.

Disclosure Statement

The author has no conflict of interest to declare.

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