Maintaining Safety in the Dialysis Facility

Alan S. Kliger

Abstract

Errors in dialysis care can cause harm and death. While dialysis machines are rarely a major cause of morbidity, human factors at the machine interface and suboptimal communication among caregivers are common sources of error. Major causes of potentially reversible adverse outcomes include medication errors, infections, hyperkalemia, access-related errors, and patient falls. Root cause analysis of adverse events and "near misses" can illuminate care processes and show system changes to improve safety. Human factors engineering and simulation exercises have strong potential to define common clinical team purpose, and improve processes of care. Patient observations and their participation in error reduction increase the effectiveness of patient safety efforts.

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Yale University School of Medicine, Yale New Haven Health System, New Haven, Connecticut

Correspondence: Dr. Alan S. Kliger, Yale New Haven Health System, 300 George Street, Room 487, New Haven, CT 06510. Email: Alan.Kliger@ynhh.org

Introduction

In the 15 years since the Institute of Medicine Report *Crossing the Quality Chasm* was published (1), much has been written about improving quality, culture change, process change, and risk reduction. We now recognize that practitioners are human, and like all humans we make mistakes—and sometimes they harm our patients. Yet little evidence has been published showing any real improvement in outcomes that result from our awareness and our efforts to deal with these vulnerabilities. For patients undergoing life-sustaining dialysis in particular, some data and much opinion (2–20) have detailed the increased risk of errors and their unintended consequences. In a survey of dialysis patients, nearly half responded that at times they had concerns for their safety in the dialysis facility (6). These studies have identified several of the highest-risk domains our patients experience and have led to improved processes of care designed to reduce the risk of error and the effect of medical mistakes on our patients. Perhaps most important, in recent years evidence has suggested that some of this attention has improved outcomes for patients with ESRD. Dialysis facility medical directors are responsible for ensuring the quality and safety of care and for fostering a culture of patient safety. It is therefore important that medical directors understand the sources of risk to dialysis patients and champion process improvements to keep their facilities safe.

In this review, I discuss the progress we have started to see in recognizing where errors occur, how they might be reduced or even eliminated, and opportunities to accelerate this process of improvement. The basic elements of a plan to recognize and prevent mistakes in caring for ESRD patients are shown in Table 1.

Culture of Safety

The Agency for Healthcare Research and Quality (AHRQ) has defined culture of safety as follows (21):

> The safety culture of an organization is the product of individual and group values, attitudes, perceptions, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's health and safety management. Organizations with a positive safety culture are characterized by communications founded on mutual trust, by shared perceptions of the importance of safety, and by confidence in the efficacy of preventive measures.

Medical care systems are highly complex, caring for patients with multiple risk factors that predispose to errors—errors of omission, errors of commission, errors in judgment. Other industries, such as the aviation industry and the nuclear power industry, have similar characteristics of complexity and risk. In such organizations, reorganization can improve reliability and safety. High-reliability organizations are defined as those that succeed in avoiding serious safety events in an environment where normal accidents can be expected because of risk factors and complexity. High-reliability organizations operate on five principles (22): (*1*) reluctance to simplify, (*2*) preoccupation with failure, (*3*) deference to expertise, (*4*) sensitivity to operations, and (*5*) resilience.

If dialysis facilities are to operate as high-reliability organizations, the medical director must educate and engage the medical and nursing staff, support staff, and patients themselves to accomplish each of these five principles. High-reliability organizations establish and maintain a culture of safety in which all staff members are encouraged to report errors or potentially harmful events in a blame-free environment without fear of punishment. At the same time, a safe organizational culture does require appropriate accountability: Each individual is responsible for his or her own action.

Of the many approaches to accomplish these goals, Crew Resource Management is one tool that has been helpful (23). Developed in the aviation industry, this technique helps physicians and dialysis staff work collaboratively to value safety as a primary goal, develop

Table 1. Elements of ESRD patient safety improvement

1. Culture of safety: Create an environment in which it is safe to recognize and report errors for yourself and coworkers Dialysis facilities should operate as high-reliability organizations
2. Regulatory protection: Create legislation and regulation protecting voluntary reporters of error
3. Human factors: Identify patterns of interaction at the machine-human interface that may predispose to error
4. Identify major causes of potentially reversible adverse outcomes Medication errors Infections Access-related errors Falls Deaths from RRT complications
5. Perform root cause analyses of adverse events and "near misses"
6. Involve patients in safety efforts
7. Address home hemodialysis issues

specific competencies in safe practice, create patterns of behavior or practice that foster patient safety, and measure the effectiveness of preventive measures. Teams of caregivers learn together to hold patient safety as a top priority and practice in a nonpunitive, accountable, safe environment. Precepts include having a questioning attitude, asking clarifying questions, and being responsible both for one's own behavior and the behavior of each other. Tools such as safety huddles, read-backs, and checklists help improve communication and minimize the likelihood of errors and harm. The effectiveness of these efforts can be measured by recording the numbers and types of serious safety events and the efforts to prevent similar future occurrences.

Simulation training in vascular access is one example of how these measured have been used in dialysis facilities (24). This training can be a powerful tool to develop procedural skill and improve patient safety. The Accreditation Council for Graduate Medical Education supports simulation training, and expects it to be part of residency training. Simulation training also can go beyond procedural skills and assist teams of caregivers to deliver safer care.

Multidisciplinary training, cofacilitated by aviation and medical experts, teaches physicians, nurses, and other dialysis personnel to work as teams and respond to dialysis access adverse outcomes or emergencies, such as bleeding. This approach differs from the traditional systems of individual-focused training and response, where undesirable outcomes are managed with incident reports, and root cause analyses, which focus on what individuals should do differently. Highly functional teams receive hands-on skills learning under direct supervision, as well as more didactic education about CKD, patient selection algorithms, and best processes to create and maintain vascular access. Multidisciplinary clinicians then learn and practice team interaction in a simulated environment. These communication skills, practiced in a safe simulation environment, are critical to prepare for real-life emergencies and are rarely taught as part of classic renal fellowship or nursing school curricula. Thus, this training of individuals in procedure-based skills, such as ultrasound-guided vascular access cannulation, and team training in managing challenging clinical problems provides a safer and more effective environment for our patients.

Regulatory Protection

In 2005, President George W. Bush signed into law the Patient Safety and Quality Improvement Act (25). Congress recognized that to create a culture of safety, clinicians and care teams need regulatory protection from discovery for voluntary reporting of safety concerns. The goal of this act is to

> improve patient safety by encouraging voluntary and confidential reporting of health care events that adversely affect patients. To implement the Patient Safety Act, the Department of Health and Human Services issued the Patient Safety and Quality Improvement Rule (Patient Safety Rule). The Patient Safety Act and the Patient Safety Rule authorize the creation of PSOs (Patient Safety Organizations) to improve quality and safety through the collection and analysis of aggregated, confidential data on patient safety events. This process enables PSOs to more quickly identify patterns of failures and develop strategies to eliminate patient safety risks and hazards.

Many state hospital associations, health care organizations, and individual specialties have developed PSOs, where care teams can share safety experiences, concerns and best practices in a protected environment to improve patient safety.

Human Factors

Dialysis facilities are complex organizations. Nurses and technicians care for patients, cannulate their vascular access, and connect them to electronically-controlled dialysis machines. Sophisticated equipment purifies water for mixing dialysate. Dialyzers are sometimes reprocessed and sterilized before delivery to the technician or nurse setting up the dialysis equipment. The interaction between dialysis staff, machines, and the environment provides a large opportunity for errors to occur.

Human factors engineering is a discipline designed to identify and address these vulnerabilities (26). Here again, we can learn from the aviation industry (27). Human factors engineering has several applications to improve patient safety.

Usability testing examines new systems and equipment under real-world conditions to identify potential safety problems leading to unintended consequences. This technique has been used to identify common "workarounds"—intentional bypassing of safety policies and procedures by frontline staff seeking presumably more efficient ways to accomplish their tasks. Often, these workarounds unintentionally bypass the safety checks purposefully built into these policies.

Forcing functions prevent unintended actions in critical areas by reducing the possibility of selecting dangerous care sequences. An example of this is to prevent the placement of dialysis machines in sterilization mode during routine machine setup.

Standardization reduces potential errors as, for example, when dialysis nurses use one dialysis machine with procedures designed for another, or when multiple central venous access devices, each with their own recommended package insert instructions, are used in a dialysis facility.

Resiliency efforts help focus clinicians on the detection, avoidance, and mitigation efforts to anticipate unsafe actions before they occur. If harm does occur, resiliency training and tools assist teams to deal effectively with the consequences, improve system function in the future, and move on to care for the next patient. For example, physicians and nurses often feel devastated when they realize that something they did (or neglected to do) caused a patient irreparable harm. This feeling can be overwhelming, can color clinical judgment, and has led some clinicians to stop practicing. Resiliency efforts can channel these self-defeating feelings into positive action to deal with the consequences of the error and to devise improvements in our care systems to make such errors unlikely in the future.

Policies and procedures are developed and taught to dialysis staff. Many of these are specifically designed to prevent errors and keep patients safe. Nonetheless, clinicians sometimes ignore or are unaware of policies and do not follow procedures as prescribed. A study of Pennsylvania dialysis patients reported that failure to follow protocol represented >12% of reported dialysis adverse events (28). A survey of dialysis staff asked which factors they thought most prominently contributed to breaches in patient safety. The number one factor chosen was staff nonadherence to policies and procedures (6). There are many reasons why staff may not follow policies and procedures. Engaging human factors tools can help understand why this is happening in a dialysis facility and suggest mechanisms and tools to correct it. Factors leading to an improved culture of safety in dialysis facilities can be identified (29).

Major Causes of Potentially Reversible Adverse Outcomes

Medication Errors

Medication errors are common among dialysis patients (4,30–33), often occurring as errors of omission (28) and upon transitioning between care settings and providers (34–36). In one study, omission of an ordered medication was the most common error, representing 69% of all errors (4). In a national survey of hemodialysis staff and patients, we found that almost half of patients take 6–10 medications daily, yet only "sometimes" discuss all their medications with their doctor (6,37). In the hemodialysis community, medication errors are reported as the most common patient safety event. A report from Pennsylvania (28) noted:

> While medication omissions were the most frequently occurring type of medication error, other medication errors during hemodialysis administration involved heparin infusion mistakes, inadequate handoff of information about patients' medications during transitions between the hemodialysis unit and other care areas, and miscommunication of medication orders.

In a small study of hemodialysis patients admitted to surgical services at a tertiary care center (38), errors in medication-prescribing were common, including inappropriate analgesic orders of morphine and nonsteroidal anti-inflammatory drugs (63% of patients), and incorrect antibiotic dosing (42%), including inappropriate dose or frequency and one case of a contraindicated antibiotic. For peritoneal dialysis patients, one report of iatrogenic hypoglycemia in patients receiving icodextrin dialysate should be noted (39). This agent, sometimes used in peritoneal dialysis solutions to augment ultrafiltration and fluid removal, is metabolized to maltose, a nonglucose sugar that is poorly excreted in patients with little endogenous kidney function. Nonglucose sugars are measured as "glucose" by some strips and the glucometer devices patients use to monitor their glucose control. In this case, a patient undergoing peritoneal dialysis measured his glucose as "high," even though the major source of the measured sugar was maltose. He injected insulin to control his high "glucose" and induced profound hypoglycemia; serum glucose in the clinical chemistry laboratory was 29 mg/dl, while simultaneous glucometer testing showed a value of 131 mg/dl.

Several strategies are needed to reduce this remarkably high level of medication error. Electronic medical records, including computerized provider order entry and a clinical decision support system, can help reduce the frequency of drug incompatibilities, medication duplication, and incorrect dosing for dialysis patients (14). However, this will be effective only if the electronic record is patient-centered, where all prescribers access and modify the single medication list that is centered on the patient rather than multiple providers and institutions. Regular and systematic use of medication reconciliation techniques can reduce errors (32,33). Other tools can be "hardwired" into the transitions of care process, such as required medication review, checklists, and sign-offs when patients return to the dialysis facility from other care settings. Human factors engineering can help physicians and others more accurately and consistently communicate about medications at times of patient admission and discharge from the hospital and dialysis facility, as well as other transitions of care. Patients and their families can play a primary role in keeping current medication lists and being proactive in questioning their caregivers about these medications, particularly at times of care transition.

Infections

Bloodstream and other infections are leading causes of death and hospitalization among hemodialysis patients, second only to cardiovascular disease (40,41). In a registry-based study of dialysis patients from Scotland, health care–associated infection contributed to 9.6% of all deaths (19).

Two specific risk areas deserve attention:

1. *Hand hygiene.* For more than a century, hand washing has been recognized as essential to prevent transmission of disease-causing organisms from caregivers to patients (42). One survey of hand hygiene practices in dialysis facilities found that during a 3-month period, 25% of staff and about 10% of patients reported that staff did not wash or use alcohol-based hand gel before touching or interacting with patients and their dialysis machines (6). While many dialysis facilities have installed alcohol-based gel dispensers at the patients' chairside, there are no published data on the frequency of use of these devices. Beyond establishing policies and installing these devices, dialysis facility operators may find it helpful to engage human factors engineering processes to assure adequate hand hygiene for physicians, nurses, and all others interacting with patients in the dialysis facility. The Centers for Disease Control and Prevention recommend several interventions to improve hand hygiene, including hand hygiene observations and sharing results with clinical staff (15,20,43).

2. *Central venous catheters (CVCs).* In his review of hemodialysis-related bloodstream infections, Camins addresses the history of CVC use for dialysis and its associated increase in bloodstream infections (15). Compared with arteriovenous fistulas, CVCs are associated with a 15- to 33-fold increase in bloodstream infections (44–46) and an increased risk for all-cause mortality (47). While efforts to increase use of arteriovenous fistulas (Centers for Medicare & Medicaid Services Fistula First initiative) have indeed increased fistula use, 80% of patients undergoing long-term hemodialysis use CVCs at initiation of dialysis, and 52% use them after 90 days (41). For patients who must use CVCs, several interventions have proven useful in reducing bloodstream infections. Application of antimicrobial ointments or solutions to the catheter exit site reduces bacteremia (48,49). The unintended consequence of antimicrobial use, emergence of drug-resistant bacteria, must be considered and examined. Mupirocin ointment applied to the nares reduces nasal colonization by *Staphylococcus aureus* and may reduce systemic infections (50). Mupirocin applied directly to the catheter exit site reduces *S. aureus* infections and catheter-related bacteremia (51,52). Of particular interest, thrice-weekly application of honey to the catheter exit site has the same efficacy as mupirocin application (52). Recently, a multisite study of two CVC-associated bloodstream infection prevention techniques—scrubbing catheter hubs before their use, and treating catheter exit sites with chlorhexidine and alcohol—proved effective in reducing these infections (53).

Care must be taken to assure that any ointment or solution applied to a CVC exit site is compatible with the plastic compound used to manufacture that particular catheter. Some CVCs specify in their package insert instructions for use that the polymers used are broken down by some ointments or solutions and should not be used. Antibiotic and nonantibiotic antimicrobial lock solutions have proven effective in reducing infections (54–57). A standard approach to catheter care, defined by facility policy and verified by practice audits, will likely result in fewer CVC-associated bloodstream infections.

Access-Related Events

An early descriptive report of errors and adverse events in hemodialysis showed that infiltration of the hemodialysis access and clotting of the hemodialysis circuit was fairly common (4). Infiltrations represented 35% and clotting 22% of all adverse events. These access-related events occurred in approximately one of every 1300 treatments (4). In a survey of hemodialysis patients, 30% reported that over the preceding 3 months, staff tried more than twice to insert needles before seeking assistance (6,37,58). Most staff reported that a policy on difficult cannulation did not exist or that they were not familiar with such a policy. In another study, fistula infiltrations leading to additional interventions occurred at an annualized rate of 5.2% (59). Access needle dislodgment has the potential for life-threatening hemorrhage (60,61), and 5% of surveyed patients reported needle dislodgment before completion of treatment (37). The Veterans Affairs National Center of Patient Safety reported that 40 of 47 bleeding episodes analyzed between 2002 and 2008 were related to venous needle dislodgment (6,62). Prolonged bleeding after dialysis is also common (6,28,58,62,63). Reducing the frequency of these events requires adherence to the safety policies and procedures in dialysis facilities, supported by the human factors engineering tools discussed above.

Patient Falls

Falls among dialysis patients are common and often result in injury. In one study, nearly half of dialysis patients older than age 65 years fell during a 1-year observation period, and 19% sustained injuries (64). In another study, 3% of all dialysis patients fell and sustained a bone fracture, and the overall fall rate was 1.18 falls/patient per year (65). This rate is substantially higher than in the nodialysis elderly population. Falls were common at home and were more common in the first half of the interdialytic cycle. The Renal Physicians Association survey of patients found that approximately 5% reported a fall in the previous 3 months (37). Factors associated with falls include age, diabetes, motor strength, visual acuity, previous falls, and medications (including antidepressants) (33–39). Strategies to reduce the risk of falls include staff education concerning fall risk, fall-risk assessment, gait assistance, use of in-floor weight scales, and reducing clutter (64–70).

Dialysis Equipment Factors

Dialysis membrane bio-incompatibility, roller pump–induced hemolysis, and errors in reprocessing dialyzers have in the past caused harm. A recent report suggested that the use of electron-beam sterilized dialyzer membranes is associated with significant thrombocytopenia following dialysis (71). The report stemmed from a root cause analysis (RCA) and underscores the potential utility of this technique in examining unexpected outcomes (72). Impure water used to prepare dialysate can be a source of morbidity (73,74).

Deaths from complications of RRT

A retrospective Scottish study of mortality among all patients treated with RRT showed that only 2.1% of deaths were directly ascribed to complications of RRT (19). In an additional 3.5% of deaths, while complications of RRT were not the direct cause of death, RRT factors that may have contributed to death were identified. Death rate due to complications of RRT was 1.35 deaths/1000 RRT patients per year. Death from hemorrhage from vascular access was very uncommon, occurring at the same frequency as death related to treatment-related accident. Death from hyperkalemia was 6-fold more common than either of these two causes. Of note, there were no cases of dialysis equipment failure causing death. The causes of potentially preventable complications leading to death were: (*1*) recognition and treatment of hyperkalemia, (*2*) medication prescription issues, (*3*) care after hours, and (*4*) prevention of infection and management of vascular access. These authors conclude that efforts to improve the safety of RRT should focus on the human factors involved in care rather than focusing only on the technical aspects.

RCA

RCA is a structured method used to examine serious safety events (75). The Joint Commission has mandated the use of RCA to examine sentinel events since 1997, and many states require RCA after any serious safety event. Whether care errors result in patient harm or not (precursor events), a systematic analysis of factors that might lead to errors often uncovers several opportunities to improve systems of care and reduces the likelihood of future error. These in-depth analyses examine institutional and regulatory factors, organizational and management policies and procedures, the work environment, the function of the care team, staffing, specific task functions, and patient-specific factors.

For example, a dialysis facility seeks to understand the causes of an event in which blood loss from a dislodged venous needle was not detected promptly and led to substantial blood loss. The RCA team examined policies and procedures, interviewed the nurse, technician, physician caring for that patient, charge nurse, and medical director. The RCA team considered people, procedures, equipment, and organizational structure and constructed a "fishbone diagram" describing the components of process for each category. They created a process map, carefully describing each step in the process of cannulating this patient, operating the dialysis machine, and monitoring the vascular access and blood flow.

The team found multiple places in this map where improved processes may make needle dislodgments less likely to occur. They found that the needle had not been secured in a safe fashion. The nurse had received adequate training but did not strictly follow facility policy. The unit was short-staffed that day and the nurse was called away to see another patient reporting pain at the time he was completing the cannulation. The patient had covered the access site because she felt the room temperature was cold, and no staff had observed or corrected this. The dialysis machine did sound an alarm, but a stressed staff hearing frequent machine alarms did not respond promptly to the alarm. The charge nurse believed that the facility's mandate to make shift changes more efficient focused staff more on efficiency than on safety.

The RCA team made several recommendations, including better education for staff and patients, creating a checklist for cannulation, and charge nurse rounding to assure access visibility and integrity. They also recommended more structured shift-change policies and supported a study to examine "alarm fatigue" to determine best solutions to this problem. While some RCA recommendations are easy to effect, others may be more challenging and deserve attention from medical directors and facility operators (76).

Patient Involvement in Safety Efforts

In 2003, a 17-year-old girl died after receiving a heart and lung transplant from a donor with an incompatible blood type. Several system failures that resulted in this tragic mistake were found. Following the nationally publicized tragedy, the patient's mother worked with the medical center to establish a patient safety program. Patient and family participation in studying and promoting patient safety in medical care is a new and often unfamiliar role for patients. Studies of the patient-related factors and caregiver factors show the barriers to its widespread use (77).

The Joint Commission requires that patients be encouraged to take an active role in their own care. The Centers for Medicare & Medicaid Services and the ESRD Networks encourage patient engagement, and many quality assurance and performance improvement committees include patient participants. Patients often report errors that were not otherwise detected (78). Patient-reported safety events are actionable (79). Patients are critical partners in establishing an institutional culture of safety (80). Care should be taken, however, when patients participate in studying and acting on error detection and reduction. In a survey of parents of hospitalized children, nearly two thirds felt personally responsible for ensuring their child received safe care (81). Thus, the care team must remain sensitive to the needs of patients and families while working together to make care safer.

Particular Issues in Home Dialysis Safety

A recent report of procedure-related serious adverse events among home hemodialysis patients found a mortality rate of 0.06 events/1000 dialysis treatments (16). Fatal mistakes can cause exsanguination (82). While life-threatening adverse events among home hemodialysis patients may be rare, home dialysis presents particular challenges to patient safety that require systematic attention from the care team (83). Unobserved adverse safety events, such as hypotension, confusion, edema, hypoglycemia, hyperkalemia, and drug reactions (18), require special precautions and protocols. Potentially fatal errors involving the vascular access are of particular concern for home hemodialysis. Appropriate use of vascular clamps, vascular catheter closure devices, one-way valves, and patient education about the risks of bleeding and air embolization must be completed, tested, and reviewed at intervals. Communication plans between patients at home and training dialysis centers require protocols of ongoing monitoring for these critical risk factors. Technological assistance from devices such as BP cuffs, scales, and dialysis machines that transmit data to dialysis centers and caregivers can play important roles in keeping home peritoneal and hemodialysis patients safe.

Summary

Errors in dialysis care can cause harm and death. Medical directors of dialysis facilities are responsible for fostering a culture of safety and for creating and supporting policies and practices that reduce errors and improve patient safety. In the past 15 years, we have learned where the major risks lie and have made some progress toward reducing these errors. Dialysis machines are rarely the major cause of morbidity. Underlying disease and patient factors, such as age, disability, hyperkalemia, diabetes, and vascular instability, may increase the risk of adverse, unintended outcomes. Dialysis patients commonly use multiple medications, and medication errors are common, including missed doses, drug incompatibilities, and mistakes in transferring care from one clinical setting to another (*e.g.*, from dialysis unit to hospital and back again). Patient falls are common and may cause fractures and other morbidity. Better risk assessment, patient assistance protocols, and environmental improvements can reduce this risk. Infections are a common cause of morbidity and mortality. Techniques to improve hand hygiene, reduce central venous catheter use, and improve adherence to sterile technique when these devices are handled reduce the incidence of infections. While vascular access infiltrations and clotting are common, these rarely result in death. Care protocols to detect and treat hyperkalemia, increase appropriate medication use, provide more robust after-hours care, and increase infection prevention may reduce mortality. Dialysis at home requires a special set of precautions to reduce the risks of bleeding, air embolism, and unobserved complications. Finally, communication lapses among caregivers and between patients and caregivers are a major source of errors and adverse outcomes. Techniques such as crew resource management and deployment of tools such as RCA may improve communication and spotlight system factors that can be fixed to improve patient safety. Patient participation in these processes may enhance error detection and improve the culture of safety.

Disclosures

None.

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