



## PATIENT SAFETY IMPROVEMENT PLAN BASICS

This Patient Safety Improvement Plan Basics guide is intended to assist renal professionals with the task of creating or re-designing a patient safety program in their dialysis facilities. As part of the Centers for Medicare and Medicaid Services (CMS) Conditions For Coverage for End Stage Renal Disease Facilities, dialysis facilities are required to develop, implement, maintain, and evaluate an effective, data-driven quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team. Further, each facility must develop a quality assessment and performance improvement (QAPI) program that will track the facility's performance based on patient outcomes. This regulation was drafted to intentionally provide flexibility for facilities to use their resources to meet the needs of individual patients and achieve better outcomes of care. **To meet the conditions, the program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors. Additionally, the dialysis facility must measure, track and analyze, quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves.**

To assist renal professionals, this patient safety guide focuses on key elements needed to implement quality assessment and improvement programs at the dialysis center level, and may serve as a resource for program planners in conjunction with other elements of the *Keeping Kidney Patients Safe* web site. It contains material specific to kidney patient safety improvement, engaging staff and creating a culture of safety.

### RENAL PATIENT SAFETY PLANNING: THE NEED

In developing the patient safety improvement plan guide, RPA and its National ESRD Patient Safety Initiative partners [[link to list of partners](#)] are responding to specific needs of dialysis professionals and patients, as identified in a 2006 Health and Safety Survey of nephrology professionals and kidney patients cosponsored by the RPA and the Kidney & Urology Foundation of America (KUFA). Survey results clearly identified the following six specific areas for improvement as well as the need for effective patient safety improvement plans in dialysis facilities:

- incorrect dialyzer/dialyzing solution;
- patient falls;
- medication errors and omissions;
- non-adherence to procedures;
- failure to maintain hand hygiene; and
- venous needle dislodgement.



The survey revealed that patients and renal health professionals have distinct and specific concerns about patient safety. For example, survey data showed that nearly half of all dialysis patients worry that someone will make a mistake during their treatment, while a remarkably high number of staff surveyed (87 percent) indicated that a mistake had been made in a patient's dialysis session in the past three months.

Further, the survey indicated that medical errors or adverse events often are the result of system failures. These complex systems can inadvertently create e possibilities for mistakes or weaknesses at various points along very long, intertwining treatment “chains.” System errors occur when the normal process is disrupted by a glitch in the chain of the system's prescribed events. Usually, that glitch is not caused by a single action or omission but by multiple missteps along the chain.

Exacerbating the situation is the fact that the systems are built and managed by humans, and even the most competent health professionals make mistakes. However, the effort must be made to avoid any error that harms a patient or has the potential to harm a patient, and a Patient Safety Improvement Plan is intended to focus on minimizing those opportunities for error along that complex chain of medical systems.

The ESRD Facility Conditions for Coverage state that the facility is responsible for maintaining and implementing policies that support sound patient care, as well as ensuring a safe and sanitary environment for patients and personnel. To foster such an environment, every facility must take proactive steps to improve patient safety. This guide is intended to assist providers of care through that process.

### **MAKING A COMMITMENT TO A PATIENT SAFETY IMPROVEMENT PLAN**

To effectively implement a patient safety plan, a facility needs to commit adequate resources to the task, including but not limited to the following areas:

- » **Personnel:** Successful patient safety planning relies on a team approach by all staff, directed and overseen by a Patient Safety Committee.
- » **Time:** A facility must take time to put patient safety checks in place. This includes providing staff with sufficient time for training, implementing the plan, and continually monitoring and modifying the plan as the team works through real-life experiences of staff and patients.
- » **Technology:** New or expanded patient safety systems may require IT updates. This may involve time and costs for updates, as well as staff training.



- » Patients: Successful patient safety planning should involve patients as active participants in their care. Facilities should make a commitment to educating patients about their care so that they become, or continue to be, knowledgeable about what should be occurring during their own treatments.

### Engaging Staff

Effective patient safety relies on an integrated, all-staff approach. One method to engage staff is to create a Patient Safety Committee to be responsible for creating the Patient Safety Improvement Plan, training and motivating staff, modifying the plan during implementation, and educating patients. Lead staff should be sure patients are represented on the committee, as well as clinical and administrative staff—all of whom play a role in patient safety.

The benefits of establishing a Patient Safety Committee include fostering teamwork, improving communication among staff and services, developing standardized approaches, and increasing visibility of the facility's commitment to patient safety.

The committee should appoint a lead safety officer who is responsible for program implementation. Effective implementation involves training staff, educating patients, evaluating ongoing patient safety, and modifying systems as needed.

Successful patient safety programs focus on a team approach, in which all staff members are trained to be extra eyes, ears and hands for one another. The goal is to prevent adverse events or errors among a team committed together to patient safety, and to foster an environment that is constructive and supportive rather than punitive.

### Creating A Culture of Safety

A culture of safety is necessary to provide optimal care. That culture becomes reality through what a facility does—its practices, procedures, and processes. A facility with a culture of safety is characterized by several elements:

- Patient-centered care
- Open communication
- Blame-free environment
- Shared responsibility for safety

*Patient-Centered Care*—Facilities should reinforce the most basic principle of patient-centered care continually and throughout the facility. Opportunities for advancing this principle include staff meetings, patient conversations and meetings, staff training, newsletters, and posting of documents outlining patient-centered goals in a high-traffic area.



*Open Communication*—Open communication reinforces patient safety as a priority and the value of everyone’s role in patient safety. It creates an ongoing forum for requesting and sharing information about errors, near misses, and ideas for improvement by everyone at the facility.

It is critically important to communicate the importance of patient safety, formally and informally, among staff and with patients, as well as to discuss patient safety at all levels—among and between administrators, patients and families, managers, clinical staff, clerical and housekeeping staff. Open communication also ensures that events are discussed and reported consistently. Facilities’ IT systems can capture documentation of events, including near misses and ideas for prevention.

*Blame-Free Environment*—One step that a dialysis facility can take to implement an effective patient safety plan is to foster an environment that encourages anyone in the facility to bring forth issues, free of blame or recrimination. This may be a dramatic or subtle shift, but successful patient safety programs create a supportive environment through the following tactics:

- » Make staff accountable for safety, rather than focusing on an ineffective “name/blame/shame” atmosphere. Initial and ongoing training and education about safety practices, as well as activities to reinforce safety skill, can foster a safety-positive environment.
- » Encourage reporting of errors & near-misses without fear of recrimination. Be sure staff members know that the facility prioritizes prevention of errors and near-misses. Prevention is best informed by errors and near-misses. Create clear systems for staff to share that vital information.
- » Focus on systems improvement rather than blame. The goal is patient safety, which will be achieved by ongoing improvements to the facility’s system. Blaming individuals will not contribute to the goal.
- » Focus on being error-aware. Train staff and educate patients to be aware when something in the system is not working properly. This will enable individuals to anticipate the likelihood of error, focus on recovery to minimize the error, and work toward prevention of that error in the future.
- » Support staff when an error is made. Team members focused on safety and prevention of future errors should learn from one another and provide support in these situations. Support may include physical assistance during recovery after an error, or emotional support.
- » Reward staff for safe actions and/or reporting errors, near misses, and patients’ concerns. Recognize staff members who bring forth specific information, to encourage others to do so. Consider a “safety staff of the week” citation, monthly reward, or other recognition that



draws attention of all staff to the importance of the reporting of errors, near misses, and patients' concerns.

*Shared Responsibility for Safety*—Facility leadership should find opportunities to reinforce this critical element of patient safety. Patient safety is a team effort, and all are responsible—clinical staff, administrative staff, as well as patients. Staff should be encouraged to focus on teamwork and always to act as a second set of eyes for one another to catch potential errors. A Patient Safety statement which declares the facility's dedication to improving and maintaining optimum patient safety should be developed and displayed prominently.

### **PATIENT SAFETY PLAN: CORE ELEMENTS**

While facilities will develop plans that reflect their individual needs, a Patient Safety Plan should include several core elements:

- Standardized systems to reduce possibility for errors
- Defined core issues/defined adverse events
- System for reporting errors/adverse events
- Data tracking system
- Root cause analyses
- Staff training
- Ongoing evaluation to modify systems
- Communication of plan and all aspects of implementation to all staff

*Standardized systems to reduce possibility for errors:* Standardized systems reduce opportunities for error. Human errors can be caused by an individual's short term memory, judgment impacted by long hours, or problem solving during a stressful event. Standardizing processes and systems minimizes the possibility for errors due to the human limitations that even the most vigilant professional can have. Standardized systems will give staff the strength to decrease variation in patient care and, ultimately, improve safety.

*Define core issues and adverse events*—Plan developers should use data from the [Health & Safety Survey](#) as well as facility-specific data to define the clinical issues and/or adverse events that will be the foundation for a Patient Safety Plan. Document facility-specific environmental elements that contribute to patient safety events; these may include security, construction, hazardous materials, facility and parking layout and design.

Further, there should be communication with all staff and patients about the defined adverse effects as well as environmental elements that contribute to patient safety. A written list of these elements should be created, with information about how to report errors and near-misses, as well as information about environmental elements.



*System for reporting errors/adverse events*—All staff—clinical, clerical, and housekeeping/maintenance—as well as patients, need specific, written directions on how to report errors or adverse events. There should be discussions to ensure that all team members clearly know what staff are responsible for responding to errors and near misses immediately. A reporting form should be created for documentation.

*Data tracking system*—Facilities should transfer all data about errors, near misses, and environmental issues into a data base, as well as train staff to ensure complete documentation. Effective data tracking will become the basis for identifying evolving issues to be solved and for ongoing modification of your Patient Safety Improvement Program.

*Root cause analyses*—Once a continuing or evolving problem is identified through data tracking, the facility should conduct a root cause analysis to determine contributing factors, including a review of systems that were in place and determining if processes were followed. If not, there should be focus on staff training to prevent similar adverse events. If processes were followed but did not ensure patient safety, the Patient Safety Officer and other key staff should identify risks that could lead to further incidents and create solutions to prevent future errors that could lead to patient injury.

*Staff Training/Education*—Staff education and training are an important element in a successful patient safety program. While training will involve people with a mix of staff responsibilities and education levels, all will be adults. Keep in mind a few basics about adult learning:

- Adults have different learning styles, so approaches should be varied and reinforced through ongoing activities and reminders.
- Adults' approaches to learning tend to be task or problem-centered.
- Adults learn best in a relaxed, collaborative, and mutually respectful environment.
- Adults learn best through experiential activities that have immediate application to life tasks.

Focused training should be brief, evidence-based, ongoing, and supplemented with regularly held safety awareness activities. Training to support a dialysis facility's Patient Safety Improvement Plan should include clinical issues, technology/data entry and tracking, and work to foster teamwork among clinical and non-clinical staff.

Based on the Health & Safety Survey, clinical issues include:

- » patient falls;
- » incorrect dialyzer or dialyzer solution;
- » medication omissions or errors;
- » non-adherence to procedures;
- » hand hygiene; and
- » venous needle dislodgement



Technology training may include introducing staff to updated software or potentially a completely new data base system. This may include training of clinical and administrative staff, who may be responsible for tracking environmental or building-specific data. All staff training should be followed up with additional classes as protocol changes are made due to modification of the Patient Safety Improvement Program. Facilities can reinforce specific training elements as well as the ongoing implementation of the Patient Safety Improvement Plan through a variety of activities and training tools detailed in the [Staff Activity Planning Guide](#).

*Ongoing evaluation to modify systems*—The facility should identify one staff person such as the Patient Safety Officer to evaluate the Patient Improvement Safety Program implementation. Staff also should regularly review data to identify if any patient safety issues are arising and modify systems to reflect problems or concerns. This may involve additional training and/or communication throughout all levels of staff as well as patients, about the changes.

*Communicate plan and all aspects of implementation to all staff*—Open and ongoing communication about all elements of the Patient Safety Improvement Plan are critical to the success of the program. The facility should distribute and post the written plan, and reinforce aspects in staff newsletters, meetings, training, email reminders, and in daily work.

## **EXTERNAL RESOURCES**

The Joint Commission International Center for Patient Safety  
<http://www.jcipatientsafety.org>

National Patient Safety Foundation  
<http://www.npsf.org>

Agency for Healthcare Research & Quality Patient Safety Network  
<http://psnet.ahrq.gov>

Journal of Patient Safety  
[www.journalpatientsafety.com](http://www.journalpatientsafety.com)

CMS Conditions for Coverage for End Stage Renal Disease Facilities  
<http://www.cms.hhs.gov/CFCsAndCoPs/downloads/ESRDfinalrule0415.pdf>

## Addendum:

### Centers for Medicare and Medicaid Services (CMS) Conditions of Coverage for End Stage Renal Disease Facilities

#### § 494.110 Condition: Quality assessment and performance improvement.

The dialysis facility must develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance

improvement program with participation by the professional members of the interdisciplinary team. The program must reflect the complexity of the dialysis facility's organization and services (including those services provided under arrangement), and must focus on indicators related to improved health outcomes and the prevention and reduction of medical errors. The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS.

#### *Standard: Program scope.*

(1) The program must include, but not be limited to, an ongoing program that achieves measurable improvement in health outcomes and reduction of medical errors by using indicators or performance measures associated with improved health outcomes and with the identification and reduction of medical errors.

(2) The dialysis facility must measure, analyze, and track quality indicators or other aspects of performance that the facility adopts or develops that reflect processes of care and facility operations. These performance components must influence or relate to the desired outcomes or be the outcomes themselves. The program must include, but not be limited to, the following:

(i) Adequacy of dialysis.

(ii) Nutritional status.

(iii) Mineral metabolism and renal bone disease.

(iv) Anemia management.

(v) Vascular access.

(vi) Medical injuries and medical errors identification.

(vii) Hemodialyzer reuse program, if the facility reuses hemodialyzers.

(viii) Patient satisfaction and grievances.

(ix) Infection control; with respect to this component the facility must—

(A) Analyze and document the incidence of infection to identify trends and establish baseline information on infection incidence;

(B) Develop recommendations and action plans to minimize infection transmission, promote immunization; and

(C) Take actions to reduce future incidents.

(b) *Standard: Monitoring performance improvement.* The dialysis facility must continuously monitor its performance, take actions that result in performance improvements, and track performance to ensure that improvements are sustained over time.

(c) *Standard: Prioritizing improvement activities.* The dialysis facility must set priorities for performance improvement, considering prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes or patient safety. The facility must immediately correct any identified problems that threaten the health and safety of patients.

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