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National ESRD Patient Safety Initiative

PHASE II REPORT

A PARTNERSHIP BETWEEN:

FORUM
OF END STAGE RENAL DISEASE NETWORKS

National Patient Safety Foundation

Renal Physicians Association

RPA
RENAL PHYSICIANS ASSOCIATION

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Introduction

Creating a culture of patient safety in the ESRD community is a long process, which requires change beginning from the most fundamental aspects of the system. Phases I and II of the National ESRD Patient Safety Initiative (NEPSI) were designed to bring the ESRD community together to address patient safety, and to begin the process of this culture change. Now, as Phase II has been completed, it is possible to see that progress has been made, and that a solid groundwork has been laid for greater change in the future.

This report is the summary of the processes and products of Phase II, or implementation-planning phase, of this initiative. It includes the reports, plans and recommendations for future actions of four Collaborative Action Teams. These teams were created as a result of the agenda-setting actions of Phase I, and were charged with developing plans to address what were determined to be the most fundamental and leveraging actions of the initiative.

Background

The last few years have seen a growing recognition of the occurrence of medical errors and other failings that compromise patient safety (c.f. IOM report). While the treatment of End Stage Renal Disease (ESRD) is one of the tremendous success stories of modern medicine, errors and other problems with patient safety occur in this area as well. Health care professionals and patients are well aware of cases of error in this field, perhaps most notoriously during hemodialysis. To address the challenge of improving ESRD patient safety, the Renal Physicians Association (RPA), the Forum of ESRD Networks (Forum) and the National Patient Safety Foundation (NPSF) initiated a project to address these issues.

Forty-two participants representing doctors, nurses, technicians, social workers, nutritionists, administrators, regulators, and patients participated in the Phase I workshop on October 30-31, 2000. At this event stakeholders were guided through an intensive, two-day workshop designed to determine the most leveraging actions (i.e., actions that will create the most long-term change) in ESRD patient safety. CWA Ltd. customized this process, using a long established methodology based in the systems sciences, specifically for the unique requirements of inter-organizational engagement. As a result of Phase I, the following four actions were prioritized as the most fundamental and leveraging actions that are needed in order to move patient safety forward in the ESRD community:

1. To develop a common language for patient safety in the ESRD community (Action Option #1)
2. To identify the primary patient safety issues in the ESRD community, from both the patient and professional perspective (Action Option #7)
3. To identify ESRD patient safety best practices and make them widely available to the ESRD community (Action Option #11)
4. To educate the ESRD community, beginning with the leadership, using a “train the trainer” approach. (Action Option #17)

Phase II of this initiative began with a one-day workshop on March 27th, 2001. The stakeholder group was divided into four Collaborative Action Teams, and charged with addressing the actions listed above. For the past six months, these teams have met regularly, researched and developed materials, and ultimately prepared a set of recommendations to be approved by the steering committee. The work of each of these teams will be presented individually. In summary, the products of phase II include the following:

- Taxonomy of patient safety terminology
- Proposal for the use and distribution of the taxonomy
- Request for proposals (RFP) for the design, distribution and analysis of two surveys to determine top patient safety issues in ESRD (one for patients, one for professionals)
- Compiled list of top patient safety issues from the dialysis chains
- Proposal and framework for a web-based ESRD patient safety best practices clearinghouse
- Initial collection of ESRD patient safety best practices
- Proposal for an education campaign
- Revised Safety Kit, based on the CMS "toolbox"

Collaborative Action Team #1, Taxonomy

The charge to this group was to: *Create a task force of stakeholders and experts on patient safety to agree on definitions of medical errors.*

The purpose of creating a taxonomy, or collection of patient safety terminology, is to provide the ESRD community with a common language for safety. Having a printed document will enable providers to become familiar with the language of safety and begin to incorporate safety processes into their daily activities.

In order to develop a compilation of patient safety terms, the group researched existing sets of definitions and classifications from approximately twenty sources, including definitions from the IOM report, JCAHO, and the QuIC Report. Terms were then extracted and compiled into a single document, initially including multiple definitions for the same terms.

With guidance from patient safety experts on the NPSF board of directors, the group proceeded to make decisions between multiple definitions, change ambiguous or confusing language, and provide ESRD examples as appropriate. In general, the group took a more inclusive than exclusive approach. Therefore, there are similar terms and classifications included in order to provide the most information to users of this document.

The completed document (see Appendix A, p. 12) is perhaps the most comprehensive compilation of patient safety terms in existence. It is broken into two main parts and an introduction. The first part is a brief list of the most basic patient safety terms. The

second part is a comprehensive list of terminology. The group believes that both parts are equally important in order to make the taxonomy the most user-friendly.

Summary of Recommendations
In addition to the taxonomy, the action team developed the following set of recommendations:
1. Distribute the taxonomy to the larger stakeholder group for a final review before final production of the document.
2. Disseminate the taxonomy freely to health care providers, once approval is gained from the stakeholder group. However, the group also believes that it will be most useful when provided within a context.
3. Include the taxonomy in the patient safety educational Safety Kit (see group #17) in order to provide a context for the taxonomy.
4. Provide the taxonomy as part of the ESRD Patient Safety web-site that will be developed in Phase III of the initiative.
5. View this document as a work in progress, to be improved and adjusted as terminology changes and more definitions become available and/or prevalent.

Collaborative Action Team #7, Surveys
The charge to this group was to: C*onduct a survey of dialysis patients and professionals to list issues of patient safety.*

It was determined that there is a need to gather further information on what the primary patient safety issues are for patients and professionals in the community. Although there are reporting systems in place for incidents, they don't focus on medical errors and don't include near misses. Therefore, two courses of action were pursued:

1. A request for information was drafted and sent to the dialysis chains on behalf of the Partnership and the survey team. These letters asked the chains for major categories of information on patient safety from their reporting systems, as well as a listing of top patient safety issues. The purpose of this information is to determine what information is already available on top patient safety issues, and to use this information as a foundation. This information has been received and compiled, and is attached to this report (see Appendix B, p. 24).
2. The survey team determined that it would be appropriate to contract with an outside survey consultant team. The team contacted 4 possible consultants who expressed interest in this project. A request for proposals has been drafted, based on the ideas that the survey team determined to be most important. The draft RFP is attached to this report (see Appendix C, p. 27).

The goal of these surveys is to determine what the leading patient safety issues are from both perspectives (patient and professional) with an aim of gaining information that the current reporting systems do not provide (i.e., a qualitative component). The survey for dialysis patients ("Patient Survey") will focus on their main safety concerns in terms of their medical treatment. The second survey will be geared towards staff in the ESRD community ("Professional Survey"), including physicians, nurses, technicians, social

workers, nutritionists and administrative staff, inquiring about the types of incidents related to patient safety. Preliminary categories for the questions to be included in the surveys are addressed below.

Topics that the **Professional Survey** will address include the following:

- *Frequency* of adverse events and near misses
- *Types/categories* of adverse events and near misses
- *Causes* of adverse events and near misses
- *Response* to incidents and near misses
- *Prevention* of incidents and near misses
- Attitudes about and *barriers to reporting* incidents and near misses
- *Level of support* from senior management for reporting (i.e., culture of safety)
- Exposure to *patient safety education*

Topics that the **Patient Survey** will address include:

- Perceptions of *staff's safety procedures* (e.g., infection control, skill in operating dialysis machine)
- Perceptions of their own *safety during care* (e.g., how safe do they feel? If they feel unsafe, what specifically makes them feel unsafe?)
- Perceptions of *staff training and competence* (specific to patient safety)
- *Patient involvement* in care planning procedure (specific to patient safety)
- Experiences with *near misses*
- Attitudes towards *reporting incidents* that happen to them
- *Safety concerns* about dialysis treatment (e.g., reuse of dialyzers, equipment safety, water safety, cleanliness of clinic)

Summary of Recommendations

In addition to the RFP and compiled information from the dialysis chains, group #7 developed the following list of recommendations:

1. To contract with an outside consultant team to develop, distribute and analyze two surveys, one for patients and one for professionals.

2. To use the attached RFP as a starting point for soliciting responses from outside survey consultant teams to coordinate the surveys (i.e., the ideas contained within the RFP should be the basis of the surveys).

3. To incorporate the information from the dialysis chains into the surveys. In addition, the findings of the surveys should be compared to results from the dialysis chains in the final report.

4. To have Action Team #7 continue in their roles and work collaboratively with the survey consultant team in the design and distribution of the surveys.

Collaborative Action Team #11, Best Practices

This group's charge was to: *Develop best practice guidelines for promoting patient safety.* However, this charge proved to be unrealistic, given time and resource constraints. As such, the group focused on gathering existing best practices, and

developing an on-going structure for the continued dissemination of best practices to the ESRD community.

Clearly, there is currently a shortage of patient safety best practices in ESRD. As a beginning, this group has identified patient safety practices (from the AHRQ report and the Massachusetts Hospital Association) and determined what would be applicable to ESRD. In addition, the group recommends exploring ESRD guidelines to determine what is applicable to patient safety.

It should be noted that "guidelines," "best practices" and "success stories" are different categories of information, all of which will be included here, as appropriate. The group also feels it is important to address CQI/Root Cause analysis processes. It was determined that a practical and relevant CQI process is needed, as well as encouragement for the use of this process in the dialysis units for patient safety specifically.

In summary, the group developed a framework for a web-based clearinghouse of best practices that will:

a) provide summaries and links to existing practices,
b) guides for how to interpret ratings and applicability of the practices, and
c) a beginning collection of specific practices that can be implemented to improve patient safety in the ESRD community (See appendix D, p. 31).

The goal is for this clearinghouse to continuously grow and improve as patient safety becomes more prevalent in the ESRD community.

Summary of Recommendations

In addition to the framework and collection of best practices, the group developed the following set of recommendations:

1. Establish a web-based clearinghouse for patient safety best practices in ESRD.
2. State that CQI/Root Cause Analysis should be used specifically for patient safety practices in ESRD. It is possible that standard CQI/Root Cause Analysis processes will need to be adapted to appropriately address patient safety issues.
3. Educate the ESRD leadership (through group #17) about the importance of this methodology.
4. Create a small focus group of CQI and patient safety experts (and an ESRD representative with no experience in CQI) to make further recommendations for practical and effective tools to be included in the clearinghouse. These tools will preferably be web-based.
5. Set a long-term goal to identify areas where best practices are needed, to conduct appropriate data collection, and to encourage the research and development of needed practices.

Collaborative Action Team #17, Education

The charge to this group was to: *Conduct education and training for the ESRD program leadership on the nature of the problem and in the safety sciences.*

The End Stage Renal Disease (ESRD) patient safety initiative is committed to improving patient safety in the ESRD community through education of the leadership. This initiative will take a "train the trainer" approach, and provide tools through an educational "Safety Kit" for broad dissemination and education. Ultimately, this campaign aims to achieve wide-spread change in the ESRD community for patient safety, through the raising of awareness and reduction of medical error. Thus, the group put together a full proposal for a comprehensive education campaign (see Appendix E, p. 43).

The goal of the education team is to build a comprehensive education campaign around the patient safety education kit, or Safety Kit. The team will build upon an existing patient safety "tool box" developed by The Forum of ESRD Networks under a contract modification from CMS. The team will build on the existing product in the following ways:

- Add resources that are appropriate for ESRD leadership, and a generally broader audience
- Build an educational campaign around the safety kit, including press releases, posters, and exhibit materials
- Include end products from other groups in the ESRD initiative, including the taxonomy, results from an ESRD patient safety survey, and information on the development of a web-based best practices clearinghouse

To view the entire contents of the proposed Safety Kit, see Appendix F (p. 48). It should be noted that the Safety Kit is intended as a "point in time" product that will need to be altered and amended as the field of patient safety changes as a whole, and within the ESRD community. However, education of the ESRD community should continue beyond this campaign, until practitioners and patients are receiving the information they need.

Summary of Recommendations

In addition to the education proposal, and revised contents of the Safety Kit, the group developed the following recommendations:

1. Produce safety kits for ESRD leadership, with the inclusions and revisions outlined in the attached proposal (Appendix E).
2. Develop the safety kit as part of a larger educational campaign, including the elements outlined in the attached proposal.
3. Work collaboratively with CMS and the networks in developing, distributing and marketing the safety kit.
4. View this safety kit as a product that will need to be revised and updated in future education efforts as the field of patient safety and the ESRD community change.
5. Track all ESRD patient safety speaking engagements (See Appendix G, p. 52).

Looking ahead to Phase III

Phase III will be the culmination of the recommendations and reports developed in Phase II. The following items are expected to be the products of Phase III, which will be launched in January, 2002, pending funding.

1. Taxonomy

The taxonomy will be a printed document containing patient safety terminology that can be distributed to organizations and individuals either by itself, or in combination with an educational program.

2. Survey Report

This report will be the end product of two surveys, one for patients and one for professionals. It will report, analyze and interpret the results, informing on top patient safety issues for these two populations in the ESRD community.

3. Best Practices Clearinghouse

The clearinghouse will be a comprehensive, searchable, web-based resource that will be easily accessible and navigable for the ESRD community. It will contain a compiled list of existing guidelines (including summaries and links), and will provide a structure for new guidelines as they are developed.

4. Education Campaign

This education campaign will target leaders in the ESRD community, using a top-down or "train the trainer" approach. It will include the following products:

- An updated Safety Kit that will supply educational tools to the ESRD Community.
- Conference materials including flyers, posters and exhibit panels.
- Marketing materials, including press release.

5. Web-site

This will be a web-site dedicated to ESRD Patient Safety. It will include pages that describe the initiative and its phases, and will have links to:

- The taxonomy
- The survey results
- The best practices clearinghouse
- The contents of the safety kit (including specific web-based tools, when possible)
- Press releases
- Information from the dialysis chains on patient safety
- Newsletters
- Links to other patient safety resources

Conclusions

In order to achieve patient safety in the ESRD community, fundamental change needs to occur in the culture of the healthcare system. This type of change takes time, and requires an approach that addresses the fundamental aspects of healthcare. That is the approach of this project. Beginning with Phase I over a year ago, stakeholders from all parts of the ESRD community came to a consensus on the most leveraging actions to pursue in ESRD patient safety. In Phase II, the stakeholder group was divided into four teams who have worked together towards creating a common language, identifying the most important issues in ESRD patient safety, providing best practices, and educating the leadership and community as a whole. It is clear that progress has been made through the development of proposals, the completion of the taxonomy and other reports, as well as bringing the community together.

As we look forward, we see the culmination of the hard work of these individuals and teams. In Phase III, the implementation plans and recommendations will be operationalized, and the information disseminated. In this way, we will be able to build upon the strong foundation that has been created in Phases I and II to measurably improve patient safety in the ESRD community.

APPENDIX A

Patient Safety Taxonomy

PATIENT SAFETY TAXONOMY

DEFINITIONS AND CLASSIFICATIONS

Prologue

The following taxonomy promotes a patient safety culture in the End Stage Renal Disease (ESRD) medical environment, especially with respect to the prevention of errors. The initial set of definitions provides a broad background for patient safety, and the second set provides a more specific focus. The taxonomy conveys the message that safety in the healthcare system can be greatly improved if we identify the many factors that contribute to error as opposed to finding fault and placing blame.

Patients and health care practitioners can make the greatest contributions in analyzing patient safety. Therefore, we feel it is critical to receive timely information from these people, and to allow a description in their own words- not just a checklist of terms that may be close. Over time, various taxonomic terms will be added, subtracted, or modified. For this reason, the textual description will be especially critical to effective root cause analysis. The utilization of this common framework will lead to identification and rectification of patient safety issues in the renal community.

Terminology and definitions in this taxonomy were pulled and adapted from a variety of sources. We would like to acknowledge the following organizations and articles:

Allina Health Systems
- Definitions and Terminology

American Society of Testing and Materials (ASTM)
- Standards

BJC Healthcare
- Patient Safety Terms Glossary

Institute of Medicine (IOM)
- To Err is Human: Building a Safer Health System

The Joint Commission of Accreditation and Hospital Organizations (JCAHO)
- Glossary of Terms

The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP)
- Medication Error Index

The National Patient Safety Foundation (NPSF)
- Current Research on Patient Safety in the United States
- A Tale of Two Stories: Contrasting Views of Patient Safety

Quality Interagency Coordination Task Force (QuIC)
- Report to the President

U.S. Food and Drug Administration (FDA)
- MedWatch: FDA's 'Heads Up' on medical Product Safety, by John Henkel

USP Quality Review
- Definition of Medication Errors and Medication Error Index

Christine Diehl
- Hospital Systems that Put People at Risk

John Gosbee
- RCA Categories and Keywords (working lists)

Robert Helmreich
- On Error Management: Lessons from Aviation

Additional thanks to the following individuals who submitted definitions and/or expertise: Jim Conway, Richard Cook, Allan Frankel, John Gosbee, William Jessee, Joe Klancher, Lucian Leape, Don Parsons, Josie Williams

BASIC PATIENT SAFETY TERMS

Quality of Care: Degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

System: set of interdependent elements interacting to achieve a common aim. These elements may be both human and non-human (equipment, technologies, etc.).

Patient Safety: Freedom from accidental injury stemming from the processes of health care. These events include "errors," "deviations," and "accidents." Safety emerges from the interaction of the components of the system; it does not reside in a person, device or department. Improving safety depends on learning how safety emerges from the interactions of the components and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them before they occur. Patient safety is a subset of healthcare quality.

Risk management: Clinical, administrative and manufacturing activities undertaken to identify, evaluate, and reduce the risk of injury to patients, staff, and visitors and the risk of loss to the organization itself. **Risk containment:** reflects a subset of immediate actions taken to safeguard patients from a repetition of an unwanted occurrence. Actions may involve removing and sequestering drug stocks from pharmacy shelves and checking or replacing oxygen supplies or specific medical devices.

Near Miss (Close Call): an event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention. Also known as close call or near hit.

Error: The failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems.

Adverse Event: Untoward, undesirable, and usually unanticipated event directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic or other facility. Examples of common adverse events include: patient falls, medication errors, unexpected reactions or complications, procedural errors or complications, completed suicides, parasuicidal behaviors (attempts/gestures/threats), and missing patient events.

Sentinel Events: An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and response.

Phenotype: The phenotype of an incident is what happens, what people actually do or what they do wrong, what you can observe. They are specific to the local situation and context – the surface appearance of an incident. **Thus the complete text of an event is critical to describe its phenotype.**
Genotype: The genotype of an incident is the characteristic collection of factors that lead to the surface, phenotypical appearance of the event. They refer to patterns of contributing factors.

Root Cause: A root cause is the most fundamental reason an event has occurred.

EXTENSIVE LIST OF TERMS

The following list of terms is an effort to capture the breadth of current terms applied to the topic of patient safety and to provide additional acceptable descriptors that are found in the literature. In our effort to be inclusive, we sacrificed efforts to avoid redundancy or to establish a single recommended set of terms.

Safety Science Terms

- **Quality of Care:** Degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.
- **Patient Safety:** Freedom from accidental injury stemming from the processes of health care. These events include "errors," "deviations," and "accidents." Safety emerges from the interaction of the components of the system; it does not reside in a person, device or department. Improving safety depends on learning how safety emerges from the interactions of the components and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them before they occur. Patient safety is a subset of healthcare quality.
- **Safety Culture:** There are the 5 high level attributes of a "safety culture." (Allina Health System – Incident Quality Council)
  - Prioritizes safety above financial and operational goals
  - Provides appropriate resources, structure and accountability to maintain effective safety systems
  - ALL workers (including front line staff, physicians, and administrators) accept responsibility for the safety of themselves, their co-workers, patients, and visitors.
  - Provides for organizational learning from accidents
  - Encourages and rewards the identification, communication, and resolution of safety issues
- **System:** set of interdependent elements interacting to achieve a common aim. These elements may be both human and non-human (equipment, technologies, etc.).
- **Components of a Safety Management System (Allina Health Systems):**
  - Leadership (accountability, measurement, participation, resources, etc.)
  - Management responsibility to prioritize and implement initiatives (communication, identify critical needs and oversight responsibilities, structure and processes to support team work, etc.)
  - Safety training (safety competencies for administrators, directors, managers, and front-line staff – MDs, RNs, others)
  - Employee involvement (participation in all aspects of safety systems)
  - Hazard prevention (tracking of ongoing quality improvement and best practice implementation)
  - Workplace analysis (accident investigation, systems analysis, inspections, reporting systems)
- **Standard:** A minimum level of acceptable performance or results *or* excellent levels of performance *or* the range of acceptable performance or results. The following represents the six types of standards (ASTM):
  - **Standard Test Method:** A definitive procedure for the identification, measurement, and evaluation of one or more qualities, characteristics, or properties of a material, product, system, or service that produces a test result.

- **Standard Specification:** A precise statement of a set of requirements to be satisfied by a material, product, system, or service that also indicates the procedures for determining whether each of the requirements is satisfied.
- **Standard Practice:** A definitive procedure for performing one or more specific operations or functions that does not produce a test result.
- **Standard Terminology:** A document comprised of terms, definitions of terms, descriptions of terms, explanations of symbols, abbreviations, or acronyms.
- **Standard Guide:** A series of options or instructions that do not recomment a specific course of action.
- **Standard Classification:** A systematic arrangement or division of materials, products, systems, or services into groups based on similar characteristics such as origin, composition, properties, or use.

An example of the above is the **AAMI** standards for ESRD medical devices.

- **Phenotype:** The phenotype of an incident is what happens, what people actually do or what they do wrong, what you can observe. They are specific to the local situation and context – the surface appearance of an incident. **Thus the complete text of an event is critical to describe its phenotype.**
- **Genotype:** The genotype of an incident is the characteristic collection of factors that lead to the surface, phenotypical appearance of the event. They refer to patterns of contributing factors.
- **Human factors:** Study of the interrelationships between humans, the equipment and methods they use, and the environment in which they live and work.
- **Classification system:** The categorizing of errors into distinguishing levels.
- **Sharp end of healthcare system:** Practitioners at the sharp end actually interact with the hazardous process in their roles. In medicine, these practitioners are anesthesiologists, surgeons, nurses, and some technicians who are physically and temporally close to the patient (Reason, taken from Cook and Woods, 1994)
- **Blunt end of healthcare system:** Those at the blunt end of the system affect safety through their effect on the constraints and resources acting on the practitioners at the sharp end. In medicine, the blunt end includes government regulators, hospital administrators, nursing managers, and insurance companies (Reason, taken from Cook and Woods, 1994).

Types of Events

- **Adverse Event:** Untoward, undesirable, and usually unanticipated event directly associated with care or services provided within the jurisdiction of a medical center, outpatient clinic or other facility. Examples of common adverse events include: patient falls, medication errors, unexpected reactions or complications, procedural errors or complications, completed suicides, parasuicidal behaviors (attempts/gestures/threats), and missing patient events.
  - In the ESRD setting, all of the above are possible adverse events. Anticipated complications, such as hypotension, would generally not be classified as an adverse event.
- **Unpreventable adverse event:** an adverse event resulting from a complication that cannot be prevented given the current state of knowledge. (QuIC)
- **Adverse drug event (adverse drug error):** Any incident in which the use of a medication (drug or biologic) at any dose, a drug-dispensing medical device, or a special nutritional product (e.g., dietary supplement, infant formula, medical food) may have resulted in an adverse outcome in a patient. (JCAHO)
- **Adverse Device Event**: Any incident in which the use of medical equipment may have resulted in an adverse outcome for the patient.

- **Adverse drug reaction (ADR):** An undesirable response associated with use of a drug that either compromises therapeutic efficacy, enhances toxicity, or both. (JCAHO)
- **Adverse Outcome:** Includes prolonged hospitalization, disability or death at the time of discharge (Brennan et al., 1991)
- **Near Miss (Close Call):** an event or situation that could have resulted in an accident, injury or illness, but did not, either by chance or through timely intervention. Also known as close call or near hit.
  - For ESRD, close calls could include events such as tubing disconnnetions and/or other problems that are detected by equipment prior to causing harm.
- **Sentinel event:** An unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase, "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Such events are called "sentinel" because they signal the need for immediate investigation and response. (JCAHO)
- **Dangerous Situation:** Both active and latent failures exist that create a hazard increasing the risk of harm (AHRQ)
- **Complication:** A detrimental patient condition that arises during the process of providing health care, regardless of the setting in which the care is provided.. A complication may prolong an inpatient's length of stay or lead to other undesirable outcomes.
  - For ESRD, complications could include blood stream infections (hemodialysis) and peritonitis (peritoneal dialysis).
- **Accidents:** A series of events that involves damage to a defined system disrupting the ongoing or future output of the system (IOM).

Types of Error

- **Error:** The failure of a planned action to be completed as intended or the use of an inappropriate plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems. (QuIC Report)
  - **Medical error:** an adverse event or near miss that is preventable with the current state of medical knowledge. These include events of omission or commission.
- **Medication Errors:** A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packing and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. (USP Quality Review)
  ***harm:** death, or temporary or permanent impairment of body function/structure requiring intervention
- **Systems error:** an error that is not the result of an individual's actions, but the predictable outcome of a series of actions and factors that comprise a diagnostic or treatment process. (QuIC Report)
- **Latent Systems Failures:** Small, individually innocuous systems faults that, if occurring in specific combination, can lead to catastrophic events. (Allina Health Systems)
- **Error of commission:** An error occurring as a result of an action taken. Examples include when a drug is administered at the wrong time, in the wrong dosage, or using the wrong route; surgeries performed on the wrong part of the body; and transfusion errors involving blood cross-matched for another patient. (JCAHO)
  Commission: Failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim (BJC Healthcare)

- **Error of omission:** An error which occurs as a result of an action not taken, for example, , when a nurse omits a dose of a medication that should be administered, or when a patient suicide is associated with a lapse in carrying out frequent patient checks in a psychiatric unit. Errors of omission may or may not lead to adverse outcomes. (JCAHO)
  Omission: Failure to carry out some of the actions necessary to achieve a desired goal (Reason)
- **Active error:** An error that occurs at the level of the frontline operator and whose effects are felt almost immediately. (IOM)
  Active failure: An error precipitated by the commission of errors and violations. These are difficult to anticipate and have an immediate adverse impact on safety by breaching, bypassing, or disabling existing defenses. (JCAHO)
- **Latent error:** Errors in the design, organization, training, or maintenance that lead to operator errors and whose effects typically lie dormant in the system for lengthy periods of time. (IOM)
  Latent failure: An error precipitated by a consequence of management and organizational processes and poses the greatest danger to complex systems. Latent failures cannot be foreseen but, if detected, they can be corrected before they contribute to mishaps. (JCAHO)
- **Proximate cause:** An act or omission that naturally and directly produces a consequence. It is the superficial or obvious cause for an occurrence. Treating only the "symptoms," or the proximate special cause, may lead to some short-term improvements, but will not prevent the variation from recurring. (JCAHO)
- **Proximal Cause:** Not “true” cause but the areas where the cause most likely exists (BJC)
- **Underlying causes:** The systems or process causes that allow for the proximate cause of an event to occur. Underlying causes may involve special-cause variation, common-cause variation, or both. (JCAHO)
- **Root Cause:** The most fundamental reason an event has occurred.
- **Negligence:** Failure to use such care as a reasonably prudent and careful person would use under similar circumstances. (JCAHO)

Causes of Error - Categories

- **Safety Concerns:** Protocols, procedures, products, or equipment that are problem prone, or risk-generating processes that may degrade our ability to provide optimal patient care (adapted from Allina Health Systems)
  - **Equipment Design Deficiencies:** Devices that are confusing to operate, lack safety features, and/or fail to alert users about equipment failures. Equipment should be designed and evaluated for ease-of-use and safety before purchase. In addition, when complete failures do occur, response plans should be available.
  - **Communication breakdown (related to treatment plan):** Discrepancies in communication of treatment plan between caregiver and patient, or between two caregivers.
  - **Constraint and forcing strategies not available:** There were no checkpoints or required steps that would force individuals to recognize and prevent the pending mistake. Some activities can be engineered so that it is impossible to make a mistake – e.g. it is impossible to attach an oxygen connector to the suction outlet because the connector is designed to fit only the O2 outlet.
  - **Environmental Stressors:** Workload, workspace, staffing, time pressures, noise, heat. Please identify specific factors contributing to the event.
  - **Equipment Not available**: Humans are prone to taking short cuts when appropriate equipment is not available.

- **Excessive Handoffs:** Information transfers and task handoffs become more error prone each time a hand-off occurs. Examples: change of shift issues, lunch breaks, unit secretaries performing order entry.
- **Lack of Training:** Lack of training or inadequate training can leave our employees unprepared to perform. Staff not oriented or not understanding the process.
- **Lack of/limited Access to Information**: No information or limited information available at the time. Our information systems, medical records, decision support systems should give our employee the information they need when they need it. Examples: missing allergy information could contribute to a medication error.
- **Look alike or sound alike situation**: Ambiguous labeling and non-distinct storage containers can lead to inappropriate use of medications or products. Examples: drug names may look or sound similar, intravenous fluids may be packaged alike, reagent bottles may be the same size and color,or two devices look alike but operate differently.
- **Multiple entry:** Multiple entry points for identical information can lead to conflicting or ambiguous data, or omissions. Examples: allergy, height and weight information may be entered into the patient record at multiple points in our system.
- **Non-standard process:** No procedure or process exists. When processes are improvised there can be subtle differences between standard and non-standard process that are missed in time pressured situations. Examples: micro-waving gel-packs when not the manufacturer's recommended warming method can result in burns; taking shortcuts on procedures; relying on folklore nursing techniques rather than following protocols.
- **Protocol/Checklist inadequate:** Checklists or user instructions often are not provided or are incomplete, difficult to understand and/or not used..
- **Indicators of Failure Absent or not Effective:** Our systems should be designed so that our people can easily recognize when systems begin to fail or have failed. For example, procedures should be in place to alert staff that a patient about to receive an MRI is wearing a pacemaker.
- **Reliance on human checks (or rechecks):** processes that rely on double-checking or triple-checking are prone to error. Where feasible, automation may be added to reduce the need for checks. However, not everything can be safely and effectively automated.
- **Reliance on memory:** Memory aids not provided or, if provided, not used. (Human memory degrades as time goes by. Reliance on memory during multi-tasking is highly error prone). Examples: Not checking MAR; Verbal hand-offs vs. written; didn't refer to an available protocol; or using an automated device lacking sufficient information or "prompts."
- **System complexity:** Process with multiple steps and/or decision points. (Complex systems require excessive attention and can be tightly coupled). Examples: a surgical tray arrives missing a critical component; or a delayed or erroneous lab result, if there are no contingencies for these types of events they could be significant consequences.

➢ **Categories of error (from aviation):**

- **Violation:** conscious failure to adhere to procedures or regulation (performing a checklist from memory.
- **Procedural:** followed procedures with wrong execution (wrong entry into computer)
- **Communications:** missing or wrong information exchange or misinterpretation Misunderstanding.
- **Proficiency:** error due to lack of knowledge or skill (inability to program automation)

- **Decision:** decision that unnecessarily increases risk (unnecessary navigation through adverse weather).

- **Behaviors that increase risk (from aviation):**
  - **Communication:**
    - Failure to inform team of patient's problem – for example, surgeon fails to inform anesthetist of use of drug before blood pressure is seriously affected.
    - Failure to discuss alternative procedures
  - **Leadership:**
    - Failure to establish leadership for operating room team
  - **Interpersonal relations, conflict:**
    - Overt hostility and frustration – for example, patient deteriorates while surgeon and anesthetist are in conflict over whether to terminate surgery after pneumothorax.
  - **Preparation, planning, vigilance:**
    - Failure to plan for contingencies in treatment plan
    - Failure to monitor situation and other team's activities – for example, distracted anesthetist fails to note drop in blood pressure after monitor's power fails.
- **Lab errors (causes and examples, from Christine Diehl)**
  - **Lab test knowledge:** Physicians unaware of a specific lab test and when to order
  - **Patient Information availability:** Patient history was not available to the clinician when needed
  - **Order Transcription:** Manually transcribed order leads to misinterpretation
  - **Interservice Communication:** Poor communication between departments in the hospital
  - **Device Use:** Improper specimen container for collection
  - **Collection Times for Drug Levels:** Dosing times are not a standard protocol in all hospitals
  - **Standardization of Procedures in hospitals:** Different procedures exist from one unit to another
  - **Transfers/Transition problems:** Identification errors when patients are transferred
  - **Conflict Resolution:** Many of the staff unaware of policies or procedures
  - **Staffing/Work Assignments:** Inability to match staffing to the current clinical load

Responses to/Prevention of Error

- **Forcing Functions:** Something that prevents the behavior from continuing until the problem has been corrected (Reason, Human Error)
- **Intervention:** may include monitoring the patient's condition, change in therapy, or active medical or surgical treatment.
- **Risk management:** Clinical, administrative and manufacturing activities undertaken to identify, evaluate, and reduce the risk of injury to patients, staff, and visitors and the risk of loss to the organization itself.
  Risk containment: reflects a subset of immediate actions taken to safeguard patients from a repetition of an unwanted occurrence. Actions may involve removing and sequestering drug stocks from pharmacy shelves and checking or replacing oxygen supplies or specific medical devices.
- **Root Cause Analysis:** A process for identifying the basic or causal factor(s) that underlie variation in performance, including the occurrence or possible occurrence of a sentinel event (JCAHO

- **Causal Analysis Investigation:** A process to investigate and analyze patient injuries and visitor incidents that identifies latent system failures and their causes. The process generally involves gathering information surrounding the event, diagramming the steps preceding and following the event, reviewing the event with content experts (2-3) to identify the causal factors responsible for latent systems failures.)
- **Hindsight Bias:** refers to our tendency to oversimplify and assign simple (human error) causes to events during post-event investigations (i.e. knowing the outcome of an event skews our perception of contributing factors). Structured analysis techniques help counteract these tendencies by forcing us to look, beyond human error, for the latent systems deficiencies that can lead our employees toward failure.

Severity Indexes

- **Error Severity Codes (Allina Health Systems):**
  - **Did not reach patient, potential injury**
    Example: prescription bottle labeled correctly but nurse notices wrong pills in bottle, wrong medications loaded in Pyxis or med drawer, nursing station keeps all multidose medication vials in same the same drawer or bin. The patient has to tell lab tech not to take blood from a specific arm, no signs or notes on order or care plan, no sign in room.
  - **Reach patient-No Injury or effect on patient**
    Example: Missed antibiotics, double dose of pain meds, wrong lab tests done, Wrong limb x-rayed, diagnostic test done incorrectly.
  - **Emotional injury**
    Example: Elopement or AMA, behavior health altercation between peers, wrongful confinement to a mental hospital, wrongful birth (birth after vasectomy, etc.), and fright, as well as 5th degree sexual conduct (touching or unacceptable sexual behavior, with no physical harm). Use of restraints.
  - **Minor Temporary**: Minor patient injury or increased patient monitoring or change in treatment plan (with or without injury). Length of stay increased by less than 1 day.
    Example: error in setting or monitoring heparin levels requiring increased number of lab tests, missed insulin dose requiring change in dosing for next administration and/or increased glucose checks. Bruising, abrasions, skin tear, complaints of pain, small number of non-facial sutures. Minor self- inflicted injury, (scratches or cutting.)
  - **Major Temporary**: A temporary injury that exceeds minor temporary or increases length of stay one day or more.
    Examples: facial sutures, minor fractures, severe drug reaction.
  - **Minor Permanent**: A permanent injury that does not compromise basic functions of daily living.
    Examples: Loss of finger, loss of testicle or ovary, removal of bowel due to circulatory compromise, loss of teeth, 2nd degree sexual conduct (forced sexual contact via threat of violence or weapon, forced sexual contact that causes injury, or sexual contact with someone < 16 years old), retained sponge/needle.
  - **Major Permanent:** Permanent injury that affects basic functions of daily living.
    Examples: Hip fracture, nerve damage from improper surgical positioning, missing limb, damage to sensory organ, 1st degree sexual assault (forced sexual penetration via threat of violence or weapon, forced sexual penetration that causes injury, or sexual penetration of someone under16 years old).
  - **Extreme:**
    Example: Brain damage, severe paralysis, death.

- **Reportable occurrence:** An event, situation, or process that contributes to, or has the potential to contribute to, a patient or visitor injury, or degrade our ability to provide optimal patient care. Reportable occurences can generally be divided into the following types based on severity (Adapted from Allina Health Systems):
  - **Sentinel events**: Any unanticipated death or serious injury resulting in a major permanent loss of function not attributed to the natural course of affected person's illness or underlying condition.
  - **Patient and visitor injuries** [adverse events]: An unanticipated physical or emotional patient injury not attributed to the natural course of affected person's illness or underlying condition
  - **Nears misses:** An event of situation, in the patient care environment, that could have resulted in a patient injury or visitor incident, but did not, either by chance or through timely intervention.
  - **Safety concerns**: Protocols, procedures, products, or equipment that are problem prone, or risk-generating processes that may degrade our ability to provide optimal patient care.

- **Serious Adverse Reaction:** Include (FDA)
  - **Death:** If an adverse reaction to a medical product is a suspected cause of a patient's death.
  - **Life-threatening hazard:** If the patient was at risk of dying at the time of the adverse reaction or if it is suspected that continued use of a product would cause death (examples: pacemaker breakdown or failure of an intravenous (IV) pump that could cause excessive drug dosing.
  - **Hospitalization:** If a patient is admitted or has a prolonged hospital stay because of a serious adverse reaction (example: a serious allergic reaction to a product such as latex).
  - **Disability:** If the adverse reaction caused a significant or permanent change in a patient's body function, physical activities, or quality of life (examples: strokes or nervous system disorders brought on by drug therapy.
  - **Birth defects, miscarriage, stillbirth or birth with disease:** If exposure to a medical product before conception or during pregnancy is suspected of causing an adverse outcome in the child (example: malformation in the child caused by the acne drug Accutane, or isotretinoin).
  - **Needs intervention to avoid permanent damage:** If use of a medical product required medical or surgical treatment to prevent impairment (examples: burns from radiation equipment or breakage of a screw supporting a bone fracture).

- **Medication Error Index (NCC MERP):**
  - **No error**
    - Category A Circumstances or events that have the capacity to cause error
  - **Error, no harm***
    - Category B An error occurred but the medication did not reach the patient
    - Category C An error occurred that reached the patient but did not cause patient harm
    - Category D An error occurred that resulted in the need for increased patient monitoring but no patient harm.
  - **Error, harm**
    - Category E An error occurred that resulted in the need for treatment or intervention and caused temporary patient harm.

Category F	An error occurred that resulted in initial or prolonged hospitalization And caused temporary patient harm
Category G	An error occurred that resulted in permanent patient harm
Category H	An error occurred that resulted in a near-death even (e.g. cardiac arrest)

- **Error, death**

Category I	An error occurred that resulted in patient death

APPENDIX B

Information from the Dialysis Chains

Information from Dialysis Chains

This document represents information from Davita, DCI, Fresenius Medical Care, National Nephrology Associates and the Renal Care Group. The first section includes a ranked list of patient safety issues compiled from chains' listings of top patient safety issues. The second section includes general categories, without ranking, from the information gathered.

Top Patient Safety Issues, Compiled Ranked List

The following issues were listed most often and prominently by the dialysis chains.

1. Patient Falls
2. Medication Errors, includes
   - Deviation from dialysis prescription
   - Allergic reaction
   - Omissions
3. Access-Related Events, including
   - Clots
   - Infiltrates
   - Difficult cannulation
   - Poor blood flow
4. Dialyzer Errors
   - Incorrect dialyzer
   - Incorrect line
   - Incorrect dialysate
   - Dialyzer or dialysis-equipment related sepses
5. Excess Blood Loss/Prolonged Bleeding

Categories of Events

The following is a listing of all categories used by the chains, with no ranking, to assess patient safety issues.

- Patient Falls
- Blood Loss
- System Separation
- Dialyzer/Bloodline Leak
- Non-system Event
- Clotted Extracorporeal System
- Incorrect Dialyzers
- Mismatched dialyzer per presecription
- Incorrect Dialyzer – Wrong Patient
- Equipment/Product Malfunction
- Dialyzer Hypersensitivity Reaction
- Dialyzer Disinfectant Exposure

- Incorrect Dialysate
- Mismatch per prescription
- Incorrect Dialysis Machine Settings
- Incorrect Line Used
- Access Clotting during treatment
- Access Infiltration
- Post Weight Variance
- Dialysis Machine Malfunction
- UFR Calculation Error
- Procedure Variance
- Medication Errors
- Omission
- Incorrect Dose
- Incorrect Medication
- Incorrect Patient
- Allergic Reactions
- Adverse Reactions
- Transfusion Reactions
- Exposure to blood, body fluids or chemicals
- Inhalation of Formaldehyde and chemicals
- Needle Dislodgment with significant blood loss
- Needles Stick
- Dermatitis Acute
- Air Embolus
- Cardiac Arrest
- Cardiopulmonary Arrest
- Respiratory Arrest
- Severe Chest Pain
- Sustained Loss of Consciousness
- Fever during treatment without obvious cause
- Deaths during treatment
- Abusive/Violent Behavior
- Patient-staff Altercations
- Non patient incidents
- Follow-up Investigations

APPENDIX C

Request for Proposals

Request for Proposals
Patient and Professional Surveys

Summary

The ESRD Consensus Initiative is seeking competitive bids to develop, distribute and analyze two surveys in the ESRD community. The objective is to identify the primary issues in patient safety from both the patient and health care professional perspective. The project will result in a final report that will be used to inform and educate the ESRD community, and ultimately improve patient safety.

Background

The last few years have seen a growing recognition of the occurrence of medical errors and other failings that compromise patient safety (c.f. IOM report). While the treatment of End Stage Renal Disease (ESRD) is one of the tremendous success stories of modern medicine, errors and other problems with patient safety occur in this area as well. Health care professionals and patients are well aware of cases of error in this field, perhaps most notoriously during hemodialysis. To address the challenge of improving ESRD patient safety, the Renal Physicians Association (RPA), the Forum of ESRD Networks (Forum) and the National Patient Safety Foundation (NPSF) initiated a project to address these issues.

Forty-two participants representing doctors, nurses, technicians, social workers, nutritionists, administrators, regulators, and patients participated in the workshop on October 30-31, 2000. At this event stakeholders explored the challenges that will be faced by any attempt to improve patient safety within the ESRD domain and chose specific actions to undertake.

ESRD Patient Safety stakeholders identified the need to gather further information on what the primary patient safety issues are for patients and professionals in the community. Although there are reporting systems in place for incidents, they don't focus on medical errors and don't include near misses. Therefore, the group decided that two surveys should be developed to gather information specific to patient safety in order to gain a more complete understanding of the issues in this field.

Project Description

The ESRD Consensus Project Survey Team is interested in sub-contracting with an organization that would design, implement and analyze patient and professional surveys under the direction of this team. The work of the consultant would be to:

1. Design two surveys in collaboration with ESRD project team
2. Develop a plan for data collection of both surveys
3. Execute distribution and collection of surveys
4. Analyze the results of the survey
5. Produce a final report

The primary role of the ESRD project team would be to:
1. Provide guidance for the content of the surveys
2. Facilitate contact information for distribution of the surveys
3. Use the survey results in planning future action in ESRD patient safety

The goal of these surveys is to determine what the leading patient safety issues are from both perspectives, with an aim of gaining information that the current reporting systems do not provide (i.e., a qualitative component). Both surveys will be:
1. Written (either mail or email)
2. Brief
3. Random samples, covering a broad geographic distribution
4. Anonymous
5. Primarily in multiple choice (or multiple answer) format, but will have brief open-ended sections.

The survey for dialysis patients ("Patient Survey") will focus on their main safety concerns in terms of their medical treatment. The second survey will be geared towards staff in the ESRD community ("Professional Survey"), inquiring about the types of incidents related to patient safety. The ESRD team has already developed a list of preliminary questions that the surveys should address. Preliminary categories for the questions are addressed below.

Professional Survey

This survey will be administered to physicians, nurses, techs, social workers, nutritionists and administrative staff. Thus, the survey will include basic demographic information about the respondent, including job category and work environment (e.g., hospital-based vs. freestanding dialysis unit). Respondents should be guaranteed full confidentiality by blinding any identifying information.

All categories in the survey should relate specifically to patient safety. The areas to be addressed in this survey include:
- Frequency of adverse events
- Frequency of near misses
- Types/categories of adverse events
- Types/categories of near misses
- Causes of adverse events
- Causes of near misses
- Response to incidents
- Response to near misses
- Prevention of incidents
- Prevention of near misses
- Attitudes about and barriers to reporting incidents
- Attitudes about and barriers to reporting near misses
- Level of support from senior management for reporting (i.e., culture of safety)
- Exposure to patient safety education

Patient Survey

This survey will target patients on dialysis and their concerns about patient safety. The areas that will be addressed are:

- Perceptions of staff's safety procedures (e.g., infection control, skill in operating dialysis machine)
- Perceptions of their own safety during care (e.g., how safe do they feel? If they feel unsafe, what specifically makes them feel unsafe?)
- Perceptions of staff training and competence
- Patient involvement in care planning procedure
- Experiences with near misses
- Attitudes towards reporting incidents that happen to them
- Safety concerns about dialysis treatment (e.g., reuse of dialyzers, equipment safety, water safety, cleanliness of clinic)

Requirements for Proposal

The proposal must be no longer than three pages, single-sided and double-spaced, with 12-point font. Final copies should be emailed to Rebecca DeVivo at rdevivo@npsf.org in Word format. Proposals are due no later than (December 1st, 2001).

The format of the proposal should be as follows:

Background: Describe your organization and why you are interested in this project.

Qualifications of individuals involved: Please name the members of the research team and describe any unique qualifications. Describe background and experience with patient safety and/or end stage renal disease (ESRD).

Methodology: What methods will you use to achieve the goals outlined above? Please describe:

- The sample size you would recommend, to achieve both economic efficiency and reliable results
- The sampling method (and distribution strategy) that you would recommend
- The response rate you would expect, and how you would maximize the response rate
- Provide a sample list of up to 6 survey items based on the identified areas.

Estimated Budget and Timeline: Detail the estimated costs and outline the timeline for completion of the work.

A decision will be made by the Partnership by (December 15th, 2001), with the intention of the project beginning (January 2nd, 2002). Please direct any questions to:

Rebecca DeVivo, MPH, MSW
Program Manager, Applications and Learning
National Patient Safety Foundation
515 North State St., 8th floor
Chicago, IL 60610

APPENDIX D

ESRD Patient Safety Best Practices Clearinghouse

ESRD Patient Safety Clearinghouse

Introduction

This is a compilation or "clearinghouse" for best practice guidelines that relate to patient safety in the End Stage Renal Disease community. We used the following criteria for inclusion:

1. A guideline or recommendation made by an authoritative source. No new or original material is included. However, we have occasionally summarized or excerpted relevant portions from a guideline taking care not to change meaning by quoting out of context.

2. The topic must be at least partially applicable to ESRD patients.

3. The topic must relate to patient safety (as defined below) and not to the much larger topic of quality of care (for which there are many textbooks, guidelines, and other authoritative sources). We realize that there are many topics where the boundaries between patient safety and quality of care are unclear; we have generally tried to err on the side of being more inclusive.

4. The guideline must make a practical and concrete recommendation that could be used to improve patient safety. Documents that primarily review the literature and/or call for further research are certainly important but are not included in this compilation.

As recommended by Action Team #1, Patient Safety is defined as:

> ***Patient Safety:*** *Freedom from accidental injury stemming from the processes of health care. These events include "errors," "deviations," and "accidents." Safety emerges from the interaction of the components of the system; it does not reside in a person, device or department. Improving safety depends on learning how safety emerges from the interactions of the components and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them when they occur. Patient safety is a subset of healthcare quality.*

It is important to reiterate that this is not an all-inclusive guide for treatment of ESRD patients, but deals with the subcategory of care that seeks to prevent injury from errors, deviations, and accidents.

A Guide to the Guides

Part of the difficulty with existing processes and guidelines is that they are not practical, understandable, or applicable to different arenas. This section will provide summaries, tables, and introductions that will explain *how* to use a given guideline, and *why* it may be relevant. Example: Providing a table that will show the rating systems of various guidelines, and how they match up across resources (See Attachment).

Strength of Evidence Scales Used by Various Guidelines and Recommendations

Guideline Source	Strongest recommendation			Weakest Recommendation	Miscellaneous
CDC/HICPAC	Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiological studies.	Category IB. Strongly recommended for implement-ation and supported by some experimental, clinical, or epidemio-logical studies and a strong theoretical rationale	Category IC. Required by state or federal regulations, rules, or standards.	Category II. Suggested for implementation and supported by suggestive clinical or Epidemiological studies or a theoretical rationale	No recommend-ation; unresolved issue. Practices for which evidence is insufficient or no consensus regarding efficacy exist
K/DOQI	Evidence	Evidence/Opinion		Opinion	--
AHRQ	Greatest strength of evidence regarding impact and effectiveness	High strength of evidence regarding impact and effectiveness	Medium strength of evidence regarding impact and effectiveness	Lower strength of evidence regarding impact and effectiveness	Opportunities for research

General Methodology

This section will provide recommendations and tools for developing best practices, primarily through CQI or root cause analysis approaches. This section will include general processes, as well as specific tools (based on the recommendations of CQI/Root Cause Analysis experts).

Domains

The best practices in the clearinghouse will be divided into specific domains, in order to make searching and classifying easier (particularly as the clearinghouse is continuously expanded). In many cases, guidelines may fall into two or more domains. Cross-referencing will be used to make navigation as easy as possible.

The following of domains may be adjusted as needed:

1. Role of the Patient
2. Organization/Structure/Systems
    - Culture of the unit
    - Communications
3. Physical Environment (e.g. falls)
4. Dialysis Technology
    - Device
    - Water Treatment
5. Surgery
    - Transplant
6. Dialysis Access
    - Hemodialysis
    - Peritoneal Dialysis
7. Infection Control
8. Adverse Drug Events
9. Pediatrics

Specific Best Practices:

These are practices that are specific to patient safety, and applicable to ESRD. At this time, the group has landed on a beginning list of practices that should be included in the clearinghouse.

Role of the Patient

Title	**Procedures for Obtaining Informed Consent**
Domain	Role of the Patient
Cross-reference	
Source	AHRQ Report, Chapter 48
Location	http://www.ahrq.gov/clinic/ptsafety/chap48.htm
Summarize	Suggested practices include readability (consents and educational material), structured discussions, ask for recall, multimedia, providing written information. The chapter states: "In addition to the ethical imperative of informed consent, it may be that informed patients are less likely to experience medical errors by acting as another layer of protection (as when a patient is able to inform providers about his/her informed consent, and to test the impact of such practices on patient safety."
Comments	Although it has not been shown to date, it is hypothesized that better informed consent could reduce medical error. Many consent forms are provided at the onset of dialysis, and throughout the years that follow. Many of these forms are at reading levels greater than patients' ability; furthermore, structured discussing, multimedia presentations and written

	information are (many times) not included. This may be helpful to improve patients' understanding regarding their role in the healthcare team to decrease medical errors and to increase patient safety.

Title	**Other Practices Related to Patient Participation**
Domain	Role of the Patient
Cross-reference	
Source	AHRQ Report, Chapter 50
Location	http://www.ahrq.gov/clinic/ptsafety/chap50.htm
Summarize	Recommends resources that may facilitate the role of patients as their own safety advocates. Discusses why patients want to take a more active role. The chapter states that this isn't intended to shift the burden entirely to patients, but to have them share responsibility.
Comments	Further research is needed in this area. However, these recommendations are very applicable to ESRD, including resources that may be helpful to patients (books, web-sites, consumer group publications) and workbooks. Also addresses practices to improve noncompliance (which may arise from misunderstandings regarding drug use, self care, language barriers/health literacy).

Organization, Structure and Systems

Title	**Nurse Staffing, Models of Care Delivery, & Interventions**
Domain	Organization, Structure and Systems
Cross-reference	
Source	AHRQ Report, Chapter 39
Location	http://www.ahrq.gov/clinic/ptsafety/chap39.htm
Summarize	While more research is needed, preliminary findings reveal a significant relationship between improving staffing ratios and reducing adverse occurrences (including medical errors; falls; post-op thrombosis; pneumonia; other infections and UTI; pressure ulcers; pulmonary compromise; CVC infection, post-op infections). Improving staff ratios is also correlated with reducing length of stay, reducing 30-day mortality, increasing patient satisfaction and reducing nurse turnover.
Comments	

Title	**Promoting a Culture of Safety**
Domain	Organization, Structure and Systems (Culture)
Cross-reference	
Source	AHRQ Report, Chapter 40
Location	http://www.ahrq.gov/clinic/ptsafety/chap40.htm

Summarize	Good article on developing organizational safety culture values, and measurable safety cultural indicators through management systems, safety systems, and individual attitudes and perceptions.
Comments	Table 40.1 has excellent bullet points.

Title	**Use of Human Factors in Reducing Device-Related Medical Errors**
Domain	Organization, Structure and Systems
Cross-reference	Dialysis Technology
Source	AHRQ Report, Chapter 41.1
Location	http://www.ahrq.gov/clinic/ptsafety/chap41a.htm#41.1
Summarize	This chapter addresses the importance of using human factors engineering (HFE) to design usable and safe medical devices. Recommendations include using available resources, performing systematic device evaluation, and training health care personnel on HFE.
Comments	

Title	**Information Transfer Between Inpatient & Outpatient Pharmacies**
Domain	Organization, Structure and Systems (Communication)
Cross-reference	Adverse Drug Events
Source	AHRQ Report, Chapter 42.1
Location	http://www.ahrq.gov/clinic/ptsafety/chap42a.htm#42.1
Summarize	This chapter discusses the importance of communication between inpatient settings and outpatient pharmacies in the reduction of adverse drug events.
Comments	Applicable and very important for safe ESRD patient care

Title	**Discharge Summaries & Follow-up**
Domain	Organization, Structure and Systems (Communication)
Cross-reference	
Source	AHRQ Report, Chapter 42.3
Location	http://www.ahrq.gov/clinic/ptsafety/chap42b.htm#42.3
Summarize	This chapter focuses on the use of structured, database-generated discharge summaries to improve the quality of the information content communicated after patient discharge, as well as to reduce the time required for this information transfer.
Comments	Applicable and very important for safe ESRD patient care

Title	**Fatigue, Sleepiness & Medical Errors**
Domain	Organization, Structure and Systems (Culture)
Cross-reference	
Source	AHRQ Report, Chapter 46
Location	http://www.ahrq.gov/clinic/ptsafety/chap46a.htm

Summarize	Although the link between fatigue and error has not been established in medicine, the intuitive connection has been demonstrated in other fields. Suggested interventions (from other fields) to address sleep deprivation include limiting work hours, changes in shift scheduling, napping, and pharmaceutical aids.
Comments	Studies not included show a link between decreased job satisfaction with working in shifts over 12 hours.

Physical Environment

Title	**A tool kit to prevent senior falls**
Domain	Physical Environment (Falls)
Cross-reference	
Source	CDC
Location	http://www.cdc.gov/ncipc/pub-res/toolkit/toolkit.htm
Summarize	Brochures: What you can do to prevent falls. Check for safety: a home fall prevention checklist for older adults Fact Sheets: Falls and hip fractures among older adults Falls in nursing homes
Comments	

Title	**Hip Protectors to Prevent Hip Fracture**
Domain	Physical Environment, Falls
Cross-reference	
Source	AHRQ Report, Chapter 26.5
Location	http://www.ahrq.gov/clinic/ptsafety/chap26b.htm#26.5
Summarize	Hip protectors are inexpensive and reduce the risk of hip fracture; however, their long-term acceptability to patients may limit implementation.
Comments	

Dialysis Technology

Title	**Water Treatment Equipment for Hemodialysis Applications**
Domain	Dialysis Technology (Water Treatment)
Cross-reference	
Source	**ANSI/AAMI RD62: 2001**
Location	
Summarize	This document establishes quality standards for water for use in all hemodialysis applications. The document is primarily aimed at providers of water treatment systems and sets forth a range of design and performance criteria for the equipment used to purify

	water to meet the prescribed quality standard.
Comments	These quality standards are intended to prevent a wide range of both acute and chronic injuries that may be caused by contaminants in the water. A parallel document (RD52) is being developed that will be aimed at users and provide guidance on maintaining water quality.

Title	**Quality Assurance for Dialysis – Quality Water and Dialysis Fluid, Subsection 3.1.1 Guidelines for the Control and Monitoring of Microbiological Contamination in Water for Dialysis**
Domain	Dialysis Technology (Water Treatment)
Cross-reference	
Source	**EDTNA/ERCA Guideline, Section 3.1**
Location	www.edtna-erca.org
Summarize	This guideline provides detailed methodology on monitoring the microbiological quality of water used for dialysis applications, including frequency of monitoring, sample collection, and test methods.
Comments	It covers some of the same material as ANSI/AAMI RD62:2001, but provides some more details and covers the use of more stringent test methods to detect low levels of contamination.

Title	**Reuse of Hemodialyzers**
Domain	Dialysis Technology
Cross-reference	
Source	**ANSI/AAMI RD47**
Location	
Summarize	This document provides a comprehensive set of recommendations on the practice of dialyzer reuse. It is aimed directly at practitioners and many sections deal with the avoidance of patient injury.
Comments	The document is presently undergoing revision and the updated version will probably appear in 2002.

Surgery

Title	**Localizing Care to High-Volume Centers (localizing specific surgeries and procedures to high volume centers)**
Domain	Surgery
Cross-reference	Organization/Structure/Systems
Source	AHRQ Report, Chapter 18
Location	http://www.ahrq.gov/clinic/ptsafety/chap18.htm
Summarize	Localizing specific surgeries and procedures to high volume centers to reduce mortality/morbidity associated with surgical procedures. Those providers that do more of a type of surgery

	are better at it and have better outcomes.
Comments	Relevant in referring patients to those providers that do a large volume of kidney transplants and/or vascular access procedures, etc.

Title	**Beta-blockers and Reduction of Perioperative Cardiac Events (use of perioperative beta-blockers)**
Domain	Surgery
Cross-reference	
Source	AHRQ Report, Chapter 25
Location	http://www.ahrq.gov/clinic/ptsafety/chap25.htm
Summarize	The administration of a therapeutic dose of beta-blocker prior to induction of anesthesia, followed by beta-blockage through the operation and in the post operative period in patients undergoing non-cardiac surgery to prevent/reduce cardiac events during the surgery.
Comments	May be applicable to ESRD patients, but further review of existing studies or new studies may be needed to understand implications for ESRD patients that have multiple co-morbid conditions and that are on many medications.

Dialysis Access

Title	**Ultrasound Guidance of Central Vein Catheterization**
Domain	Dialysis Access
Cross-reference	Surgery
Source	AHRQ Report, Chapter 21
Location	http://www.ahrq.gov/clinic/ptsafety/chap21.htm
Summarize	The guideline concerns the use of real-time ultrasound to visualize the desired vein and surrounding anatomic structures prior to and during insertion of the needle, guidewire and catheter.
Comments	The use of ultrasound guidance is directly applicable to the placement of catheters for hemodialysis access.

Title	**Clinical Practice Guideline for Vascular Access**
Domain	Dialysis Access
Cross-reference	
Source	NKF K/DOQI
Location	http://www.kidney.org/professionals/doqi/doqi/doqiva.html
Summarize	This is a comprehensive guideline dealing with all aspects of vascular access for hemodialysis, including choice of access, monitoring access performance, and preventing and managing complications.
Comments	Much of the guideline is evidence based. Some sections are more applicable than others to patient safety.

Infection Control

Title	**Guideline for Prevention of Intravascular Device-Related Infections**
Domain	Infection control
Cross-reference	Dialysis Access
Source	CDC
Location	Current guideline: http://www.cdc.gov/ncidod/hip/IV/Iv.htm Draft new guideline: http://www.cdc.gov/ncidod/hip/ivguide.htm
Summarize	Guideline prepared by the CDC and the Hospital Infection Control Practices Advisory Committee (HICPAC). Summarizes recommendations to prevent catheter-associated infections through proper infection control technique. Includes selecting, inserting, maintaining, monitoring for infections, and when to remove.
Comments	Sections which relate to hemodialysis catheters have been summarized in "Summary for Hemodialysis Catheters.

Title	**NKF-K/DOQI Clinical Practice Guidelines for Vascular Access: Update 2000. III**
Domain	Infection Control
Cross-reference	Dialysis Access
Source	NKF-K/DOQI
Location	Prevention of Complications: Infection. Am J Kidney Diseases 37 (No. 1, Suppl 1), 2001-S157-S159. http://www.ajkd.org/content/vol37/suppl_1/
Summarize	Methods to prevent hemodialysis access infections for permanent AV accesses and catheters. Includes skin preparation, technique for cannulation, considerations for accessing the bloodstream using catheters.
Comments	

Title	**Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients**
Domain	Infection control
Cross-reference	
Source	CDC
Location	http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5005a1.htm
Summarize	Focuses on preventing transmission of hepatitis viruses, but principles applicable to HIV and bacterial infections. Includes vaccination, infection control techniques, and monitoring for infection.
Comments	

Title	**Impact of Changes in Antibiotic Use Practices on Nosocomial Infections and Antimicrobial Resistance - Clostridium Difficile and Vancomycin-Resistant enterococcus.**
Domain	Infection Control
Cross-reference	
Source	AHRQ Report, Chapter 14
Location	http://www.ahrq.gov/clinic/ptsafety/chap14.htm
Summarize	Summarizes interventions to limit use of antibiotics; of 10 studies reviewed, 7 showed benefits of these interventions.
Comments	

Title	**Prevention of Intravascular Catheter-Associated Infections: Use of Maximum Barrier Precautions during Central Venous Catheter Insertion.**
Domain	Infection Control
Cross-reference	Dialysis Access
Source	AHRQ Report, Chapter 16.1
Location	http://www.ahrq.gov/clinic/ptsafety/chap16a.htm#16.1
Summarize	16.1 recommends that maximal barrier precautions, including a full body-sized sterile drape, be used for insertion of central catheters.
Comments	This practice is also recommended by CDC/HICPAC

Title	**Prevention of Intravascular Catheter-Associated Infections: Use of Chlorhexidine Gluconate at the Central Venous Catheter Insertion site**
Domain	Infection Control
Cross-reference	Dialysis Access
Source	AHRQ Report, Chapter 16.3
Location	http://www.ahrq.gov/clinic/ptsafety/chap16b.htm#16.3
Summarize	16.3 discusses using chlorhexidine rather than povidone iodone.
Comments	This chapter does not make a firm recommendation.

Title	**Vaccine Recommendations for Patients on Chronic Dialysis**
Domain	Infection Control
Cross-reference	
Source	Seminars in Dialysis 13: 101-107, 2000. Strikas, R., Coronado, V.
Location	
Summarize	Current recommendations from the Advisory Committee on Immunization Practices (ACIP) are summarized.
Comments	

Title	**Recommendations for Preventing the Spread of Vancomycin Resistance**
Domain	Infection Control
Cross-reference	
Source	CDC: MMWR, 1995; 44 (No. RR-12): 1-13
Location	http://aepo-xdv-www.epo.cdc.gov/wonder/prevguid/m0039349/m0039349.asp
Summarize	CDC/HICPAC guideline with review of literature on VRE, guidelines for infection control, and recommendations for vancomycin use.
Comments	

Adverse Drug Events

More to come.

Pediatrics

More to come.

APPENDIX E

Education Campaign Proposal

ESRD Education Campaign Proposal

Introduction

The End Stage Renal Disease (ESRD) patient safety initiative is committed to improving patient safety in the ESRD community through education of the leadership. This initiative will take a "train the trainer" approach, and provide tools through an educational "safety kit" for broad dissemination and education. Ultimately, this campaign aims to achieve wide-spread change in the ESRD community for patient safety, through the raising of awareness and reduction of medical error. This proposal represents the recommendations of the ESRD Education and Training Collaborative Action Team.

Background

The last few years have seen a growing recognition of the occurrence of medical errors and other failings that compromise patient safety (c.f. IOM report). While the treatment of End Stage Renal Disease (ESRD) is one of the tremendous success stories of modern medicine, errors and other problems with patient safety occur in this area as well. Health care professionals and patients are well aware of cases of error and near misses in the field of nephrology. To address the challenge of improving ESRD patient safety, the Renal Physicians Association (RPA), the Forum of ESRD Networks (Forum) and the National Patient Safety Foundation (NPSF) initiated a project to address these issues.

Forty-two participants representing doctors, nurses, technicians, social workers, nutritionists, administrators, regulators, and patients participated in the workshop on October 30-31, 2000. At this event stakeholders explored the challenges that will be faced by any attempt to improve patient safety within the ESRD domain and chose specific actions to undertake.

Four actions were chosen as top priority, and stakeholders were divided into Collaborative Action Teams to answer their charges. The charge of the Education Team is to:
Conduct education and training for the ESRD program leadership on the nature of the problem and in the safety sciences.

The goal of the education team is to build a patient safety education kit, or "Safety Kit." The team will build upon an existing patient safety "tool box" developed by The Forum of ESRD Networks under a contract modification from CMS. The team will build on the existing product in the following ways:

- Add resources that are appropriate for ESRD leadership, and a generally broader audience
- Build an educational campaign around the safety kit, including press releases, posters, and exhibit materials
- Include end products from other groups in the ESRD initiative, including a comprehensive compilation of patient safety terminology, results from an ESRD patient safety survey, and information on the development of a web-based "Best Practices Clearinghouse"

It should be noted that the Safety Kit is intended as a "point in time" product that will need to be altered and amended as the field of patient safety changes as a whole, and within the ESRD community. However, education of the ESRD community should continue beyond this campaign, until practitioners and patients are receiving the information they need.

Campaign Goals

The goals for the proposed education campaign are to:

1. Increase awareness about issues of patient safety in the ESRD leadership.
2. Provide the ESRD leadership with a structure and practical tools in order to promote ongoing education of the community.
3. Collaborate with CMS and the networks to build upon the work that has already been developed, and to promote a structure for continued education into the future.
4. Through education and collaboration, build a strong foundation for future patient safety initiatives (e.g., an error reporting system).

Target Audience

The immediate audience is the ESRD opinion leaders, corporate owners, professional boards and administrators. However, this campaign is intended as a "top down" approach. Therefore, the ultimate goal is to reach health care providers (including nurses, technicians, physicians, nutritionists, social workers, pharmacists) and consumers.

Key Messages

A broad message is intended for the ESRD leadership and community, promoting change and awareness. Specifically, these messages include:

- Raising awareness about patient safety will reduce medical error.
- Health care providers need to take responsibility for their actions, while avoiding a culture of blame.
- It is important to be proactive about reducing medical error, including performing CQI/Root cause analysis specifically for patient safety purposes.

Communication Tactics

The following tactics will be part of the campaign communication plan:

- A "Safety Kit" to be distributed among the ESRD leadership
- Press release
- Journal articles
- Exhibit panels
- Posters
- Give-aways (stickers, buttons, pens, etc.)
- Brief flyer for insert in packets
- Public service announcements (print, radio)
- Web-site

Distribution Strategy

This campaign will take advantage of all available communication channels to enhance its outreach efforts. Channels that will be utilized to distribute our messages include the following:

- Distribution through the ESRD patient safety initiative stakeholder group and their organizations, including:
  - National ESRD professional organizations
  - Government organizations
  - ESRD networks
  - Corporate dialysis providers
- Internet
- Journals and newspapers
- Exhibits and meetings

Campaign Implementation

Where we are now:

- ✓ The group has reviewed the existing "toolbox" from CMS and has made recommendations for additions and changes for this initiative's Safety Kit (please see attached inventory to view the original toolbox contents, as well as proposed additions).
- ✓ A patient safety taxonomy is under final review for inclusion in the Safety Kit.
- ✓ A draft press release has been written for when the safety kit will be released to the community
- ✓ A slogan and potential logo is being developed

Next Steps:

Phase I - Planning and Fundraising

April – December, 2001

- Active fundraising for the educational campaign
- Finalize additions and changes to the Safety Kit
- Finalize press release
- Develop slogan and logos
- Begin tracking speaking engagements in ESRD patient safety
- Work with CMS to determine avenues for collaboration
- Finalize the distribution plan

Phase II - Information Development and Dissemination

January – April, 2002

- Release the safety kit, with a kick-off meeting with the stakeholder group
- Partner with marketing agency for campaign
  - Market the new Safety Kit
  - Develop exhibit panels
  - Create give-aways
- Publish press release
- Publish journal articles

- Develop web-site
- Develop a plan for continued education, until the information is adequately reaching practitioners and patients
- Maintain a registry of speaking engagements in ESRD patient safety

Phase III – Evaluation
April – October, 2002
- Track speaking engagements for patient safety in ESRD
- Track production and distribution of the toolbox, and materials within (e.g., taxonomy)
- Count hits on web-site
- Review of Safety Kit evaluation forms

APPENDIX F

Contents of the Safety Kit

CONTENTS OF SAFETY KIT

Original contents of CMS toolbox:

Websites of Interest & Special Thanks

Listing of websites that contain informative patient safety material. List of members of the Centers for Medicare and Medicaid Services and the Forum of ESRD Networks Patient Safety Steering Committee.

"Improving Patient Safety" - Leadership Video (25 min.), by Institute of Healthcare Improvement

A taped conversation between Drs Leape and Berwich, leaders in the field of patient safety. Video profiles errors of care in terms of injury to patients. Promotes "systems approach" to improving safety. Describes leadership responsibilities, need to accelerate awareness and need for safer care.

"Beyond Blame" Video (10 min.), by Bridge Medical, Inc.

Dramatic candid presentation of three medication errors from the viewpoint of medical professionals involved in cases where patients died due to systems failure. Excellent video to provoke interactive discussion with professionals and patients.

PowerPoint Presentations

These five presentations were originally presented to leadership of ESRD Networks and Centers for Medicare and Medicaid Services at Annual Meeting, held June 13th, 2001.

- **"What is Patient Safety", by Lou Diamond, MB, Ch.B.**

Describes the structure and purpose of the National Patient Safety Foundation. Defines a framework for dealing with errors. Fundamental change in approach required to identify errors. The current national patient safety initiatives are outlined.

- **"Creating the Environment for Safety", by Alan Kliger, MD**

Case examples of errors are illustrated. Discussion of why errors in medicine occur. Highlights system analysis model to identify failures/weakness. A model program is offered on ways to create a safe environment.

- **"The National Collaborative ESRD Safety Initiative", by Glenda Harbert, RN, CNN, CPHQ**

Describes National ESRD stakeholder Patient Safety Initiative, sponsored by Renal Physicians Association, Forum of ESRD Networks, and National Patient Safety Foundation. Framework for identifying challenges in improving ESRD safety is outlined with levels of barriers defined for resolution at national level. Action plan outlined with next steps.

- **"Safety is an Outcome of CQI", by Peter DeOreo, MD**

Role of leadership at the ESRD provider level and organizational structure that foster a learning environment is outlined. IOM data and adverse events highlighted. CQI and safety science defined. Case examples presented.

- **"A CQI Success Story; Decreasing Patient Falls", by Connie Oden, RN, CNN**

Describes a team approach using root cause analysis and problem resolution to reduce patient falls that occurred in a dialysis program in Texas. Baseline data, use of CQI techniques, and team structure is described. Successful results are reported.

Copy of Consensus Statement from the National Quality Forum "Patient Safety: A Call to Action", by Kenneth W. Kizer, MD, MPH

The National Quality Forum contains recommendations for action needed in ten strategic high priority areas, which can be implemented by all health care organizations immediately.

Copy of "Patient Safety in ESRD: How Do We Create A Safe Environment?" *Advances in Renal Replacement Therapy* by Alan Kliger, MD and Louis Diamond, MB, Ch.B. (April 2001)

Article calls for a paradigm shift to create a culture of safety and elimination of current blaming/shaming approach. Describes the patient safety movement in health care with specific attention to ESRD. Two ESRD case examples are presented.

Executive Summaries of Institute of Medicine Reports (with website address)

- **"To Err is Human" http://www.nap.edu/books/0309068371/html/**

Report describes the fragmented nature of the USA health care delivery system. The report contains data from hospital records detailing the magnitude of medical errors and its costs to society. The goal of this report is a call to eradicate the status quo.

- **"Crossing the Human Chasm: A New Health System for the 21st Century" http://books.nap.edu/catalog/10027.html?onpi_newsdoc030101**

The Committee on Quality Health Care proposes six aims for improving the health care system for the 21st Century, with 13 recommendations, which impact all participants. The goal is to change behavior and create a patient-centered evidence-based system.

- **"Envisioning the National Health Care Quality Report" http://www.nap.edu/catalog/10073.html**

The President's Advisory Commission on consumer protection recommends there be an annual national health care quality report for the President and Congress to gauge progress in improving the performance of the health care delivery system. Recommendations are given using the conceptual framework of quality "report cards", process for selection of measures, and reporting format at national and state levels.

Patient Safety Culture Survey for Provider Staff

Brief self-administered questionnaire to evaluate individual organizational readiness to embrace a culture of non-blame for a systems approach to patient safety. Good tool to engage audiences about individual and collective action steps that can be taken at the provider or corporate level.

Sample of Patient Safety Policy for a Medical Organization

Model language that can be adapted for an ESRD provider to express the key responsibilities and principles of patient safety within various organizations.

Additions or Modifications to the original toolbox that have already been implemented:

Copy of "High Time for Action" *New England Journal of Medicine* by Asha R. Kallianpur, MD, Katherine A. Poehling, MD, and Robert S. Dittus, MD, MPH (January 2001)

A detailed case study of medical management for a hemodialysis patient after transplant failure. Complications develop due to error in dispensing an outpatient prescription.

Annotated Bibliography (31 references)

Important articles and reports on patient safety are listed with notations on content. Seven of the most significant documents are noted in bold type.

"Strategies for Leadership: An Invitation to Conversation." Quality-of-care workbook and video series, produced by the Institute for Healthcare Improvement.

This booklet is a part of the series with the video "Improving Patient Safety" listed above. The booklet includes questions for discussion on improving patient safety, as well as a complete reference list.

Additions that will be included in Safety Kit:

"Strategies for Leadership: Hospital Executives and their Role in Patient Safety."

This is a second booklet to be included with the video. It is a workbook including a checklist for evaluation of a medical setting and concrete actions for promoting a culture of safety.

Copy of "Implementation of Rules-Based Computerized Bedside Prescribing and Administration Intervention Study" *BMJ Volume 320,* by Nightingale, P.G., Adu, D., Richards, N.T., and Peters, M. (March 18, 2000)

This article describes the implementation and assessment of a rules based computerized prescribing system in a 64 bed renal unit in a teaching hospital.

"Analysis of JCAHO Patient Safety Standards, Effective July 1, 2001" by Carson Porter, *eHealth Solutions*

This document provides a brief summary of the standards that will be in effect within the year.

"ESRD Patient Safety Taxonomy" Taxonomy Action Team, ESRD Patient Safety Initiative

This document is a comprehensive list of patient safety terms, with examples specific to ESRD. It is intended to provide a common language for speaking about patient safety.

Safety Kit Evaluation Survey

Give us your feedback on the toolbox, including what you found useful. This evaluation will be used in shaping future education efforts.

Potential Additions that have not been decided upon:

Power Point Presentation: "Building the Foundation for Patient Safety: Redefining the Culture of Safety," by Doni Haas, RN, LHRM, *National Patient Safety Foundation*

This presentation discusses the culture of safety, covering the "swiss cheese" model, blunt and sharp ends of the health system, hindsight bias, and a non-punitive culture.

Power Point Presentation: "Building the Foundation for Patient Safety: Overview and IOM Reports," by Doni Haas, RN, LHRM, *National Patient Safety Foundation*

This presentation provides an overview of the history of the patient safety movements, as well as summaries of the IOM reports.

"Best Practices Clearinghouse" Best Practices Action Team, ESRD Patient Safety Initiative

This document is a first attempt at gathering and adapting patient safety best practices in ESRD. The document contains summaries of guidelines, as well as web-sites and other source information.

APPENDIX G

ESRD Patient Safety Speaking Engagements

ESRD Speaking Engagements
On Patient Safety

Date	Speaker	Audience
February, 2001	Glenda Harbert	ANNA Advance Practice Meeting in New Orleans
March, 2001	Alan Kliger	RPA
April, 2001	Alan Kliger	NKF
April, 2001	Glenda Harbert	ANNA National Symposium in Las Vegas
May, 2001	Peter DeOreo	Network 9/10 Annual Meeting, Indianapolis
June, 2001	Peter DeOreo	HCFA/Forum Meeting, Baltimore
August 29, 2001	Peter DeOreo	Network BOT, Chicago
September, 2001	Alan Kliger	NKF of Maine
September, 2001	Alan Kliger	Yale University Dept Pediatrics Grand Rounds
September 4, 2001	Curt Johnson	Local Nephrology Group
September 12, 2001	Peter DeOreo	Network MRB, Chicago
September 20, 2001	Peter DeOreo	Cntrs for Dialysis Care All Lead Meetings, Cleveland
September 27, 2001	Peter DeOreo	Cntrs for Dialysis Care All Lead Meetings, Cleveland
September/October, 2001	Alan Kliger	Hospital of St. Raphael, 2 Grand Rounds (department of medicine, department of surgery)
October, 2001	Alan Kliger	ASN
October, 2001	Alan Kliger	DCI Annual Meeting, Tampa
October, 2001	Alan Kliger	Medical Technicians of Connecticut, Annual Meeting
October, 2001	Linda Duval	Network 13, Fall 2001 Workshop Series
October 4, 2001	John Newmann	NKF, New York
October 4, 2001	Barbara Fivush	MRB of Network 5
October 24, 2001	Alan Kliger	Yale University Pediatric Grand Rounds
November 9, 2001	Peter DeOreo	Ohio Renal Administrators, Columbus, Ohio
November 17, 2001	Peter DeOreo	Texas Network Annual Meeting
December 5, 2001	John Newmann	Forum Network 1, Philadelphia
January, 2002	Alan Kliger	RRI
March, 2002	Glenda Harbert	Annual Dialysis Conference in Tampa
May 10, 2002	Barbara Fivush	Network 5 Spring Council Meeting

APPENDIX H

List of Participants and Organizations
By Collaborative Action Team

List of Phase II Participants
By Collaborative Action Team

Action Team #1, Taxonomy

Chester Amedia, Jr.	*Renal Disease Management*
Rebecca DeVivo	*National Patient Safety Foundation*
Eugene Freund	*Health Care Financing Administration*
Maureen Herget	*Fresenius Medical Care*
Shirley Kellie	*Health Care Financing Administration*
Coleman Mosley (Team Leader)	*Renaissance Healthcare*
Janel Parker	*Nephrology Nursing Certification Commission*
Marie Reid	*Food and Drug Administration*
Dick Sawyer	*Food and Drug Administration*
Michael Sorkin	*AdvaMed*

Action Team #7, Surveys

Rebecca DeVivo	*National Patient Safety Foundation*
Diane Frankenfield	*Health Care Financing Administration, OCSQ*
Wendy Funk-Schrag (Team Leader)	*Council of Nephrology Social Work*
Pat Hansen	*National Renal Administrators Association*
Glenda Harbert	*Forum of ESRD Networks*
Judith Kari	*Health Care Financing Administration*
Paul McGinnis Replaced by Drew Silverman	*American Association of Kidney Patients*
Allen Nissenson	*Renal Physicians Association*
Glenda Payne	*Texas Department of Health*
Maureen Potter Replaced by Dorothy Hailston	*RMS Disease Management and Lifeline*

Action Team #11, Best Practices

Susan Bray	*American Society of Nephrology*
Marilyn Campbell (Team Leader)	*Dialysis Clinic, Inc.*
Rebecca DeVivo	*National Patient Safety Foundation*
Pamela Frederick	*Health Care Financing Administration, OCSQ*
Bertram Kasiske (No longer active)	*American Society of Transplantation*
Robert Kossman	*Renal Physicians Association*
Lori Lambert Replaced by Susan Reams	*National Kidney Foundation's Council on Renal Nutrition*
Jerry Tokars	*Centers for Disease Control and Prevention*
Richard Ward	*Association for the Advancement of Medical Instrumentation*

Action Team #17, Education and Training

Carl W. Armstrong	*Hospital & Health System Association of Pennsylvania*
Peter DeOreo	*Forum of ESRD Networks*
Rebecca DeVivo	*National Patient Safety Foundation*
Barbara Fivush	*American Society of Pediatric Nephrology*
Carol Lynn Hallal	*National Kidney Foundation*
Curtis Johnson	*University of Wisconsin*
Jenny Kitsen	*Network of New England*
Alan Kliger	*Renal Physicians Association*
Joe Mazzilli	*National Association of Nephrology Technicians*
Jean Nardini	*American Nephrology Nurses Association*
John Newmann	*American Kidney Fund*
Ida Sarsitis (Team Leader)	*Health Care Financing Administration*

Steering Committee

Janet Crow	*Forum of ESRD Networks*
Peter DeOreo	*Forum of ESRD Networks*
Rebecca DeVivo	*National Patient Safety Foundation*
Lou Diamond	*National Patient Safety Foundation*
Alan Kliger	*Renal Physicians Association*
Robert Kossman	*Renal Physicians Association*
Allen Nissenson	*Renal Physicians Association*
Dale Singer	Renal Physicians Association