Collaborative Leadership for ESRD Patient Safety

Phase 1 Report of the National Patient Safety Consensus for the Community of Stakeholders in End Stage Renal Disease

An Application of the National Patient Safety Foundation’s Applications and Learning Program Collaborative Action Planning Model

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The most meaningful thing a reader of this report can do is to embrace the voice of representative stakeholders in the ESRD community in their directive to ‘educate and train the ESRD program leadership on the nature of the problem, and in the safety sciences; and to forge agreement on the definition of medical errors specific to the context of ESRD.’ Then ask one’s self “how can I get involved?”
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Acknowledgements

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EXECUTIVE SUMMARY

Forty-two stakeholder representatives and nine observers from 34 organizations involved in the care of End Stage Renal Disease (ESRD) described fifty-nine challenges to ESRD patient safety and proposed more than forty actions for addressing these challenges. The representatives were engaged in a collaborative action planning workshop that was facilitated with a methodology founded in the systems sciences. Unanimous convergence was achieved on two highly influential actions as the highest priority. The key directive from the ESRD Patient Safety workshop is to launch the next stage of this initiative in collaborative leadership with the two dozen people that have indicated their commitment to: educate and train the ESRD program leadership on the nature of the problem, and in the safety sciences; and to forge agreement on the definition of medical errors specific to the context of ESRD.

Before the workshop, interviews and a limited literature review identified a variety of possible problems with ESRD patient safety and articulated many possible approaches to improving patient safety in this area. Although most interviewees asserted that serious problems with ESRD patient safety exist, most also agreed that the concepts of medical error and patient safety are ill-defined in this area and that more data will be needed. Adverse events during hemodialysis were described as prototypical problems, but many other potential areas were also identified and many possible contributing factors were described. These included: staff training and turnover, cost pressures, reporting of problems, oversight and regulation, water purification, dialyzer reuse, medication errors, patient compliance, patient education, primary care, prevention, vascular access, infection, location and layout of dialysis units, and the increased age and comorbidities of the ESRD population. Respondents also mentioned the failure to adequately treat comorbidities, provide adequate amounts of dialysis, accomplish timely and efficient transplantation, or adequately encourage home hemodialysis and peritoneal dialysis.

In the first stage of the workshop, participants described and clarified fifty-nine anticipated challenges. The participants identified the fourteen challenges they
considered the most important to address. Through a robust investigation of influences among the challenges, decided by over seventy strong majority opinions, three key drivers were agreed upon:

- **Lack of agreement on what constitutes a medical error.**
- **Difficulty in gathering relevant data without appropriate legal protection from litigation or regulatory action.**
- **The need for financial and other support to reduce errors.**

Two features of this analysis stood out. First of all, although the triggering question describes the goal of improving “patient safety,” the clarifications and discussions about two of these three most influential drivers focused more narrowly on “medical error.” Secondly, one of the most influential drivers, and a number of less influential ones, focused on collecting data. Two of these recommended “achieving the appropriate balance between confidentiality and public accountability,” and “removing the element of blame” in the culture of dialysis units. The driver of these two challenges emphasizes the need to address the legal and regulatory issues, if possible, before tackling the issues of confidentiality or blame. Interpreters of these findings intimated that actions directed to achieving better alignment on “what error means” within the overall ESRD community and within the units would at least decrease the confusion in approaching these other challenges.

In the second stage of the workshop the participants generated and clarified more than forty-five proposed actions with emphasis on the three most influential challenges. Participants identified the thirteen most important action options.

In the third stage of the workshop these action options were considered for inclusion in the initiative by eight small teams. Six action options stood out both with respect to the importance attributed to them by the teams and their leverage on the three most influential challenges. Two actions clearly related to the need to define relevant concepts of medical error and patient safety within the context of ESRD:

- **Create a taskforce of stakeholders and experts on patient safety to agree on definitions of medical errors.**
• **Conduct education and training for the ESRD program leadership on the nature of the problem and in the safety sciences.**

Two influential action options related to data collection:

• **Establish a central clearinghouse for patient safety for ESRD, including definitions, programs, real-time error tracking, that would be available at no charge to dialysis facilities.**

• **Create a database of medical errors and near-misses maintained by a non-regulatory group and protected from legal disclosure.**

Two influential options related to policy changes that would help support any initiative:

• **Make patient safety a high priority for ESRD networks and PRO’s to leverage current funding for these organizations as well as state health departments.**

• **Support incorporation of patient safety activities into the conditions of coverage for ESRD.**

Of these six influential action options, the first two – related to concept definition – were the highest ranked and unanimously endorsed by the eight teams. They call for the inculcation of lessons of patient safety from other medical communities, and drawing on the fields of systems science and safety science, in order to align the ESRD community on the challenge of patient safety and actions to address it.

In stage four, conducted via a follow-up DELPHI survey, workshop participants were asked to confirm their commitment to collaborative leadership on the top ten of their recommended actions. As of the date of this report, twenty-four participants from the ESRD community have expressed their commitment to inter-organizational collaboration on selected actions in the launch of the next phase of this initiative.

Twenty-four of these respondents have identified their interests to focus their effort on addressing these most widely endorsed, and highly influential actions. This feedback further supports the participant’s directive that the highest priority should be accorded to:
• Create a taskforce of stakeholders and experts on patient safety to agree on definitions of medical errors.

  Stakeholders would be a group such as the one assembled today, plus people with knowledge of patient safety from other disciplines. The taskforce could operate in a number of ways, including data collection, surveys, or other activities.

• Conduct education and training for the ESRD program leadership on the nature of the problem and in the safety sciences.

  The focus here is on the leadership: without leadership buy-in we can't succeed. Leadership includes people such as those in this room: leadership of payers, individual units, networks, etc.
INTRODUCTION

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 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, patients, and others 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), Forum of ESRD Networks (Forum), and the National Patient Safety Foundation (NPSF) initiated a project to address these issues. It was launched with a workshop that is the subject of this report.

The findings in this report, and participant commitment to the consensus actions complete Phase One of this initiative. These findings represent the voice of representative stakeholders of the ESRD community that participated in the workshop. Their statements, clarifications, and dialogue are preserved in their original form in this report as documented and distributed during the workshop.

Forty-two participants, and nine observers, representing doctors, nurses, technicians, social workers, nutritionists, administrators, regulators, and patients participated in the workshop on October 30-31, 2000. The list of participants and their organizations is presented in Appendix A. 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 in the near future.

PRE-WORKSHOP DISCUSSION PAPER

A Discussion Paper was produced in preparation for the workshop, based on interviews with fifteen representative stakeholders and a limited literature review. This analysis revealed that the definition of terms and the collection of data in this field are in their infancy. Adverse events that occur during hemodialysis serve as prototypical cases of the failure to assure patient safety, and almost every interviewee could describe specific cases in their experience. Cases described included the following: a patient being dialyzed with the wrong dialyzer or the incorrect dialysate; significant blood loss
occurring due to a leak in the system; and inadequate water purification causing illness in multiple dialysis patients. Of note, though, these are almost exclusively events described anecdotally or in the popular press. There is no easily accessible information about the true prevalence of such events or their effect on outcomes: in many cases, patients did not suffer serious or long-lasting harm from the event described.

Many respondents emphasized a wide range of ways in which ESRD patient safety may be considered to be compromised, ranging from the danger of violence occurring in dialysis units to the low number of kidneys available for transplant. In all interviews, the goal of eliminating error, improving patient safety, and simply improving care blurred into one another. Many respondents mentioned a need for better definition of the terms “patient safety” and “error,” and the need for more data to assess the prevalence and effects of the various sorts of problems.

Interviewees were able to identify multiple areas where problems in ESRD patient safety may be compromised. One of the most commonly mentioned was overburdened staff, along with high staff turnover and inadequate training, and many pointed to the cost-pressures that lead to this. Cost-pressures were also implicated in other problems, such as excessive dialyzer reuse. Many respondents said that problems are insufficiently reported in the current environment, partly due to the fact that such reporting can create the risk of legal or regulatory actions. Interviewees also bemoaned that the medical field has ignored lessons from other industries that have addressed and minimized safety problems, such as aviation. Many describe a “culture” in dialysis units that blames individuals involved in adverse events or near misses rather than using such events to identify systemic problems. Respondents offered many areas that could be improved, including testing and certifying staff, oversight and regulation of dialysis units, patient education, and the primary care and prevention of ESRD. The Discussion Paper in Appendix B provides a summary description of the analysis conducted prior to the workshop.
A Guide to Reading this Report

The narrative in this report consists of two interwoven parts, one briefly explaining the system methodology used during the workshop (including graphics that are displayed as Exhibits), the other describing the findings of the workshop (including products displayed as Tables & Figures). The methodology sections simply answer the question “how did the participants get from one set of findings to another?” It is not necessary to read the methodology sections in order to understand the findings.

At the end of the report there is a compendium of the participant’s contributions that are referred to throughout the findings. We encourage you to use the narrative of the report primarily as a guide to interacting directly with the voice of the participants through the compendium in its tables and figures. For example, the first section on findings below suggests that the reader at least scan the diversity of opinions, presented in Appendix C, before continuing.
1) CHALLENGES

1.1) METHODOLOGY: DEFINING COMPLEX PROBLEMS THROUGH COLLABORATION

1.1.1) Background

The approach to Phase I of the National Patient Safety Consensus for the ESRD community is based on a Collaborative Action Planning model that has been developed for the NPSF’s Applications and Learning Program. The model uses a methodology with a long established track record of applications in the systems sciences, and has been extensively subjected to the peer-review literature of the systems community. CWA Ltd. has customized the model to the unique requirements of inter-organizational stakeholder engagement essential to the formation of collaborative leadership in patient safety.

For the sake of brevity, specific discussion on the basis of this model in systems science has not been included in this report (see Appendix H). The presentation of the methodology here is solely employed to tie the flow of the findings together for the reader.

1.1.2) The Challenge of Collaboration in Complex Situations

Any group of people, when trying to solve a complex problem confronts three challenges that actually represent opportunities.

1. First, the problem often seems vast, unwieldy, bewildering. Individual people often find one aspect of the problem easy to understand, but to each person the entire problem is overwhelming. If all the individual understandings could be somehow joined together, real progress would occur.

2. Second, individual people – depending on their backgrounds and training – perceive the problem differently, and use different terms or language to describe their perceptions. Again, uniting these differing perspectives could be a real opportunity to improve everyone’s understanding of the problem, but often groups do not allow individuals enough time to clarify their perspective so that
others understand them sufficiently, cutting short the group learning that is so essential to solving complex problem situations.

3. Finally, while no one in the group comprehends the entire problem, the group as a whole possesses a collective understanding of the problem that would enable them to map out how different components of the problem are related to each other. The trick is to devise a method that facilitates a group tapping into this collective understanding and wisdom in a constructive, goal-oriented manner.

The workshop used a facilitation methodology that addresses each of these challenges, striving to turn them into collective opportunities. The facilitation approach in this workshop proceeds through four basic stages – the first three of which are conducted during the workshop, the fourth completed in a follow-up DELPHI survey.

**Exhibit 1: The Stages of Collaborative Inquiry**

<table>
<thead>
<tr>
<th>Stage 1 Findings</th>
<th>Stage 2 Findings</th>
<th>Stage 3 Findings</th>
<th>Stage 4 Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gain a deeper appreciation of challenges</td>
<td>Generate potential solutions (Action Options)</td>
<td>Choose the most important Actions to pursue</td>
<td>Deepen collective commitment and promote effective action.</td>
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**Exhibit 2: Directory of Findings from Each Stage**

<table>
<thead>
<tr>
<th>Stage 1 Findings</th>
<th>Stage 2 Findings</th>
<th>Stage 3 Findings</th>
<th>Stage 4 Findings</th>
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<tbody>
<tr>
<td>1) Discussion Paper in Appendix B</td>
<td>1) Clarification of Action Options, Table 2 in Appendix E</td>
<td>1) Action Option Voting Results, Table 3</td>
<td>1) Commitments to Collaborative Leadership on Ten actions, the DELPHI Survey in Appendix G</td>
</tr>
<tr>
<td>2) Clarification of Challenges, Table 1 in Appendix C</td>
<td>2) Consensus Action Scenario, Figure 2</td>
<td>2) Review Committee</td>
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<td>3) Clusters of Challenges in Appendix D</td>
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<td>4) Influence Pattern of Challenges in Figure 1</td>
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1.1.3) Stage One: Gain a Deeper Appreciation of Challenges

The first stage – gaining a better appreciation of component challenges – proceeded in six steps:

1. Before the workshop, define a preliminary outline of the problem by interviewing knowledgeable people. These interviews are used as a means to provide participants at the workshop with a rough sketch of the problem, to frame the question that starts the workshop deliberations, and sensitize them to the diversity of opinion on the situation.

2. At the workshop, describe the complex problem by articulating its component parts, with participants individually listing separate challenges that they think are important parts of the complex problem, in order to simplify matters.

3. Clarify individual perceptions about these challenges in order to promote group learning.

4. Present challenges within Affinity Clusters, i.e., categories of similar characteristics, and compile individual judgments (by voting) to further understand which challenges are of higher comparative importance.

5. Use group judgments (through strong majority votes) to understand how challenges are interrelated in terms of their influence upon one another.

6. Use this collective understanding to identify the most influential of the important challenges of the problem.

The products of these steps can also be viewed as a diagram. Exhibit 3 depicts how the group decomposed the complex situation into component challenges, worked to understand exactly what these challenges meant to the individual who authored them, and then deepened their collective understanding of these challenges by seeing how they were interrelated. This results in the identification of challenges which are considered “deep drivers” of the situation (indicated by a ! in Exhibit 3) that influence the outcome of many other challenges. Resources committed to the deep drivers attain the highest overall leverage.
We now turn to the findings of the workshop during this first stage, namely gaining a deeper appreciation of the challenges to improving ESRD patient safety.
1.2) FINDINGS: THE DEFINITION OF CHALLENGES

On the first day of the workshop, stakeholders proposed and clarified responses to the following triggering question:

“What challenges do we anticipate the community of stakeholders will face in improving ESRD patient safety?”

Stakeholders described fifty-nine challenges and clarified their meanings during discussion with the entire group. The anticipated challenges and their clarifications appear as Table 1 in Appendix C. The challenges were grouped into clusters based on distinctions between challenges made by the stakeholders, during clarification. Each participant chose five challenges, ranking them from 1 to 5 (most important to less important). Fourteen challenges received at least four votes. These were used for the next step.

Note to the reader – if you were not a participant in the workshop you should at least scan Appendix C in order to appreciate the diversity of opinions about the situation before continuing. You should determine whether your perspective on ESRD Patient Safety is represented.

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1 The clusters of challenges is presented in Appendix D. Cluster analysis was conducted by a member of the facilitation team, following a prescribed analysis method, and who relied solely on distinctions between challenges invoked by individual participants and interviewees. This was done primarily to enable the participants to vote for the challenges they considered most important in the context of a categorical view of challenges. Collaboration time on this step was minimized in favor of according more time to the investigation of influences. As such it carries the caveat that not too much should be read into this particular arrangement at this stage of the project. It is primarily a tool of inquiry rather than a product.
1.3) METHODOLOGY: DETERMINING INFLUENCES AMONG THE CHALLENGES

After describing a complex problem in terms of its component parts or challenges and perspectives on the challenges, people can better plan what to do if they take the time to understand how various challenges influence other challenges. Often, through this disciplined inquiry, people are able to discover that a seemingly insignificant challenge in fact directly and indirectly affects our ability to address a wide range of other challenges; meanwhile, a challenge that initially looked to be critical in fact has little influence on any other parts of the overall problem. The facilitation method takes the group through this discovery process by focusing the group on the question: “if we surmount this challenge, will we be better able to surmount another challenge?” This question is asked repeatedly with pairs of challenges. The group collectively decides yes or no by voting, and slowly a pattern of influence emerges. A computer program helps to discern this pattern by taking the results of the voting and using some basic inference logic. (For example, if surmounting A helps us tackle B, and surmounting B helps us tackle C, then surmounting A helps us tackle C and the question “does A influence C” does not have to be posed to the group). This saved the group two thirds of the time to complete this step in a robust fashion as compared to not having such support.

Those challenges that influence many other components of the problem can be thought of as having a lot of LEVERAGE, in that if we surmount these challenges, we are significantly better off in meeting lots of other challenges.

The entire group explored the influences among the fourteen most important challenges resulting in the influence pattern represented in Figure 1 of the participant’s workbooks and also appears as Figure 1 (see page 16) of this report.
1.4) FINDINGS: THE PATTERN OF INFLUENCE AMONG THE CHALLENGES

Participants were asked relational questions that followed the following format:

“Suppose the community of stakeholders is able to make progress in meeting

(Challenge X),

will this help significantly in meeting

(Challenge Y)

in the context of designing an action agenda for improving ESRD Patient Safety?”

Based on a strong majority opinion of participant judgments about the interdependence between pairs of challenges, and the assistance of systems analysis software, an Influence Pattern was generated and is depicted in Figure 1: Influence Pattern Among the Most Important Challenges (see next page). Arrows show cases where meeting one challenge will help significantly in meeting another challenge. This diagram represents the compilation of a strong consensus. It was generated by the assertions of at least thirty-two of the forty-two participants for each of seventy-seven relational questions. Unanimous opinions grew in frequency as the inquiry progressed.

Addressing challenges that appear lower in the Influence Pattern have more wide-ranging effects than addressing ones that are higher, and thus the deeper challenges are the ones to tackle preferentially. Challenges that are lower in the influence pattern count as “more deeply leveraging” than higher ones, and this terminology will be used below.

The discussion starts with the challenges that are at the bottom level of the influence pattern and that count, therefore, as having the most leverage on other challenges. The discussion then progresses up through the levels of the influence pattern, studying various aspects of the challenges, their clarifications, and the influence relationships. Each challenge and its clarification are printed along with the discussion. Note that the statement of challenges and their clarifications are printed in italic type to emphasize that these words are quoted or paraphrased from the stakeholders’ comments.
Figure 1: Influence Pattern among Most Important Challenges

LEVEL I

13 - Challenge
UNDERSTANDING HOW TO TRAIN AND EDUCATE PATIENT-CARE STAFF

LEVEL II

19 - Challenge
ACHIEVING A COMPREHENSIVE APPROACH TO PATIENT SAFETY THAT INCLUDES BOTH REGULATORY AND NON-REGULATORY APPROACHES

LEVEL III

9 - Challenge
ENSURING THAT ERROR REDUCTION TECHNOLOGIES THAT ALREADY HAVE BEEN DEVELOPED ARE DISSEMINATED AND WIDELY USED

LEVEL IV

8 - Challenge
OBTAIN ACCURATE DATA TO DETERMINE PROBLEM AREAS AND TO DEVELOP BASELINE MEASURES OF CURRENT SAFETY

LEVEL V

22 - Challenge
ENSURING INFORMATION GATHERING AND PROCESSES CROSS PHYSICAL VENUES

LEVEL VI

5 - Challenge
RESOURCES ARE LIMITED. OUR COMMUNITY SHOULD ONLY PURSUE QUESTIONS THAT ARE LIKELY TO HAVE AN IMPACT ON OUTCOMES. THE FIRST CHALLENGE IS TO GENERATE ESTIMATES OF THE MAGNITUDE OF THE PROBLEM AND TO ESTIMATE COST OF HOW TO FIX IT

35 - Challenge
TO DEVELOP A REPORTING SYSTEM THAT ENCOURAGES THE FULL REPORTING OF "ERRORS" AND THEIR ROOT CAUSES BY ACHIEVING THE APPROPRIATE BALANCE BETWEEN CONFIDENTIALITY AND PUBLIC ACCOUNTABILITY

25 - Challenge
THE NEED FOR FINANCIAL AND OTHER SUPPORT TO REDUCE ERRORS

23 - Challenge
DIFFICULTY IN INVOLVING OR ACHIEVING BUY-IN BY ALL LOCAL STAKEHOLDERS (THAT IS MANDATORY VS. INCENTIVIZED PROCESSES)

3 - Challenge
LACK OF AGREEMENT ON WHAT CONSTITUTES A MEDICAL ERROR, A LACK OF COMMON TAXONOMY

7 - Challenge
DIFFICULTY IN GATHERING RELEVANT DATA WITHOUT APPROPRIATE LEGAL PROTECTION FROM LITIGATION OR REGULATORY ACTION

KEY

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<td>Y</td>
<td>Addressing X</td>
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<tr>
<td>X</td>
<td>Significantly Helps in Addressing Y</td>
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Produced by the participants at the NPSF/RPA/FOURM Workshop -- October 30, 2000
1.4.1) Level VI: Deep Drivers of The Situation

Three challenges were found to have the deepest leverage (highly-leveraging) among the most important challenges identified by participants. These three challenges are discussed in this section.

Challenge 3: Lack of agreement on what constitutes a medical error, a lack of a common taxonomy. Clarification:

In our various constituencies there is a lack of knowledge of what, for instance, a near miss is. That’s a lack we have to recognize if we are to identify a way to identify and decrease near misses. We have to come to an agreement on a common language. “Medical error” is meant as a generic term, not limited to physician error, for instance. It’s meant to refer to a system error.

In interviews conducted before the workshop, multiple respondents bemoaned the lack of a common definition of what counts as a medical error, both in general and within ESRD in particular. The triggering question specifically refers to patient safety rather than medical error, but stakeholders emphasized medical error in stating this and other challenges. Many recent studies in the area of patient safety emphasize occurrence of medical errors, most influentially the recent IOM report on this topic (Kohn et al 2000). In pre-workshop interviews, many people emphasized the importance of eliminating errors in improving ESRD patient safety.

The clarification of this challenge also emphasizes the idea of a “near miss” and that “error” refers to “system error.” Once again, these are topics that arose multiple times in the pre-workshop interviews. The safety sciences and safety improvement programs in other industries predominantly treat errors as problems with the system rather than simply the people involved in executing the system. This approach discourages blaming individuals, instead using adverse events as an opportunity to make changes that will help avoid such events in the future. In this paradigm, “near misses” become valuable opportunities to identify areas where improvements can be made before anyone suffers great harm.

But what exactly comprise errors or near misses in the treatment of ESRD, and
how is this related to patient safety? The influential IOM report defines “safety” as “freedom from accidental injury,” and defines “error” as “failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim” (p. 4). Specific adverse events during hemodialysis may be prototypical errors, such as when a patient is treated with another patient’s dialyzer or with a dialysate that has a dangerous amount of potassium for him or her.

Questions immediately arise, both in making sense of this terminology in general and in applying it to ESRD. According to the IOM definition, it seems that any adverse event during ESRD treatment could count as an error in some sense, since adverse events are certainly never “planned.” Is this the intention of the stakeholders? Of the different ways in which ESRD treatment may fall short of the ideal, which of these count as errors? Which are near misses? How do these concepts in other areas, such as peritoneal dialysis or transplantation? Is the relevant standard “ideal” treatment or just treatment that matches the standard of care? How should we classify the failure to screen and preventatively treat an ESRD patient at risk for coronary artery disease? These questions seem to be the sort that need answers if the stakeholders are to develop a “common taxonomy” or a “common language,” as emphasized by the author of this challenge.

Challenge 7: Difficulty in gathering relevant data without appropriate legal protection from litigation or regulatory action. Clarification:

Right now there’s a vulnerability in collecting data, with regard to its use in malpractice or regulation. We can’t get that data without some protection. There’s no protection right now. Any effort at data collection at a national level, outside of a hospital, is not protected from use in a legal or regulatory context.

Agreeing on common definitions will not help improve patient safety unless they lead to the identification of actual errors and near misses, and it will be necessary to collect other data as well about the treatment of ESRD. In pre-workshop interviews, people described this challenge in various ways, recommending for instance that hemodialysis (HD) units “make errors visible and learn from them,” “train staff to recognize errors and deal with them,” “create an environment of learning and quality improvement,” “support a non-blame culture,” and/ or institute Continuous Quality Improvement methodology. All these proposals have the goal of encouraging people to
report problems and collect the data they need. Staff must not feel that they will be punished in some way for doing so.

As Challenge 7 emphasizes, such reporting is strongly inhibited by the possibility that it could be used in litigation or regulatory action. Furthermore, it is not easy to restrict such uses, because of the demands of regulators to evaluate dialysis units and of patients to have legal remedies in at least some situations. Expertise in law and regulatory policy, and possible legislation, could be needed to address this challenge. However, this challenge’s deeply leveraging position in the influence pattern indicates that addressing these issues would significantly help meeting many other challenges.

**Challenge 25: The need for financial and other support to reduce errors.**

Clarification:

*Many people have talked about resource and financial issues, for example in collecting data, but this challenge is meant to broaden that. If we as a community strongly believe that patient safety is a priority for us, then resources and money will have to be allotted to our activities. It will take money if we want to improve recruitment and maintenance of staff, for example. If we decide to add computers at point-of-service to improve patient safety, for example, that would have a high price tag too.*

The mention of the previous discussion regarding “resource and financial issues” refers to challenges presented and clarified before this one at the workshop. One of these was Challenge 4: *Conflict between financial viability and an appropriate use of resources to achieve resources.* The clarification for this challenge says, “*Today we are challenged to ‘pay our way’ with increasingly restricted resources, trying to achieve excellence in multiple arenas: staffing, technology, patient education, patient care, etc. Trying to spend our money appropriately in all these arenas is difficult.*” Challenge 5 also appears relevant. Part of this challenge reads, “*Resources are limited,*” and the clarification includes the author’s comment that “*It’s not easy to collect data: even paying people at high rates to do this, it’s a painful process. In dialysis units, even the most well meaning staff are just busy, busy, busy. It’s a real challenge to find money to do this kind of studies we may want to do.*” (Challenge 5 also received a deep position in the influence pattern, as will be discussed below (Level V).)

As the clarification emphasizes, Challenge 25 is meant to be even broader than
these other challenges, including the need to obtain support for any and all activities related to improving patient safety. The author specifically points to the cost of improving staff training and retention and the cost of buying new computer systems. As mentioned in the White Paper, interviewees listed staff training and retention highest when asked to rank significant problems with ESRD patient safety (see the Discussion Paper, in Appendix B and discussion on pp. 3-4). Many pointed to the low pay of these positions and the resulting high turnover, and many identified stagnant (or even decreasing) governmental reimbursement for dialysis treatment as a key cause for the low pay. The need to improve and expand computer systems was mentioned in interviews as part of various initiatives, including improved patient-record keeping and data collection. Computers have been successfully utilized in patient safety initiatives in other areas, such as reducing prescription errors.

But as Challenge 25 emphasizes, collecting better data, improving staff training and retention, and buying computers are only three possible areas for ESRD patient safety improvement that will cost money. The full list of possible areas of expense depend on the shape and progress of the project to improve safety. The fact that Challenge 25 is stated so generally may have contributed to its deep position in the influence pattern.

1.4.2) Level V

These challenges fall on the second-deepest level in the Influence Pattern and thus will also be crucial to any attempt to improve ESRD patient safety. Level V is also the most highly-populated level, with six challenges. Two pairs of challenges at this level form “reinforcing cycles,” with Challenges 6 and 12 in one and Challenges 11 and 23 in the other. In each of these cycles, meeting each of the challenges will “help significantly in meeting the other.” This section of the report discusses all challenges at this level, their clarifications, and their influence relationships.
Challenge 5: Resources are limited. Our community should only pursue questions that are likely to have an impact on outcomes. The first challenge is to generate estimates of the magnitude of the problem and to estimate the cost of how to fix it. Clarification:

It’s not easy to collect data: even paying people at high rates to do this, it’s a painful process. In dialysis units, even the most well meaning staff are just busy, busy, busy. It’s a real challenge to find money to do the kind of studies we may want to do. What’s striking is that we don’t have much of an estimate of how big a problem ESRD patient safety is. Are changes likely to yield an outcome that is worth the money we’ll need to invest in bringing them about? The federal government is cheap, so you have to make a case that there is a problem.

Parts of this challenge and its clarification were discussed in the last section (under Challenge 25), but now we can see that there’s more to it. In particular, Challenge 5 insists on the importance of estimating the magnitude of the problem and the cost of fixing it, and remaining focused on making changes that “have an impact on outcomes.” As the influence pattern indicates, addressing Challenge 3 will significantly aid in addressing Challenge 5: agreeing on a common language and taxonomy of error will help, for example, in estimating the magnitude and cost of the problem.

Almost everybody in the pre-workshop interviews mentioned the need for more data to delineate the scope and nature of the problem. The need for such data was the second highest-ranked problem facing ESRD patient safety (see the Discussion Paper in Appendix B, and discussion p. 2). In addition, interviewees linked this deficiency to a lack of well-accepted definitions of error and patient safety. Challenge 5 and its clarification also links the drive for data to the search for support for improvement efforts. Data that convincingly shows a problem, supplemented if possible with studies showing how changes can improve outcome, will be necessary to convince the government and other funding entities to support any initiative.

Challenge 35: To develop a reporting system that encourages the full reporting of ‘errors’ and their root causes by achieving the appropriate balance between confidentiality and public accountability. Clarification:
Relates to Challenge 7. There has to be confidentiality if errors are going to surface and information necessary to do root cause analysis is to become available. But there also needs to be public accountability of the institutions involved. Have to balance these two needs. Includes the issue of obtaining informed consent, for example as now happens when patients apply for Medicare coverage of their treatment.

This challenge’s clarification emphasizes its relation to Challenge 7, and the influence pattern confirms this connection. Whereas Challenge 7 emphasizes protection of reporting from legal and regulatory use, Challenge 35 emphasizes the need for confidentiality. And just as meeting Challenge 7 must be balanced against legal and regulatory needs, providing confidentiality must be balanced with “public accountability of the institutions involved.” Challenges 7 and 35 highlight two aspects of a multi-faceted problem.

It should not escape attention, though, that stakeholders placed Challenge 7 at a deeper level in the influence pattern than Challenge 35. This suggests that protecting data from legal and regulatory use is more deeply leveraging than protecting confidentiality, and thus the legal and regulatory issues ought to have priority (in at least one sense).

Reinforcing cycle (challenges which are mutually influential):

Challenge 6: Engaging patients in their role in their care. Clarification:

The only factor that is constant across the ESRD care continuum is the patient; empowering the patient would have therefore substantial effects. This engagement would include education, but not be limited to education.

Challenge 12: Mismatch between the growing number of patients and the available workforce. Clarification:

There is only so much time in the day, and only so many people to do the work; as we add more tasks, specifically regarding the monitoring and improvement of patient safety, we will need more people: not just those with direct patient care roles (physicians, technicians, nurses, social workers, etc.), but also clerical workers. The shortfall in the workforce reflects both insufficient ‘training pipeline’ output and inadequate funding for adequate staffing and retention.

As mentioned above, these two challenges form a “reinforcing cycle”: making progress in meeting Challenge 6 would significantly help meeting Challenge 12, and vice
versa. We can make sense of the connection as follows: Meeting Challenge 6 would help meet Challenge 12, since patients’ becoming involved in their own care could help ease over-burdened health-care providers. And meeting Challenge 12 could aid meeting Challenge 6, presumably, since increasing the workforce would allow more time and manpower to educate or empower patients to take a more active role in their own care.

Challenge 6’s clarification emphasizes that improving education is an important tool in increasing patient involvement in their care. During pre-workshop interviews, respondents described patient education as the third-highest ranked problem facing ESRD patient safety (see the Discussion Paper in Appendix B and discussion p. 6). Patients range from being very involved in their care to being almost completely uninvolved. A number of interviewees asserted that the “do for me” attitude exhibited by some is one of the most important risk factors for suffering adverse events. Behaviors that can help patients protect themselves range from being more conscientious taking prescribed medications to being more attentive during dialysis and asking more questions of medical professionals.

Challenge 12 and its position in the influence pattern emphasizes that the high workload and time pressure faced by health care providers probably contributes significantly to problems with ESRD patient safety. Addressing the even more deeply-leveraging Challenge 25 (Level VI) would significantly aid in meeting Challenge 12.

**Reinforcing cycle (challenges which are mutually influential):**

**Challenge 11: Removing the element of blame and endorsing an atmosphere of improvement for proposed action.** Clarification:

*This point relates to data issues, since a disincentive to report interferes with the collection of data. It also relates to culture issues: if there’s a mistake and we just blame the person involved, then we’re not doing what we should do to improve the system.*

**Challenge 23: Difficulty in involving or achieving buy-in by all local stakeholders (that is mandatory vs. incentivized processes).** Clarification:

*Related to Challenge 10 and Challenge 13. Assuring ESRD patient safety involves many people doing many different things. It includes, for example, a housekeeping clerk mopping the floor and a truck driver not leaving dialysate outside in cold weather. How do we involve these
workers in the process of improving patient care? Any attempt to improve ESRD patient safety will likely result in additional mandatory requirements affecting such workers, and this will reduce “buy-in” by them.

Challenge 11 emphasizes the importance of “eliminating blame” and creating a conducive “atmosphere” in making progress in improving ESRD patient safety. These were clearly influential concerns for stakeholders: this challenge received more votes than any other challenge and it has a deeply leveraging position in the influence pattern. As mentioned above (in the discussion of Challenge 7), the goal of creating a “non-blame culture” was prominently mentioned in pre-workshop interviews.

In the clarification, the author of Challenge 23 mentions how a truck driver’s decision – to leave dialysate outside in freezing cold weather -- can affect ESRD patient safety. It’s tempting to overlook such actors and roles, focusing on health care professionals instead, but this example highlights the range of people whose actions will be crucial to improvements in this area.

The interaction of these two challenges, highlighted by their position in a reinforcing cycle, makes sense: creating a non-blame culture will help aid buy-in by all relevant actors, and vice versa. The influence pattern also highlights an important relationship between Challenges 7, 35, and 11. In the attempt to improve data collection, addressing regulatory and legal issues (Challenge 7) has priority (in one sense) over addressing confidentiality (Challenge 35) or creating a blame-free environment (Challenge 11). Note however, that if the most deeply-leveraging Challenge 7 cannot be met, then Challenges 35 and 11 are the appropriate places to start.

1.4.3) Level IV

Challenge 22: Ensuring information gathering and processes cross physical venues.

Clarification:

The salient aspect here is this notion of ‘crossing’: since patients spend time in many venues, from home to intensive care units of hospitals, we need to focus across all these venues and ensure that information and safety-improvement processes flow across them.

Challenge 22 addresses a very interesting part of the issue: the many different
venues in which care for ESRD is provided. Perhaps the most interesting aspect of this challenge arises from its place in the influence pattern: it will be “significantly affected” by meeting any and all challenges at deeper levels (every challenge at Level V is linked to Challenge 22).

1.4.4) Level III

At this level of the influence pattern, there are only two challenges, and their connections to the challenges at lower levels are very interesting. All the challenges at Level V influence Challenge 8 and none influence Challenge 9. Only challenges at Level VI (Challenges 3 and 25) influence Challenge 9. The two challenges at Level III represent what might be considered the two sides of improving ESRD patient safety: understanding the problem and addressing it. Then these two sides come together at Level II, with both influencing Challenge 19.

Challenge 8: Obtain accurate data to determine problem areas and to develop baseline measures of current safety. Clarification:

If our challenge as a group is to improve patient safety, we need to know what we are dealing with; this requires us to obtain accurate data in a timely manner. This idea is similar to Challenge 5.

This challenge once again emphasizes the need to gather data concerning ESRD patient safety, and its position in the influence pattern indicates that meeting any and all challenges at lower levels will aid in meeting it.

Challenge 9: Ensuring that error reduction technologies that already have been developed are disseminated and widely used. Clarification:

There’s no need for us to reinvent the wheel. The pharmaceutical area, for instance, already has developed ways to minimize prescription mistakes, and these techniques are not being used in dialysis units. Another example is connectivity, making it impossible to connect things incorrectly. (For example, a computer’s ports are each different, so you can’t connect a cord to the wrong port.) We had a patient who died recently since TPN solution was infused into her peritoneal dialysis catheter. Ensuring implementation of these techniques also involves ensuring financial support for such implementation.

This challenge emphasizes the importance of adopting techniques that work from
other fields, both within medicine and outside (e.g. in pharmaceuticals). Just as collecting data will be important, as emphasized by the other challenge at this level, so will be collecting lessons from the safety sciences and previously successful initiatives in other areas. The influence pattern shows that meeting this challenge would be helped by meeting Challenge 25 and Challenge 3 and this also makes sense: once a “common taxonomy” of medical error has been identified, and once support for an initiative has been garnered, the relevance and possible usefulness of techniques used in other areas will be clearer.

1.4.5) Levels II and I

Challenges residing at these levels are the ones with the least leverage on solving other problems. This is not to say that stakeholders thought that these challenges were unimportant: Challenge 19 received the 8th highest number of votes and Challenge 13 the 10th out of the 60 proposed challenges. But their position in the influence pattern indicates that meeting other challenges would help in meeting a higher number of the problems with ESRD patient safety.

Challenge 19: Achieving a comprehensive approach to patient safety that includes both regulatory and non-regulatory approaches. Clarification:

There are reasonable concerns about the potential punitive use of information collected in an effort to improve patient safety. But there are also reasons why regulators need information to ensure patient safety. We as a group need to construct a safe way to provide that data.

There’s a role for helping entities improve safety, but if an entity is unsafe and remains unsafe the regulatory agency has to close it down. This is something that only a regulatory agency can do and it’s an important part of ensuring patient safety.

Like the deeply leveraging Challenges 7 and 11, this challenge emphasizes the importance of striking a balance between the need for confidentiality and possible regulatory use of data collected in assessing patient safety. This challenge may have been distinguished from those earlier ones partly on the basis of its demand for a “comprehensive approach.” Although such an approach is desirable (as seen in the importance given this challenge in voting), it may not be a good first step.
Challenge 13: Understanding how to train and educate patient-care staff.

Clarification:

This point refers to the often-heard concerns that staff don’t understand what they need to do, perhaps partially because of high turnover and the need to train many new people quickly. There may be other disciplines where training and engaging the person being trained may be done more effectively than what has customarily been done in the ESRD community. If so, these insights should be utilized in training and educating patient-care staff.

This challenge harkens back to challenges that were positioned deeper in the influence pattern and also concerned the ESRD treatment workforce, for example in Challenges 12 and 23. Unlike those, this one concentrates on the issue of training and education. Stakeholders judged the challenge of addressing such issues as having little leverage on other important challenges, and thus it is positioned at Level I of the influence pattern. Making progress in addressing other challenges will aid in addressing this one, rather than vice versa.

Challenge 19 and 13 can be viewed as target objectives of this initiative, but the collective judgment of the group indicates that resources towards that end would be more highly leveraging if focused on deeper levels such as Level VI in addressing Challenges 3, 7 and 25.

Six participants studied the implications of the influence pattern of challenges and presented their interpretation of it based on their personal experience.
The Wall Display of the System of Challenges

This wall display was employed to illustrate participant’s interpretation of the anticipated pathways of challenges they will jointly face in collaborative action to address ESRD Patient Safety. There were a variety of interpretive styles employed.

Some participants “walked through” the pathways, starting with a deep driver such as Challenge 3 in Level VI. They were oriented to the influences between the challenges illustrating how addressing one challenge would help address other challenges along the way drawing on their personal experience. Others employed the display as a story board to highlight the personal meaning of individual challenges. Another style was to start with a challenge that before the workshop they thought was very important, such as Challenge 9 in Level III. They then shared the insight they gained from the structured dialogue amongst the participants that convinced them that there were deeper challenges that would impede progress if not adequately addressed. There was a participant that focused directly on Challenge 6 of Engaging patients in their role in their care. They highlighted how a focus on self-care would leverage challenges all the way up to Level I and then considered the challenges that need to be addressed in order to enable such a focus. Finally, one participant started from the standpoint of having addressed Challenge 13 Understanding how to train and educate patient-care staff, at Level I, and “looked back” to recount all the challenges they met along the way.

The credit for this photograph is accorded to one of the participants that felt it was important in assisting participants in sharing their workshop experience with others not in attendance. The wall display is the same as Figure 1.
2) ACTIONS

2.1) METHODOLOGY: DESIGNING ALTERNATIVE ACTION SCENARIOS

2.1.1) Stage Two and Three: Gain a Better Appreciation of Possible Actions

Having gained a deeper appreciation of the challenges as articulated by different individuals, and their interdependencies, the group next moves on to consider what can be done to surmount these challenges. The second stage proceeds in four steps:

1. Envision parts of the solution to the overall problem, with participants individually listing separate potential action options that address specific challenges.

2. Clarify individual perceptions about each action option, in order to promote group learning.

3. Cluster Action Options based on their similarity and compile individual judgments (by voting) to further understand which action options are of higher comparative importance.

4. Use this collective understanding to identify the most important action options.

In Stage 3 the teams construct alternative action scenarios. The teams achieve a working consensus on which Actions to include in each team’s proposed scenario and present it to the group.

Again, a diagram is helpful in seeing how the group moves from listing a wide variety of potential action options, to deepening their understanding of how these possible actions are similar to and different from each other, and finally choosing the most important action options and assembling them into alternative action scenarios.
### Exhibit 4: Displaying the Products of the Steps of Stage Two and Three

<table>
<thead>
<tr>
<th>Action Options</th>
<th>Classification of Action Options</th>
<th>Alternative Action Scenarios</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>2</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>3</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>Etc.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Stage 2: Steps 1-2 | Stage 2: Steps 3-4 | Stage 3

Different groups will devise alternative scenarios. Some groups will prioritize those action options that address very influential challenges (designated by a ! in the diagram) as the first steps to be taken, whereas other groups might delay taking these actions until later. Having the groups explain their reasoning underlying their scenario provides another opportunity for group learning and advances the group towards making the wisest choices of what actions to pursue and how.

We now turn to the findings of the workshop regarding potential solutions to the complex problem of enhancing ESRD patient safety.
2.2) FINDINGS: THE ACTION OPTIONS

On the second day of the workshop, the stakeholders proposed and clarified ways to improve ESRD patient safety. The stakeholders were divided into eight groups, and each group selected one of the three challenges from Level VI of the influence pattern (i.e. Challenges 3, 7, or 25) on which to concentrate. Stakeholders then proposed action options in response to the following triggering question:

“What are action options which, if adopted and implemented by the community of stakeholders, will help in meeting this particular challenge?”

Participants generated and clarified forty-seven Action Options, which appears as Table 2 in Appendix E.

Note to the reader – if you were not a participant in the workshop you should at least scan Appendix E in order to appreciate the variety of alternatives in addressing the situation before continuing.

The workshop participants grouped similar action options together in “clusters,” and drew distinctions amongst them by responding to questions according to the following format:

“In the context of designing an action agenda for improving ESRD Patient Safety, does:

(Action Option X)

have significant characteristics in common with

(Action Option Y)?”

The resulting clusters form the basis for the categorical view of action options which was provided to the workshop participants. This pattern was also displayed on the walls of the facilitation room. Participants were engaged in developing names that would characterize the overall intent of each cluster. In the context of this categorical view of stakeholder intentions, participants then voted for the action options they judged to be most important.

Teams of stakeholders were asked to consider on how they would combine action options to improve ESRD patient safety. They presented selections as “scenarios” to the
group, also explaining how their plan would meet specific Challenges from Day One. The Action Options that received four or more votes from individuals, and that were employed in at least half of the scenarios, are listed in Table 3: Action Option Voting Results. They are also presented in the context of the affinity clusters as Figure 2: Consensus Action Scenario (see pages 34 to 36).

In this section, we discuss these action options, their clarifications, and their importance as indicated by the day’s voting. The discussion will concentrate on one cluster at a time, emphasizing the most preferred action options within the cluster. Where relevant, we will analyze the relationships to Challenges that were identified previously (again, concentrating on the most highly-leveraging challenges). The clusters are discussed roughly in the order in which they might be tackled in an initiative to improve ESRD patient safety.
Table 3: Voting Results on Action Options for Meeting the System of Challenges (Individual Votes and Team Scenarios Votes)

<table>
<thead>
<tr>
<th>Team Scenario</th>
<th>Individual Votes</th>
<th>Action Option:</th>
</tr>
</thead>
<tbody>
<tr>
<td>All 8 Teams</td>
<td>(29)*</td>
<td>(1 - Action Option) CREATE A TASKFORCE OF STAKEHOLDERS AND EXPERTS ON PATIENT SAFETY TO AGREE ON DEFINITIONS OF MEDICAL ERRORS (Cluster #1).</td>
</tr>
<tr>
<td>All 8 Teams</td>
<td>(20) *</td>
<td>(17 - Action Option) CONDUCT EDUCATION AND TRAINING FOR THE ESRD PROGRAM LEADERSHIP ON THE NATURE OF THE PROBLEM AND IN THE SAFETY SCIENCES (Cluster #4).</td>
</tr>
<tr>
<td>6 Teams</td>
<td>(19) *</td>
<td>(20 - Action Option) ESTABLISH A CENTRAL CLEARINGHOUSE FOR PATIENT SAFETY FOR ESRD, INCLUDING DEFINITIONS, PROGRAMS, REAL-TIME ERROR TRACKING, THAT WOULD BE AVAILABLE AT NO CHARGE TO DIALYSIS FACILITIES (Cluster #2).</td>
</tr>
<tr>
<td>3 Teams</td>
<td>(13)</td>
<td>(28 - Action Option) MAKE PATIENT SAFETY A HIGH PRIORITY FOR ESRD NETWORKS AND P-R-Os TO LEVERAGE CURRENT FUNDING FOR THESE ORGANIZATIONS AS WELL AS STATE HEALTH DEPARTMENTS (Cluster #6).</td>
</tr>
<tr>
<td>5 Teams</td>
<td>(11) *</td>
<td>(11 - Action Option) DEVELOP BEST PRACTICE GUIDELINES FOR PROMOTING PATIENT SAFETY (Cluster #3).</td>
</tr>
<tr>
<td>5 Teams</td>
<td>(11) *</td>
<td>(14 - Action Option) CREATE A DATA BASE OF MEDICAL ERRORS AND NEAR-MISSES MAINTAINED BY A NON-REGULATORY GROUP AND PROTECTED FROM LEGAL DISCLOSURE (Cluster #2).</td>
</tr>
<tr>
<td>6 Teams</td>
<td>(10) *</td>
<td>(4 - Action Option) DEVELOP UNIFORM EDUCATIONAL MATERIALS/PROGRAMS FOR TRAINING OF STAFF IN SAFETY SCIENCES (Cluster #3).</td>
</tr>
<tr>
<td>5 Teams</td>
<td>(10) *</td>
<td>(23 - Action Option) PROVIDE TOOLBOX TO DIALYSIS UNITS TO HELP IDENTIFY AND CHARACTERIZE ISSUES IN PATIENT SAFETY (Cluster #2).</td>
</tr>
<tr>
<td>6 Teams</td>
<td>(8) *</td>
<td>(36 - Action Option) SUPPORT INCORPORATION OF PATIENT SAFETY ACTIVITIES INTO THE CONDITIONS OF COVERAGE FOR ESRD (Cluster #6).</td>
</tr>
<tr>
<td>4 Teams</td>
<td>(6) *</td>
<td>(7 - Action Option) CONDUCT A SURVEY OF DIALYSIS PATIENTS AND PROFESSIONALS TO LIST ISSUES OF PATIENT SAFETY (Cluster #1).</td>
</tr>
<tr>
<td>1 Team</td>
<td>(4)</td>
<td>(6 - Action Option) ADOPT A FACILITY-BASED, ANONYMOUS REPORTING SYSTEM THAT TRACKS VARIANCES AND FEEDS THEM BACK TO THE STAFF (Cluster #2).</td>
</tr>
<tr>
<td>0 Team</td>
<td>(4)</td>
<td>(31 - Action Option) UNDERSTAND THE CULTURE WITHIN THE DIALYSIS UNIT THAT MAY BE ADVERSE TO THE IMPLEMENTATION OF PATIENT SAFETY ISSUES (Cluster #8).</td>
</tr>
<tr>
<td>4 Teams</td>
<td>(2) *</td>
<td>(37 - Action Option) IDENTIFY POSSIBLE / PROBABLY OUTCOME CRITERIA OF MEDICAL ERRORS AND NEAR-MISSES AND CONSTRUCT ROOT CAUSE ANALYSIS OF THE MAJOR CATEGORIES (Cluster #8).</td>
</tr>
</tbody>
</table>

* These ten action options are identified in Figure 2 as those selected for the Consensus Action Scenario.

Produced by the participants at the NPSF/RPA/Forum Workshop – October 31, 2000
### CLUSTER #1: DEFINING AND IDENTIFYING THE PROBLEM

- **(Action Option 1)** Create a task force of stakeholders and experts on patient safety to agree on definitions of medical errors
- **(Action Option 2)** Develop a process flow chart to identify the components of risk in the continuum of care in order to define the taxonomy
- **(Action Option 5)** Develop a vocabulary of definitions and key concepts by stakeholders
- **(Action Option 7)** Conduct a survey of dialysis patients and professionals to list issues of patient safety
- **(Action Option 8)** Patient safety issues to be divided into sentinel events or near misses
- **(Action Option 9)** Focus less on formal taxonomy for the present and begin a broad based error identification system which can be internal and/or external
- **(Action Option 10)** Develop a specific list of what is considered an error from the identified flowchart
- **(Action Option 13)** Identify the characteristics of medical errors in contrast to quality of care issues
- **(Action Option 15)** Integrate current work on patient safety taxonomy from others e.g., anesthesia and pharmacology into ESRD
- **(Action Option 24)** Identify and analyze existing data on errors in ESRD care within a protected environment
- **(Action Option 29)** Conduct literature search of patient safety definitions used in other health care settings
- **(Action Option 45)** Enlist established safety experts and techniques to analyze, evaluate, and recommend change for current safety problems

### CLUSTER #2: COLLECTING AND ANALYZING DATA

- **(Action Option 6)** Adopt a facility based anonymous reporting system which tracks variances and feeds them back to the staff
- **(Action Option 12)** Develop a software system to track errors that can be implemented / installed in all dialysis facilities
- **(Action Option 14)** Create a data base of medical errors and near misses that can be maintained by a nonregulatory group and protected from disclosure
- **(Action Option 20)** Establish a central clearinghouse for patient safety in ESRD including definitions, programs, real-time error tracking, that would be available at no charge to dialysis facilities
- **(Action Option 22)** Archive data centrally by patient without provider I.D.
- **(Action Option 23)** Provide tool box to dialysis units to help identify and categorize issues in patient safety
- **(Action Option 25)** Conduct research into medical error identification and its importance in regards to future system failures and negative patient outcomes
- **(Action Option 32)** Develop and promote electronic or computerized data collection to ease the burden of reporting by staff
- **(Action Option 35)** Collate the facility survey data and use it as feedback information
- **(Action Option 41)** Provide patients information about their role and ability to access error reporting systems

Note: Those options connected to the **TIE LINE** have been included in the Consensus Action Scenario
Figure 2: Consensus Action Scenario Based on Small Team Work

<table>
<thead>
<tr>
<th>CLUSTER # 3: APPLICATIONS</th>
<th>CLUSTER # 4: LEADERS</th>
<th>CLUSTER #5: NON-REGULATORY</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Action Option 3) Identify collaborative possibilities with other communities for research, education and money</td>
<td>(Action Option 17) Conduct education and training for the ESRD program leadership on the nature of the problem and in the safety sciences</td>
<td>(Action Option 19) Gain commitment from industry to provide patient safety funds and technologies as part of contracts</td>
</tr>
<tr>
<td>(Action Option 4) Develop uniform educational materials / programs for training of staff in safety sciences</td>
<td>(Action Option 48) Create conducive culture for ESRD patient safety</td>
<td>(Action Option 39) Develop a proforma to determine the system &quot;ROI&quot; of a broad based safety program</td>
</tr>
<tr>
<td>(Action Option 11) Develop best practice guidelines for promoting patient safety</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Action Option 18) Using a defined list of medical errors identify stakeholders and their responsibilities in responding to a medical error</td>
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</tr>
<tr>
<td>(Action Option 21) Establish a plan to educate the renal community on what patient safety is</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Action Option 27) Encourage adaptation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Action Option 43) Promote inclusion of patient safety science in direct care staff core curriculum</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: Those options connected to the TIE LINE have been included in the Consensus Action Scenario
**Figure 2: Consensus Action Scenario Based on Small Team Work**

<table>
<thead>
<tr>
<th>CLUSTER # 6: POLICY</th>
<th>CLUSTER # 7: DISSEMINATION</th>
<th>CLUSTER # 8: UNDERLYING ISSUES</th>
</tr>
</thead>
<tbody>
<tr>
<td>• (Action Option 28) MAKE PATIENT SAFETY A HIGH PRIORITY FOR ESRD NETWORKS AND PROS TO LEVERAGE CURRENT FUNDING FOR THESE ORGANIZATIONS AS WELL AS STATE HEALTH DEPARTMENTS</td>
<td>• (Action Option 47) SUPPORT EXISTING LEGISLATIVE EFFORTS TO HAVE A POT OF MONEY IN MEDICARE DEDICATED TO NEW TECHNOLOGIES THAT CAN ENHANCE PATIENT SAFETY</td>
<td>• (Action Option 31) UNDERSTAND THE CULTURE WITHIN THE DIALYSIS UNIT THAT MAY BE ADVERSE TO THE IMPLEMENTATION OF PATIENT SAFETY ISSUES</td>
</tr>
<tr>
<td>• (Action Option 30) EXPEMPT DATA FROM ADMISSABILITY VIA FEDERAL LEGISLATION</td>
<td></td>
<td>• (Action Option 37) IDENTIFY POSSIBLE / PROBABLE OUTCOME CRITERIA OF MEDICAL ERRORS AND NEAR MISSES AND CONSTRUCT ROOT CAUSE ANALYSIS OF THE MAJOR CATEGORIES</td>
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<tr>
<td>• (Action Option 33) INCREASE PROVIDER PAYMENT</td>
<td></td>
<td>• (Action Option 31) UNDERSTAND THE CULTURE WITHIN THE DIALYSIS UNIT THAT MAY BE ADVERSE TO THE IMPLEMENTATION OF PATIENT SAFETY ISSUES</td>
</tr>
<tr>
<td>• (Action Option 34) MODIFY THE CURRENT FACILITY REIMBURSEMENT SYSTEM TO ENSURE INCLUSION OF THE COST FOR SAFETY PROGRAMS, UPDATED ON A REGULAR BASIS, AS WELL AS THE TRUE COST AND REASONABLE RETURN ON INVESTMENT FOR THE PROVISION OF CARE</td>
<td></td>
<td>• (Action Option 44) REQUEST ANALYSIS FROM CDC, FDA, AND ESRD NETWORKS OF MEDICAL ERRORS AND ADVERSE EVENT REPORTS FOR THE PAST THREE YEARS</td>
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<tr>
<td>(Action Option 36) SUPPORT INCORPORATION OF PATIENT SAFETY ACTIVITIES INTO THE CONDITIONS OF COVERAGE FOR ESRD</td>
<td>• (Action Option 40) LEVERAGE EXISTING ANALYTICAL ORGANIZATIONS, E.G. USRDS, TO ANALYZE DATA AND REPORT ON PATIENT SAFETY OUTCOMES</td>
<td>• (Action Option 46) PUBLISH CLINICAL OUTCOMES OF MEDICAL ERRORS ANNUALLY</td>
</tr>
<tr>
<td>(Action Option 38) STUDY PRESENT BUDGET ALLOCATIONS FOR ESRD AND REDISTRIBUTE MONIES MORE APPROPRIATELY TO INCLUDE ISSUES OF PATIENT SAFETY</td>
<td></td>
<td>• (Action Option 37) IDENTIFY POSSIBLE / PROBABLE OUTCOME CRITERIA OF MEDICAL ERRORS AND NEAR MISSES AND CONSTRUCT ROOT CAUSE ANALYSIS OF THE MAJOR CATEGORIES</td>
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Note: Those options connected to the **TIE LINE** have been included in the Consensus Action Scenario.
2.2.1) Cluster 1: Defining and Identifying the Problem, and Cluster 4: Leaders

Action Option 1: *Create a taskforce of stakeholders and experts on patient safety to agree on definitions of medical errors.* Clarification:

*Stakeholders would be a group such as the one assembled today, plus people with knowledge of patient safety from other disciplines. The taskforce could operate in a number of ways, including data collection, surveys, or other activities.*

Individual votes: 29  Scenarios: All 8 teams

This action option received the highest number of individual votes, was included in the scenarios of all eight teams, and was the first or second step in six of these scenarios. This action option’s importance makes sense, given that one of the three most deeply-leveraging challenges on Level VI was Challenge 3: “Lack of agreement on what constitutes a medical error.” As in the statement and clarification of that challenge, the statement and clarification of Action 1 concentrates on medical error rather than other areas of patient safety, and therefore implies a concentration on this part of the larger issue. This focuses the initiative somewhat, but because of ambiguity in the term “error” much is left undecided (as described above). For example, an initiative may choose to focus on one type of error or another in the care of ESRD. Challenge 3 also emphasized the importance of defining “near miss” and concentrated on “system errors,” although these issues were not mentioned in the statement or clarification of Action 1.

Many interviewees before the workshop agreed that patient safety was “ill-defined,” and the lack of clear definition was listed as a substantial problem facing any attempt to improve ESRD patient safety. Before the workshop, though, there might have been some question as to the absolute importance of this issue and when it should be addressed: the problem was 7th on the list of important problems in the interviews (Discussion Paper, Appendix B). The importance of Challenge 3 in the influence pattern and the prominent place of Action 1 in the voting and scenarios confirms the saliency of addressing this issue early in any initiative to improve ESRD patient safety.

Action 1 proposes a specific way to define error that attracted wide support. As the clarification emphasizes, the taskforce should have a range of representatives similar
to those gathered for the recently concluded workshop, perhaps supplemented by people with expertise in the safety sciences. Action 1 explicitly leaves some questions unanswered, such as whether the work will be purely definitional and simulative or whether it might also involve issuing a survey or collecting data. The mapping of challenges and action options accomplished so far will hopefully inform any decision made by such a taskforce. For example, the list of proposed Action Options in Cluster 1 and their clarifications (including ones that did not attract significant support in voting and scenario formation) provide a resource for participants in such a meeting.

**Action Option 17: Conduct education and training for the ESRD program leadership on the nature of the problem and in the safety sciences.** Clarification:

*The focus here is on the leadership: without leadership buy-in we can't succeed. Leadership includes people such as those in this room: leadership of payers, individual units, networks, etc.*

Individual votes: 20  Scenarios: All 8 teams

This Action Option received the second-highest number of individual votes and was included in the scenarios proposed by all eight teams. In half of these scenarios, it was one of the first three options to be performed. Action 17 was placed in a cluster of its own, called “leadership,” but it seems to have deep connections to Action 1 and Cluster 1. Like Action 1, Action 17 envisions a gathering of leaders similar to the workshop just concluded, although it stresses that such a gathering should be focused on “education and training” and “leadership buy-in.” Of course, such activities could be part of a workshop such as the one envisioned by Action 1. In the early part of any such initiative, the sort of “education and training” that would be most relevant would concern the previously utilized definitions of medical error and the safety sciences.

The workshop that was just completed has identified this and other Challenges and Actions as key to an initiative in ESRD patient safety. It also has initiated the process of leadership education and buy-in. However, as Action 1 emphasizes, there is the need for definition and clarification, requiring future group work.

**Action Option 7: Conduct a survey of dialysis patients and professionals to list issues of patient safety.** Clarification:
We’re trying to develop a taxonomy of patient safety, but current databases are inadequate to do this. This action option proposes carrying out a survey that will elicit experiences of patients and professionals that relate to patient safety. Then we can look at categories and frequencies so we have some initial handle on the scope and the relevance of the problem. "Patient safety” includes medical errors. This would be a survey designed specifically to develop a taxonomy, and would not include things like attitudes to patient safety, for example.


This Action Option attracted significantly less support than Actions 1 or 17, but it has the advantage of specificity. As the clarification of Action 1 explicitly recognized, a taskforce attempting to define medical error for an initiative on ESRD patient safety could use a survey to do this. Action 7 suggests one such survey, although it is stated as involving “patient safety” rather than just “medical error.”

2.2.2) Cluster 2: Collecting and Analyzing Data

Action Option 20: Establish a central clearinghouse for patient safety for ESRD, including definitions, programs, real-time error tracking, that would be available at no charge to dialysis facilities. Clarification:

Similar to the previous concept (OPTION #12) of a central data repository, but with the caveat that access to the data would be free for individual facilities.

Individual votes: 19.  Scenarios: 6 teams

This Action also garnered impressive support, with 19 individual votes and inclusion in six scenarios. It received the most votes of any Action in Cluster 2, although other Action Options in this cluster also received significant support (see below). In fact, on the list of most preferred actions, there are more from Cluster 2 than from any other cluster. This makes sense because of the number of Challenges dealing with this issue, and the deep leverage of a few of these (including Challenge 7 on Level VI). The clarification of Action 20 refers to Action 12, which proposes installing a software system in dialysis facilities to facilitate data collection. Note, however, that Action 20 was one of the last of the options to be carried out in many of the scenarios in which it was included.
To make sense of this, we should return to the challenges and the influence pattern among them. A total of five of the 13 challenges included in the influence pattern concentrate on the need for better data concerning ESRD patient safety. The most deeply leveraging of these challenges (at Level VI) emphasized the importance of protecting such data from legal and regulatory use:

- **Challenge 7:** Difficulty in gathering relevant data without appropriate legal protection from litigation or regulatory action. Clarification: Right now there’s a vulnerability in collecting data, with regard to its use in malpractice or regulation. We can’t get that data without some protection. …

Stakeholders judged that meeting Challenge 7 would help significantly in meeting Challenge 35, which resides one level higher (Level V). Challenge 35 emphasizes the importance of providing enough confidentiality:

- **Challenge 35:** To develop a reporting system that encourages the full reporting of ‘errors’ and their root causes by achieving the appropriate balance between confidentiality and public accountability. Clarification: … There has to be confidentiality if errors are going to surface and information necessary to do root cause analysis is to become available. But there also needs to be public accountability of the institutions involved. Have to balance these two needs.

Meeting this challenge, stakeholders decided, would significantly help meet the two other challenges related to data collection, which fell at higher levels of the influence pattern:

- **Challenge 22:** Ensuring information gathering and processes cross physical venues.
- **Challenge 8:** Obtain accurate data to determine problem areas and to develop baseline measures of current safety.

Action Option 20 may have been generally judged to be one of the last steps of the scenarios, rather than an early one, because it fails to address the issues emphasized by the most deeply leveraging Challenges related to data collection. As we see above, these issues were most prominently protecting data from legal or regulatory use and protecting confidentiality. A data collection scheme that addresses these concerns has a higher chance of success, the Influence Pattern suggests, than if these concerns are not addressed.
**Action Option 14:** Create a database of medical errors and near-misses maintained by a non-regulatory group and protected from legal disclosure. **Clarification:**

Fairly self-explanatory. If there is a mechanism that would protect a privately-held data-base from being accessed through legal inquiry, which does exist for governmental data-bases, then such a data-base would enhance trust level.

Individual votes: 11. Scenarios: 5 teams

This Action Option addresses one of the main concerns of the deeply leveraging Challenge 7, indicating that it may warrant further study. In addition, it garnered impressive support in the voting and scenario writing.

**Action Option 23:** Provide toolbox to dialysis units to help identify and characterize issues in patient safety. **Clarification:**

It will be helpful to give specific guidance to end users on how to identify and classify patient safety issues. This will could be the form of a "toolbox" that gives specific guidance in many areas, for example in distinguishing between sentinel events vs. near misses. PRO's have used such "toolboxs" to enable end-users to follow guidelines and record events clearly. These toolboxes include data collection forms, definitions for categories, and flow charts for analyzing data. Want to enable and empower end users to understand what we are talking about here and record data in a meaningful way. The idea of establishing a clearinghouse (in action option #20) might include providing such tools, but this action option (#23) concentrates on providing such tools.

Individual votes: 10. Scenarios: 5 teams

Like Action 20, this one does not address the issues highlighted by the deeply leveraging Challenges 7 and 35. The idea of a “toolbox,” however, offers an attractively concrete and pragmatic way to proceed, if the more critical issues are judged to be too difficult or time-consuming to address. The attractive features of the toolbox should not be mistaken for a way to address these deeper issues, though.

**Action Option 6:** Adopt a facility-based, anonymous reporting system that tracks variances and feeds them back to the staff. **Clarification:**

Right at the grass roots level, this immediate feedback will prepare individual units to respond to the challenges to change practices in light of this facility-level information as well as information that will stem from larger data sets. Since this information is gathered and used at the facility level, the data need not be de-identified.
This option arises out of the observation that you'll never track the
‘near-misses’ if the data collection system is not anonymous; people
simply will not self-report due to fear of repercussions. The identification
of individual ‘perpetrators’ is not necessary, at a corporate or larger
organizational level, to track trends in error types and to investigate
further. Concerns about the anonymity were raised, citing concerns about
data verification, missing that a particular individual is committing errors
repeatedly, etc. The rejoinder is simply that without anonymity, data
regarding these near misses simply will never be collected.

Individual votes: 4. Scenarios: 1 team

This Action Option attracted significantly fewer votes than the other Actions in
this cluster, and it was included in only one scenario. However, it does propose a way to
address the question of confidentiality, which was emphasized by a deeply leveraging
challenge in this area (i.e. Challenge 35).

2.2.3) Cluster 6: Policy

Action Option 28: Make patient safety a high priority for ESRD networks and PRO’s
to leverage current funding for these organizations as well as state health
departments. Clarification:
Clear.

Individual votes: 13. Scenarios: 3 teams

Action Option 36: Support incorporation of patient safety activities into the conditions
of coverage for ESRD. Clarification:
Self-explanatory. To encourage universal engagement in patient safety
participation, these regulatory requirements would help.

Individual votes: 8. Scenarios: 6 teams

Both of these action options address one of the three most deeply leveraging
challenges (Level VI) identified on day one: Challenge 25: “The need for financial and
other support to reduce errors.” And both of these actions were positioned as one of the
earliest steps in a number of scenarios in which they were included, often as the second
or third step. In discussing challenges and action options, stakeholders emphasized that
obtaining support will be crucial to any initiative in these areas.

Although these two Action Options, with their somewhat scanty clarifications, do
not provide much guidance in how to move forward in this area, they provide two places to start. They emphasize seeking help from organizations such as ESRD networks, PROs, state health departments, and other organizations paying for ESRD treatment.

2.2.4) Cluster 3: Applications

**Action Option 11: Develop best practice guidelines for promoting patient safety.**

Clarification:

*Lots of individual units have already developed ways to prevent bad things from happening. Those ideas can be assembled together to develop best practices for promoting patient safety, whether they involve technology or process. We should give people guidance about what has worked the best. We have data that allow us to know that certain facilities have better outcomes than others, and we can look at their practices and make them available in the form of guidelines to other facilities.*

Individual votes: 11. Scenarios: 5 teams

This idea garnered impressive support, receiving a comparatively large number of individual votes and being included in multiple scenarios. It has an obvious attraction: if we could identify which dialysis units provide the best patient safety, for example, and could identify what they are doing differently, getting other units to adopt similar methods would conceivably have positive effects. Identifying and disseminating “best practices” can be a powerful one in any initiative.

One limitation of this Action, however, is the difficulty in identifying best practices. During interviews carried out before the workshop, there was no consensus on what entities might have “best practices.” In addition, Action 11 was not positioned as one of the first few steps in any of the scenarios: in four out of the five scenarios in which Action 11 appears, it is the fourth or later step. This makes some sense since Action 11 is not closely related to any of the highly leveraging challenges identified on the workshop’s first day.

On the other hand, Action 11 is at least somewhat related to data collection, since identifying best practices presumably would involve obtaining better data. Before the workshop, one interviewee emphasized the danger that collecting data would occupy all the energy of any initiative and take too long, as it has in other similar efforts. Instead, he
suggested the model of attempting multiple small changes at various sites providing ESRD care and studying the effects on patient safety closely. Such a project might be seen to be a form of Action 11: implementing changes that some would consider to be best practices and studying the effects.

**Action Option 4:** *Develop uniform educational materials/programs for training of staff in safety sciences.* Clarification:

*The concept here is that there is a cost associated with developing these materials; to the degree that these uniform materials can be jointly-developed and used across many settings, the fixed development costs can be shared and thus lessened on each individual facility. Such standardized curricula already exist for education of technicians and nurses on performing dialysis.*

*The OPTION expressed here would extend these curricular materials into the as-yet underdeveloped safety sciences realm for ESRD specifically. Some general material on patient safety already exists, and this could be used in the interim while more specific material is developed. Examples of safety sciences include how teams communicate among members or how new technologies can be safely introduced into clinical practice.*

Individual votes: 10. Scenarios: 6 teams

Although this Action was utilized in six of the eight scenarios, in most of these (5 of the 6) it was placed relatively late in the scenario, after the accomplishment of many other action options. Teams predominantly judged that other challenges would have to be accomplished first -- such as defining the problem, collecting data, and obtaining support -- as was shown in the influence pattern. It may be necessary to educate leadership in the safety sciences early on (as seen in Action Option 17, discussed above), in order to accomplish these other goals.

**2.2.5) Cluster 8: Underlying Issues**

**Action Option 31:** *Understand the culture within the dialysis unit that may be adverse to the implementation of patient safety issues.* Clarification:

*To be successful in improving patient safety, we need to gain data from staff members and patients in the units and to educate them in various ways. To do so we need to understand aspects of the culture in the units.*
that is adverse to data collection and education.

Individual votes: 4. Scenarios: 0 teams

**Action Option 37: Identify possible / probable outcome criteria of medical errors and near-misses and construct root cause analysis of the major categories.**

**Clarification:**

Once possible / probable outcome criteria are developed, it would be a good use of time to sit down and do root cause analysis of the major categories. This information could then be provided to facilities to give them a place to start in addressing these issues.

Individual votes: 2. Scenarios: 4 teams

Compared to the action options discussed so far, these two received relatively few votes and were included in relatively few scenarios. They did attract some votes, and one scenario described Action 37 as the first step in addressing patient safety. These Actions stand out from the others due to their relation to “underlying issues,” and for this reason they were grouped together under Cluster 8. Understanding and changing the “culture” of dialysis units and doing root cause analyses came up multiple times in pre-workshop interviews. Actions 31 and 37 also seem related to Cluster 2 – “Collecting and Analyzing Data” – although each differs from actions in that cluster by requiring deeper or different sorts of analysis. In short, although these action options may be valuable at some point, but it is not strongly indicated by the workshop participants that they should be employed to launch an initiative.
3) CONSENSUS

3.1) METHODOLOGY: SCENARIO CONSTRUCTION

The participants were arranged in eight small groups based on maximizing the diversity of perspectives within each group. The groups deliberated on selecting actions that they would include in a prospective Action Plan. The Clusters of Action Options they had developed in the large group, during the previous step were provided as a working template. The groups were instructed to first consider the inclusion of each of the one dozen action options that had received at least four individual votes. One of these options was not selected by any of the teams. They then moved on to consider the inclusion of action options that had not previously been accorded importance by more than four people. One of these action options were included by half of the teams – a shift of roughly twenty individual preferences.

The groups were then coached in developing narrative descriptions of their plans. The groups presented their scenarios to the full set of participants. The groups typically employed a narrator, two people using the wall displays of the structure of challenges and the Clusters of Action Options, and one person with a Laser Pointer to guide the participants through the scenario from display to display. The group’s scenario narratives were tracked by the facilitation team for further analysis.

Ten Actions were selected by four or more teams. This constitutes the Consensus Action Scenario which is shown in Figure 2.
3.2) FINDINGS: SMALL TEAM ACTION SCENARIOS

The Consensus Action Scenario, was developed as a composite of small group work by eight interdisciplinary teams, and appears in Figure 2. The summary of their selected actions appears in Table 3. Ten actions were selected by four or more of the eight teams. According to the tally of the team selections they are Actions 1, 17, 4, 20, 36, 7, 23, 11, 37, and 14. (The reader is directed to Appendix E to review the clarification of their intent.) The overriding intent of the action scenarios most directly targeted Challenge 3. It was suggested by several of the teams that actions undertaken to address Challenge 3 would probably help support actions undertaken to address the other two deep challenges, namely Challenges 25 and 7.

Action 1 and Action 17 received unanimous endorsement by the eight teams. Actions 1 and 17 also stood out in the presentation of the scenarios. Action 1 was presented as the first or second action to undertake by seven of the eight teams. Action 17 was presented as the first or second action to undertake by three of the teams and as the third action by one. No other action had as high a precedence rating. So too, the implied influence of Actions 1 and 17 on other actions, as presented in the small group scenarios, were two to three times greater than the next most influential one, Action 7.

Amongst all the groups, Action 7 was noted as having fewer dependencies on all other proposed actions except Action 1. This suggests that the implementation of Action 7 would be the action with the fewest prerequisites to undertake after work is initiated on Action 1. Action 37 is the next in this regard.

Action 37 stands as the next action that has the fewest prerequisites after Actions 1, 17, and 7 are initiated and one of the highest leverages on the system of challenges (see Figure 1). However, the insight regarding the priority of Action 37 was not previously acknowledged in terms of individual votes and emerged a high priority for only one of the teams.

Based on the scenario presentations, Action 11 stood as the next highest precedent with respect to the other consensus actions.
The recommended priority, for the ten consensus actions displayed in Figure 2, based on the selection by the small teams, the influence on other actions, and the minimum of prerequisite actions are Actions 1, 17, 7, 37, and 11.
4) COMMITMENT TO COLLABORATIVE LEADERSHIP

The five actions, namely Actions 17, 1, 7, 11 and 37, highlighted in section 3.2 were confirmed through a post-workshop DELPHI Survey, as the Actions to focus on for the Launch of Phase II of the initiative. The DELPHI Survey Cover Letter appears in Appendix F, and the responses appear in Appendix G.

The level of commitment to collaborative leadership on Actions 1 and 17 mirrored the unanimity of preference in the Small Team Action Scenarios. Actions 7, 11, and 37 were accorded the next highest level of commitment. Actions 17, 1, 7, and 11 had the clearest demarcation of roles and indications of readiness to act in the survey responses. This complemented their comparative influence on other actions, their minimal prerequisites compared to the others, and the strength of their influence of deep drivers in the system of challenges. Survey respondents indicated strong interest in Action 37, which also stands as a strong influence on the system of challenges and support for other actions. However, the differentiation of roles, and capacity to act did not come out strongly in the survey.

The top recommended actions for the launch of Phase II are restated below:

(ACTION 17): CONDUCT EDUCATION AND TRAINING FOR THE ESRD PROGRAM LEADERSHIP ON THE NATURE OF THE PROBLEM AND IN THE SAFETY SCIENCES

*The focus here is on the leadership: without leadership buy-in we can't succeed. Leadership includes people such as those in this room: leadership of payers, individual units, networks, etc. (Cluster #4)*

(ACTION 1): CREATE A TASK FORCE OF STAKEHOLDERS AND EXPERTS ON PATIENT SAFETY TO AGREE ON DEFINITIONS OF MEDICAL ERRORS

*Stakeholders would be a group such as the one assembled today, plus people with knowledge of patient safety from other disciplines. The taskforce could operate in a number of ways, including data collection, surveys, or other activities. (Cluster #1)*
(ACTION 7): CONDUCT A SURVEY OF DIALYSIS PATIENTS AND PROFESSIONALS TO LIST ISSUES OF PATIENT SAFETY

We’re trying to develop a taxonomy of patient safety, but current databases are inadequate to do this. This action option proposes carrying out a survey that will elicit experiences of patients and professionals that relate to patient safety. Then we can look at categories and frequencies so we have some initial handle on the scope and the relevance of the problem. "Patient safety" includes medical errors. This would be a survey designed specifically to develop a taxonomy, and would not include things like attitudes to patient safety, for example. (Cluster #1)

(ACTION 11): DEVELOP BEST PRACTICE GUIDELINES FOR PROMOTING PATIENT SAFETY

Lots of individual units have already developed ways to prevent bad things from happening. Those ideas can be assembled together to develop best practices for promoting patient safety, whether they involve technology or process. We should give people guidance about what has worked the best. We have data that allow us to know that certain facilities have better outcomes than others, and we can look at their practices and make them available in the form of guidelines to other facilities. (Cluster #3)

(ACTION 37): IDENTIFY POSSIBLE/PROBABILE OUTCOME CRITERIA OF MEDICAL ERRORS AND NEAR MISSES AND CONSTRUCT ROOT CAUSE ANALYSIS OF THE MAJOR CATEGORIES

Once possible / probable outcome criteria are developed, it would be a good use of time to sit down and do root cause analysis of the major categories. This information could then be provided to facilities to give them a place to start in addressing these issues. (Cluster #8)

The details for the recommended Collaborative Leadership Teams and Working Groups for the top five actions, based primarily on the self-identification of roles can be found in Appendix G.
APPENDICES

Appendix A: Participants
Appendix B: Discussion Paper
Appendix C: Clarification of Challenges
Appendix D: Challenge Clusters
Appendix E: Clarification of Action Options
Appendix F: DELPHI Survey Cover Letter
Appendix G: DELPHI Survey Responses
Appendix H: Bibliography Relevant to the Methodology
APPENDIX A

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APPENDIX B

Discussion Paper
DESIGNING AN ACTION AGENDA FOR IMPROVING END STAGE RENAL DISEASE (ESRD) PATIENT SAFETY WITH REPRESENTATIVES OF THE COMMUNITY OF STAKEHOLDERS

A White Paper

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I. INTRODUCTION

The current interest in patient safety stems from many factors, ranging from the physician’s age-old pledge to “primum non nocere” (first, do no harm), to the recent publication of an Institute of Medicine report (and the attendant publicity) showing the medical errors may be responsible for a high number of deaths. In such an environment of heightened awareness of patient safety, it is natural for End Stage Renal Disease (ESRD) to draw attention, since treatment is necessarily so invasive and extensive. Patients on dialysis undergo an invasive medical procedure multiple times a week, while patients with a renal transplant live in a world governed by multiple medications and constant attention to the dangers posed by immunosuppression. Add to this potent mix the widespread changes in the provision of modern medicine, occasional media reports of problems in dialysis centers, and the fact that the direct costs of ESRD care are borne primarily by the government, and patient safety in ESRD becomes a pressing social problem to address.

With this goal in mind, the Renal Physicians Association (RPA), Forum of ESRD Networks (Forum), and the National Patient Safety Foundation (NPSF) has decided to convene a group of stakeholders in the care of ESRD -- including physicians, nurses, administrators, social workers, and others -- to provide leadership in improving ESRD safety. A workshop designed and conducted by CWA Ltd. will take place October 30-31, 2000, in which stakeholders will assess and define the problem situation and explore possible options for resolving it. In preparation for this workshop, CWA has drafted this introductory “white paper” for participants to read and consider prior to their deliberations at the workshop. It is based on interviews with 15 stakeholders in the field of ESRD patient safety, and its purpose is to stimulate thought and discussion among participants in the workshop. Preparation for the workshop includes only the careful reading and consideration of this paper.

Many interviewees pointed out that the term “patient-safety” and related terms have not been well-defined. Cases of patient injury during, or as a consequence of, hemodialysis were central issues mentioned by many interviewees, but a tremendous range of other issues also arose as possible areas for improvement of patient safety. In many cases, the issues were described as only possible ones for concern and areas for improvement.

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possible advancement, and many respondents described a need for more data to evaluate these possibilities. In the interest of allowing stakeholders to define the problem as they see fit, most topics mentioned as relevant issues for ESRD patient safety are included in this report, with some indications of the emphasis placed on different topics. Participants at the Workshop will likely want to restrict or redefine these topics in various ways. In this way they may take steps in the definition and mapping of the problem situation.

Almost every respondent described the need for more data concerning ESRD patient safety, and many recommended existing data sets or improved methods for collecting data. Data is needed in some cases to map the extent of the problem and in other cases to evaluate whether there is a problem at all. As some respondents stressed, although there may be no question of the occurrence of certain sorts of events, we need a better understanding of the rate of such events, especially as a proportion of all care given for ESRD. Other interviewees said that even if some supposed threats to patient safety are not real, the very perception of such dangers poses a challenge to providing safe and effective care. The process of problem definition and data collection certainly will inform each other.

Section II presents a survey of perceived problems in ESRD patient safety (in bold print when first mentioned) that arose during the 15 interviews. Some relevant literature citations have been included as well. The text indicates how often each topic was raised and what weight interviewers gave them, and Appendix A presents a measure of relative weighting based on interviewees’ responses to one question. This is just a rough measure, and based on the response to only one of the questions asked. Ranking, comparing, and defining the problem will be a project for the workshop.

Section III surveys again the challenges in defining and measuring the problem of ESRD patient safety and some of the proposals for advances.

Fifteen stakeholders in ESRD patient care were interviewed, including physicians, nurses, administrators, a social worker, and a person with ESRD (see Appendix B). A list of questions guided the interviews, although not all the respondents were asked all questions. The protocol included sections concentrating on problems in ESRD patient safety, opportunities for advancement, areas for further research, and cultural and social factors that could be relevant to making changes. Interviewees were also asked to describe and analyze cases of patient safety failures, including cases where an investigation occurred, and they were asked to describe any areas of medicine or industry
II. PROBLEMS IN ESRD PATIENT SAFETY

Almost all respondents described serious complications during hemodialysis and these are in many ways the classic failures in assuring ESRD patient safety. They are also the sort of cases that attract a large amount of media interest and sensationalist reporting. Although many respondents reported that such cases exist, a number also cautioned that we lack any clear measure of the prevalence of such cases, and that the track record for avoiding such problems may be quite good.

Some case vignettes of this sort are the following:

• The needle for venous blood return falls out of the access site of a sleeping patient, and a significant amount of blood collects on the floor before anyone notices.

• A confused patient removes the needle from his access site, resulting in some blood loss.

• A patient’s dialysate has an incorrectly low concentration of [K⁺], leading to a low serum [K⁺] and a cardiac arrhythmia.

• A patient has a bleeding problem after receiving an excess of heparin.

• A patient is dialyzed using another patient’s dialyzer.

• A patient experiences hypotension and chest pain during dialysis.

• Some chemical cleaner is left in a dialysis machine, resulting in hemolysis.

• An air embolus enters an arterial blood line and causes a stroke.

Respondents cited multiple possible contributing causes for such events, from machine malfunction to human error, and they appear to range from the clearly preventable to the possibly inevitable. While most of the foregoing examples have in common the idea that they are avoidable, clearly there may also be complications of dialysis that are unavoidable, and quantifying the relative proportion of such types of problems may be important.

Many interviewees mentioned problems with staff training and turnover as being an important cause of these and other problems. In many dialysis centers, one nurse oversees a larger number of technicians, who themselves oversee the dialysis of a
larger number of patients. One respondent described dialysis units where a nurse used to oversee three technicians providing dialysis to three patients each, but now each of the technicians treat four patients each and the nurse has separate patient care responsibilities. Interviewees reported that technicians without previous health-care experience are sometimes trained in 1-2 weeks. Rapid staff turnover leads to a high number of relatively inexperienced workers. It was widely stated that there can be no return to a time when nurses provided most dialysis care, due to cost constraints and a shortage of nurses nationwide.

A number of respondents proposed more uniform testing and certification for dialysis technicians, in many cases pointing out that there are such requirements for nursing home workers and x-ray technicians. Many respondents stressed the need for increased training of technicians and increased uniformity in that training. Some pointed out that even if personnel perform technical tasks correctly, they may lack skills in interacting with patients. Some respondents proposed that any increase in training should include instruction in inter-personal interaction and the patient population involved.

Many interviewees identified the cost-pressures experienced by all providers of dialysis as driving these personnel difficulties, and as having other negative effects on patient safety. Reimbursement for hemodialysis has declined in real dollars since Medicare began paying for the treatment, and this has forced dialysis providers to cut their labor costs. The resulting pressure to increase productivity -- for each worker to oversee more dialysis treatments -- was widely described as an important cause of adverse events in dialysis units. Respondents mentioned that any safety initiative, including any changes in staff training or certification, would be correctly felt as a hardship by dialysis providers if there was no corresponding way to pay for it. On the other hand, one interviewee advocated resisting any request for increased reimbursement, pointing out that the Medicare has already spent more money on the care of ESRD than any other chronic disease.

Almost all respondents pointed out difficulties in the current environment with problem reporting. Mandatory reporting requirements are obeyed, but the current system discourages people from reporting and addressing potential problems ahead of time. The litigious nature of American society plays a large role, many felt, by making everyone reluctant to report errors in a way that could be used against them in a lawsuit. The “blame culture,” where there is a tendency to affix blame to individuals instead of concentrating on more general system issues, also plays an important role in the under-recognition of potential problems in dialysis units, many respondents felt. Interviewees
described many factors that discourage healthcare providers from reporting possible problems, including fear of reprisal from employers who themselves fear being embarrassed or sued. Patients also may observe dangerous situations in the dialysis unit but keep quiet due to fear of disapproval or even retribution by their care providers. The decreased physician presence in dialysis units was described by some respondents as a problem that contributes to the lack of appropriate oversight.

Many interviewees emphasized the need for more widespread application of systems of Continuous Quality Improvement (or Total Quality Management) in which feedback could be collected and utilized. Instituting a “blame-free” and “learning” culture would improve recognition of dangers and near-misses. Many respondents pointed to the airlines or other industries where such programs are widely utilized. The possibility for anonymous reporting by staff and/or patients, as well as the creation or strengthening of external bodies to evaluate such reports, was raised as important as well. Some respondents also pointed to limitations in oversight and regulation of dialysis units, advocating more frequent, extensive, and perhaps unannounced examinations. Some emphasized the need for such oversight to review the regular maintenance and modernization of equipment.

A number of other issues involving hemodialysis arose as posing possible threats to patient safety. Failures in water purification continue to pose occasional problems, especially involving fluoride levels or microbiological contamination. Dialyzer reuse attracted extensive attention. Although some studies have supported the safety of reusing dialyzers a certain number of times (three times in one study), some interviewees questioned whether safety and efficiency are maintained when dialyzers are reused many more times (up to 20-60 times in some dialysis units, according to interviewee reports). Reuse also creates the danger of one patient being dialyzed with another patient’s dialyzer, and some respondents questioned the safety of the disinfectants used. One interviewee argued that the best reason for reuse is that it allows units to buy more efficient dialyzers than would be possible without reuse due to cost constraints. However, at high levels of reuse, the efficiency could be radically reduced.

Medications form another area of concern for ESRD patient safety. In other areas of medicine, investigations have shown concerning numbers of prescribing mistakes, drug-drug interactions, and other adverse drug events, and numerous respondents emphasized the existence of similar problems in the dialysis population. One study found

2 Jochimsen et al (1998) reports a case which occurred in Brazil.
that dialysis patients are on a mean of more than 10 prescribed medications, and respondents report similar amounts of medication use in their patients. Abnormal renal function increases the challenges of dosing and the dangers of mistakes and side-effects. Many respondents bemoaned the lack of suitable information systems to keep track of a patient’s medications, and the need for more contact between patients and their health care practitioners to allow closer monitoring of a patient’s medications.

Many voiced worries about the lack of patient compliance with prescribed medications. The general issue of patient compliance also involves other areas, including diet and lifestyle issues. Most practitioners felt that some patients do not take all the medications they have been prescribed, for various reasons including cost. One physician described a patient who was not able to afford her 15 medications, even though she has a prescription drug benefit that requires just a $10 per month co-payment. Other interviewees described needing to wait until a patient came in to the dialysis unit, or even needing to hospitalize a patient, in order to give medications so that they would be covered by insurance. In addition, the older or more disabled patients with ESRD may face greater hurdles in acquiring their medications and remembering to take them.

Many respondents emphasized the lack of adequate patient education in contributing to many of these problems. In particular, patients failing to understand their own role in assuring their safety contributed. Patients who adopt a “do for me” attitude, some respondents mentioned, face greater dangers in their care. Improved communication between health care providers and patients, and improved attention to psychosocial issues, some asserted, could lead to great improvements in patient safety. Almost every interviewee felt that health care practitioners did not adequately confront patients about the risks of their care and the patient’s role in avoiding such risks. Some felt that tools exist for improving patient education, and once again many fingered the limitations on contact between patients and health-care providers that contribute to such failures. Once again cost-constraints play a role by limiting the amount of ancillary staff available to provide education.

Many respondents felt that primary care can be improved and that prevention of ESRD or the complications that go along with it could do much to improve patient safety. Some respondents emphasized primary care that would identify and more aggressively

treat the conditions known to lead to ESRD (such as diabetes and hypertension), and would carry out the proper evaluation and treatment of early kidney disease. Money spent in these areas, some interviewees argued, will increase patient safety by helping more patients avoid or postpone ESRD. A number of respondents claimed that doctors wait too long to refer patients to a nephrologist, in many cases until renal disease has advanced to the point where dialysis is needed emergently. In such cases, there’s no opportunity to establish a fistula or other permanent vascular access, leading to increased risks for patients.

Vascular access continues to be a major problem for many patients receiving hemodialysis, and difficulties in this area were described by many respondents. Some doctors complained about an increase in the use of temporary or only semi-permanent access for dialysis. Infection is an important issue for dialysis: in hemodialysis, the risk of hepatitis, HIV or other blood borne infections have central importance, while in peritoneal dialysis peritonitis remains a key issue. Some felt that improvements could be made in the recognition and treatment of these and other infections. Many respondents pointed to the increase in age and comorbidity of the ESRD patient population as worsening these and other threats to patient safety. Dialysis is being initiated in older patients and those with more severe comorbidities than ever before, some interviewees asserted.

A number of respondents worried that patients are not being treated aggressively enough for conditions that are correlated with ESRD. Anemia and hypertension, for example, may be adequately managed. Some voiced concern that there is a failure to adequately treat comorbidities, such as coronary artery disease and peripheral vascular disease, which cause so much morbidity and mortality in the ESRD patient population. Partial blame for this was assigned to limitations in the amount of time patients spend with their doctor or nurse practitioner, inadequate information systems, and barriers to

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4 For an overview of the risk of Hepatitis C infection in patients on hemodialysis and advances made in limiting the spread of this disease, see van der Poel (1999).

5 Byrne et al. (1994) found that among patients beginning ESRD at ages > 55, mortality rate increased dramatically with increased age at initiation of treatment.

6 Joki et al. (1997) reports performing angiography on 24 patients within one month of beginning maintenance hemodialysis and found coronary artery disease in 53% of asymptomatic patients.
referral to other specialists. Some respondents emphasized that improving patient rehabilitation forms a serious issue in improving patient safety.

A number of respondents said that many patients often fail to receive the prescribed or recommended amount of dialysis, due to access difficulties or other intercurrent medical problems. There has been a continuing debate over what is the optimal amount of dialysis to provide for patients and how best to measure adequacy, and some respondents emphasized the need to make advances in these areas in order to improve patient safety. Physicians and nurses pointed to the difficulty of accurately assessing a patient’s fluid status, and emphasized that this challenge has become more important as patients with medical conditions such as congestive heart failure make up a larger percentage of the dialysis population.

Inadequacies in keeping and transferring patient care information posed a problem that many cited as contributing to many dangers for ESRD patients. A change in the setting in which a patient receives his care, for example when he enters the hospital or goes to a new dialysis center, poses a challenge for assuring patient safety due to the risk that important information will fail to be transferred. One respondent proposed a system of information gathering based in the patient's dialysis center and including information such as blood pressure trends, medications, complications, etc..

The role that the location and layout of dialysis units plays with regard to patient safety was also emphasized. Respondents reported concern in some locations over the danger of physical violence in the unit, directed toward patients or providers. In some cases, patients or their visitors appear threatening to staff or other patients, and extreme situations can occur if a patients is a gang member or brings a weapon into the dialysis unit. Disruptive patients pose a risk to other patients’ safety, some respondents emphasized, but such patients cannot be easily excluded because of their need for this life-sustaining treatment. In rural settings, there can be serious challenges to a patient’s getting to the dialysis unit for his treatment, and these logistical problems pose serious threats to patient safety, some said. Some respondents pointed to dialysis-unit layout as a relevant factor for patient safety, especially as it affects infectious disease transmission, the risk of falls, and the ability of care providers to oversee dialysis being performed.

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7 Sherman et al. (1994) found that in a group of 860 ESRD patients randomly selected from 54 dialysis centers, 50% had experienced missed or shortened dialysis treatments in a 12-week period.
Patients receiving dialysis at home, either **home hemodialysis or peritoneal dialysis**, were largely described as facing fewer threats to their safety. This is partly due to their being a self-selected group of relatively healthy and responsible patients, but a number of respondents suggested that more patients could be adequately treated at home. Most respondents said that in-unit HD is the most problematic setting for assuring patient safety.

Some interviewees stressed the importance of finding ways to perform more kidney **transplantations** and to keep grafts functional for longer. Some respondents mentioned the need to improve **post-transplant care**, through everything from providing better coverage for immunosuppressive drugs, to obtaining a better understanding of the psychosocial issues that relate to poor patient compliance, or to finding better ways to recognize or block chronic rejection.

### III. OPPORTUNITIES FOR IMPROVEMENT

As the large range of issues discussed above indicates, almost anything related to the health of patients with ESRD can be considered in some way to be an issue of patient safety. And any person involved in trying to assure ESRD patient safety will want to narrow the problem in one way or another. Although the concepts of “harm” and “risk” are often invoked in describing threats to patient safety, many respondents voiced difficulty arriving at clear definitions of these two concepts. Most respondents said that there is no clear source for defining the language of patient safety, although some pointed to the IOM report as a place to start. Given this situation, important decisions will have to be made about which areas are truly the most pressing ones. Should an initiative focus on hemodialysis (as some respondents proposed)? Should it also include peritoneal dialysis and/or transplantation? What risks or harms in each of these areas make up the most important challenges to ESRD patient safety? Where should attention be focused -- on patients, dialysis centers, providers, etc.?

As mentioned above, most respondents emphasized the importance of data collection for assessing and addressing patient safety. As one respondent said:

> “You can’t fix something unless you know what’s broken. You can’t change a system and eliminate errors and near misses unless you know that they are happening. The fundamental first step is to make errors visible so that they can be studied and corrective action implemented.”

Appendix B – Page 9
When asked to identify existing data systems to utilize, numerous areas were mentioned as possibilities, although there were many questions about the availability and usefulness of any data. They included:

- FDA data on patient deaths related to device failure;
- USRDS data, and other data derived from Medicare;
- CDC data from an annual survey of dialysis units;
- ESRD network and HCFA data;
- internal data from manufacturers and corporate dialysis chains;
- in pediatrics, voluntary data collected by NAPRTCS on ESRD patient outcomes.

One respondent cautioned that the process of data collection, especially if attempted at a national level, could bog down attempts to make improvements in ESRD patient safety. Instead, initiatives could be instituted at a local level, with careful measure of any effect on outcome.

Numerous respondents asserted that, in the current system, inadequacies and limitations of reporting systems would undermine any attempt to quantify ESRD patient safety. Changes that would improve data collection include:

- improvements in (and computerization of) information systems;
- a change in dialysis unit culture (toward a “blame free” and “learning” model);
- more widespread institution of CQI or TQM methodology;
- protected reporting (including anonymity and protection from legal discovery).

Although there was some concern about confidentiality issues, most respondents felt that these could be addressed.

Instituting better information systems and improving mechanisms by which problems can be reported were mentioned as possible ways to address many different problems with ESRD patient safety. As mentioned above, problems with staff training and competence were mentioned by almost all respondents and were often given relatively high importance (see Appendix A). Possible ways to address staffing issues include:
• increasing reimbursement for hemodialysis and increasing technician pay;
• decreasing pressure on dialysis staff;
• applying CQI methodology;
• instituting better record keeping and problem reporting mechanisms.

Any way to increase staff retention and continuing education would be helpful as well, interviewees felt. Some respondents pointed out that the repetitive nature of providing hemodialysis creates some of the dangers due to boredom and inattention and recommended collecting information from other industries that have tried to address these issues (e.g., technicians screening luggage at airports).

Other prominently mentioned opportunities for advancing ESRD patient safety included improving feedback and safety mechanisms in hemodialysis machines and improving machine maintenance. Better treatment between dialysis sessions -- including better medication management, nutrition, exercise, and rehabilitation -- were all cited as ways to improved ESRD patient safety. Improved patient education, through the improved use of tools for education and improved contact between patients and healthcare providers, would also help in addressing many other patient safety issues. All this would require more money, many respondents pointed out. Thus, it would be desirable to improve the reimbursement of dialysis care, respondents felt, although many questioned whether such a change would occur.

Many respondents feel that there is good cohesiveness in the community of stakeholders and good communication among members, although a few were less optimistic. Some of the strengths of the community included the fact that it is “semi-closed,” with a defined group of providers and patients, and that there has been relatively high collaboration between the many different professions and employees involved (including social workers, dietitians, doctors, nurses, technicians, administrators, and others). A lack of leadership and the existence of such tight cost constraints were mentioned as weaknesses of the community.
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One of the early questions in each interview was: “What do you think are the most substantial problems that must be addressed in ESRD Patient Safety?” Interviewees were guided to produce a list of problems and to rank them in order of importance. Many other questions in the interviews elicited other and more extensive descriptions of possible problems with ESRD patient safety, but the responses to this initial question provides one measure of which ones were most salient or pressing in their minds.

In this appendix, responses have been grouped into categories and given a score to reflect the number of times they were mentioned, weighted by their rank. For each interviewer, the self-identified most substantial problem received 1 point, the second problem .9 point, the third .8 point, etc. If a single problem was listed more than once by a given interviewee (for example, under two different descriptions), it only received the points appropriate for its highest ranking. Classifying and grouping responses certainly involves subjective factors and might have been done differently, and the point system is almost entirely arbitrary. As mentioned above, the list and weighting is provided solely to provide one rough and imprecise measure that may stimulate further discussion.

<table>
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<th>Problem</th>
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<td><strong>Staff training</strong>, competence, turnover, certification.</td>
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<tr>
<td>3.6</td>
<td><strong>Data</strong> on patient safety.</td>
</tr>
<tr>
<td>2.8</td>
<td><strong>Patient education</strong>, compliance, communication.</td>
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<td>2.7</td>
<td>Identification and <strong>reporting of problems</strong>, errors.</td>
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<td>2.7</td>
<td>Maintaining and modernizing <strong>equipment</strong>.</td>
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<td>2.3</td>
<td><strong>Medication</strong> issues.</td>
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<td>1.8</td>
<td>Imprecise <strong>definition</strong> of patient safety.</td>
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<td>1.6</td>
<td><strong>Dialyzer reuse</strong>.</td>
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<td>1.5</td>
<td><strong>Regulation/ oversight</strong>.</td>
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<td>1.5</td>
<td><strong>Cost pressures</strong>, inadequate reimbursement.</td>
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<td>1.3</td>
<td>Need for better <strong>charting</strong>, patient care information.</td>
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<td>1.0</td>
<td>Dialysis center <strong>violence</strong>.</td>
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<tr>
<td>0.9</td>
<td><strong>Transplantation</strong> rate and post-transplant care.</td>
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</table>
0.9 Access to treatment, dialysis.
0.9 Inadequate care planning.
0.7 Delayed diagnosis.
0.7 Increasing Age and morbidity of dialysis patient.
0.6 Water quality.
0.6 Misc. dialysis center safety, e.g. falls.
0.6 Misc. difficulties with providing adequate dialysis, including access failures.
0.5 FDA limitations on availability of new devices.
APPENDIX B
List of Stakeholders Interviewed

Ms. Carmella Bocchino, MBA, RN
Vice President of Medical Affairs
American Association of Health Plans

Mr. Troyce Crucchiola
NKF of Oregon and Washington

Dr. Peter DeOreo
Forum of ESRD Networks

Dr. Louis Diamond, M.B.,
Ch.B., F.A.C.P
Vice President and Medical Director
The Medstat Group
National Patient Safety Foundation

Barbara Fivush, MD
American Society of Pediatric
Nephrology

Ms. Wendy Funk-Schrag,
MSW, LMSW
Renal Care Group

Dr. Alan Kliger
Renal Physicians Association
Metabolism Associates

Dr. Robert Kossmann
Renal Physicians Association

Dr. Paul Scott McGinnis
AAKP

Ms. Jean Nardini, MSN, RN, CNN
American Nephrology Nurses
Association
Mass General Hospital, Nursing
Department

Dr. Richard Rettig
Health Policy Analyst
RAND

Dale Singer, MHA
Renal Physicians Association
Executive Director

Michael I. Sorkin, MD
Associate Medical Director
Advamed
Baxter Healthcare Corporation
Renal Division

Dr. Richard Ward
American Association for Medical
Instrumentation
University of Louisville
Kidney Disease Program

Dr. Hock Yeoh
Kaiser Permanente Southern California
APPENDIX C

Clarification of Challenges
Table 1: Preliminary Clarifications of the Challenges in Improving ESRD Patient Safety

**Triggering Question:**

“What challenges do we anticipate the community of stakeholders will face in improving ESRD patient safety?”

1 - Challenge

**THE DIFFERING VIEWS OF THOSE FAMILIAR WITH THE MEDICAL MODEL OF MEASUREMENT AND IMPROVEMENT AS COMPARED TO SAFETY AND HUMAN ERROR MEASUREMENT, AVOIDANCE AND IMPROVEMENT**

Trying to get beyond a model many of us have been dealing with for years, one that differs in crucial ways from the model of thinking about safety. This new model is focused on near misses, which are in some ways more important to track than actual events. In this model, the term “making errors visible” is more appropriate than “reporting errors.” There’s a real tension between training we get professionally and this way of thinking.

2 - Challenge

**DEALING WITH DIFFERENT CULTURES BE THAT EACH PROVIDER AT THE LOCAL LEVEL, CORPORATE LEVEL, AND INTERDISCIPLINARY.**

Within each institutional facility there is a different culture; and furthermore, within each institution there are further subcultures, such as a nursing culture, a technician culture, etc. By culture, the statement intends to mean particular types of rights and roles, values and behaviors.

3 - Challenge

**LACK OF AGREEMENT ON WHAT CONSTITUTES A MEDICAL ERROR, A LACK OF A COMMON TAXONOMY**

In our various constituencies there is a lack of knowledge of what, for instance, a near miss is. That’s a lack we have to recognize if we are to identify a way to identify and decrease near misses. We have to come to an agreement on a common language. “Medical error” is meant as a generic term, not limited to physician error, for instance. It’s meant to refer to a system error.

4 - Challenge

**CONFLICT BETWEEN FINANCIAL VIABILITY AND AN APPROPRIATE USE OF RESOURCES TO ACHIEVE EXCELLENCE.**

Today we are challenged to ‘pay our way’ with increasingly restricted resources, trying to achieve excellence in multiple arenas: staffing, technology, patient education, patient care, etc. Trying to spend our money appropriately in all these arenas is difficult.

5 - Challenge

**RESOURCES ARE LIMITED. OUR COMMUNITY SHOULD ONLY PURSUE QUESTIONS THAT ARE LIKELY TO HAVE AN IMPACT ON OUTCOMES. THE FIRST CHALLENGE IS TO GENERATE ESTIMATES OF THE MAGNITUDE OF THE PROBLEM AND TO ESTIMATE COST OF HOW TO FIX IT.**

It’s not easy to collect data: even paying people at high rates to do this, it’s a painful process. In dialysis units, even the most well meaning staff are just busy, busy, busy. It’s a real challenge to find money to do this kind of studies we may want to do. What’s striking is that we don’t have much of an estimate of how big a problem ESRD patient safety is. Are changes likely to yield an outcome that is worth the money we’ll need to invest in bringing them about? The federal government is cheap, so you have to make a case that there is a problem.
Table 1: Preliminary Clarifications of the Challenges in Improving ESRD Patient Safety

6 - Challenge  ENGAGING PATIENTS IN THEIR ROLE IN THEIR CARE.

The only factor that is constant across the ESRD care continuum is the patient; empowering the patient would have therefore substantial effects. This engagement would include education, but not be limited to education.

7 - Challenge  DIFFICULTY IN GATHERING RELEVANT DATA WITHOUT APPROPRIATE LEGAL PROTECTION FROM LITIGATION OR REGULATORY ACTION

Right now there’s a vulnerability in collecting data, with regard to its use in malpractice or regulation. We can’t get that data without some protection. There’s no protection right now. Any effort at data collection at a national level, outside of a hospital, is not protected from use in a legal or regulatory context.

8 - Challenge  OBTAIN ACCURATE DATA TO DETERMINE PROBLEM AREAS AND TO DEVELOP BASELINE MEASURES OF CURRENT SAFETY.

If our challenge as a group is to improve patient safety, we need to know what we are dealing with; this requires us to obtain accurate data in a timely manner. This idea is similar to IDEA #5.

9 - Challenge  ENSURING THAT ERROR REDUCTION TECHNOLOGIES THAT ALREADY HAVE BEEN DEVELOPED ARE DISSEMINATED AND WIDELY USED.

There’s no need for us to reinvent the wheel. The pharmaceutical area, for instance, already has developed ways to minimize prescription mistakes, and these techniques are not being used in dialysis units. Another example is connectivity, making it impossible to connect things incorrectly. (For example, a computer’s ports are each different, so you can’t connect a cord to the wrong port.) We had a patient who died recently since TPN solution was infused into her peritoneal dialysis catheter.

Ensuring implementation of these techniques also involves ensuring financial support for such implementation.

10 - Challenge  MISMATCH BETWEEN ACTUAL RESPONSIBILITY FOR PATIENT SAFETY AND THE PERCEPTION OF RESPONSIBILITY FOR PATIENT SAFETY.

We already have some regulations in place that lay out who is responsible for patient safety. At the level of individual dialysis units, the culture of that individual unit somehow does not perceive that they are responsible to the degree that the regulations specify, and this in turn leads them not to pursue safety. This phenomenon may grow out of the ineffective enforcement of the regulations, or perhaps faulty interpretation of the regulations. The main concern of this idea is that management or leadership of the individual units is remiss in creating effective safety practices in their units that would be in compliance with regulations. For example, medical directors often do not realize that they are responsible for safe water, even though that responsibility is clearly laid out in the regulations. If the leadership does not perceive that they are responsible, it is difficult to create a culture of safety.
Table 1: Preliminary Clarifications of the Challenges in Improving ESRD Patient Safety

11 - Challenge  **REMOVING THE ELEMENT OF BLAME AND ENDORSING AN ATMOSPHERE OF IMPROVEMENT FOR PROPOSED ACTION**

This point relates to data issues, since a disincentive to report interferes with the collection of data. It also relates to culture issues: if there’s a mistake and we just blame the person involved, then we’re not doing what we should do to improve the system.

12 - Challenge  **MISMATCH BETWEEN THE GROWING NUMBER OF PATIENTS AND THE AVAILABLE WORKFORCE.**

There is only so much time in the day, and only so many people to do the work; as we add more tasks, specifically regarding the monitoring and improvement of patient safety, we will need more people: not just those with direct patient care roles (physicians, technicians, nurses, social workers, etc.), but also clerical workers. The shortfall in the workforce reflects both insufficient ‘training pipeline’ output and inadequate funding for adequate staffing and retention.

13 - Challenge  **UNDERSTANDING HOW TO TRAIN AND EDUCATE PATIENT-CARE STAFF.**

This point refers to the often-heard concerns that staff don’t understand what they need to do, perhaps partially because of high turnover and the need to train many new people quickly. There may be other disciplines where training and engaging the person being trained may be done more effective than what has customarily been done in the ESRD community. If so, these insights should be utilized in training and educating patient-care staff.

14 - Challenge  **PROVIDING SIMPLE IMPLEMENTATION OF A SOLUTION TO A COMPLEX ISSUE.**

Thinking about the example of DOQI (Dialysis Outcomes and Quality Improvement), we need a plan that does not overwhelm people, but rather is simple enough to be understood and implemented throughout the clinical level.

15 - Challenge  **REALIZING EACH OTHER AS EQUAL STAKEHOLDERS, BOTH IN THIS ROOM AS WELL AS ACROSS THE BOARD, IN THE SAFETY ISSUE.**

Everybody needs to work together, including the physicians, nurses, ancillary staff, and patients. Unless we treat each other as equals in the process of improving patient safety, patients will never receive the care or patient care they need. This is also related to the issue of authorship of anything produced by this group.

16 - Challenge  **LACK OF PROFESSIONAL EDUCATION AND INTERACTION BETWEEN THE PRIMARY AND SPECIALIZED CAREGIVERS.**

We may have tried to encompass too much in this statement, trying to capture two major aspects of transplantation safety: how to get a range of medical providers to approach potential organ donors; and how to educate patients post-transplant, along with transplant coordinators and nurses, specifically with regard to drug interactions and the timely seeking of care. Primary care physicians who are well educated could both provide better care themselves, but also recognize situation that absolutely require specialty care.

Produced by the participants at the NPSF/ RPA/Forum Workshop – October 30th, 2000
Table 1: Preliminary Clarifications of the Challenges in Improving ESRD Patient Safety

17 - Challenge THE EXISTENCE OF EXTRAORDINARILY COMPLICATED INSURANCE SYSTEMS IN OUR COUNTRY.

Because we don’t have uniform health care, patients are covered by multiple types of health insurance. This makes it hard to figure out what is covered and by whom. It’s become so complicated that patients don’t know what resources are available for them to get good coverage for their care and medications. One group at particular risk is patients turning 18 and moving into a new care setting with new insurance coverage.

We need to organize the health insurance that exists to help our patients get the coverage they deserve. Patients will do better if we get them access to care. If patients don’t have the funding they won’t take their medications and they won’t be safe. If they can’t get to the dialysis unit, they’re not going to be safe. These problems make dialysis much more complicated.

This complexity also means that one insurance entity may be less willing to invest money in improving patient safety in one area if the financial benefit would be realized for another insurance entity.

18 - Challenge MISMATCH OF KNOWLEDGE AND SKILLS OF CLINICIANS WHO ARE PROMOTED INTO POSITIONS OF LEADERSHIP WITHOUT APPROPRIATE TRAINING AND/OR EDUCATION.

Similar to IDEA #13, but moves more directly into the issues that arise from the challenges of leadership. For example, a highly-skilled dialysis nurse who, based on performance at that level of work, is promoted to a leadership role without adequate training and perhaps ability for the new role.

19 - Challenge ACHIEVING A COMPREHENSIVE APPROACH TO PATIENT SAFETY THAT INCLUDES BOTH REGULATORY AND NON-REGULATORY APPROACHES

There are reasonable concerns about the potential punitive use of information collected in an effort to improve patient safety. But there are also reasons why regulators need information to ensure patient safety. We as a group need to construct a safe way to provide that data.

There’s a role for helping entities improve safety, but if an entity is unsafe and remains unsafe the regulatory agency has to close it down. This is something that only a regulatory agency can do and it’s an important part of ensuring patient safety.

20 - Challenge RESISTENCE BY STAKEHOLDER GROUPS TO RECOGNIZE AND POSITIVELY RESOLVE ISSUES OF CONFLICT.

This idea expands on IDEA #2, because it includes payers as well as patients and providers. This concept also means to incorporate the notion of ‘equality of stakeholders’ that is manifest in IDEA #15. Examples of conflict include those between providers and payers regarding costs and reimbursement, or between providers and regulators regarding ‘red tape’ generating processes.

21 - Challenge TO DEVELOP DATA COLLECTION TOOLS WHICH COVER THE BROADEST ASPECTS OF PATIENT SAFETY.

This is a corollary to #8: the need to obtain accurate data. Patient safety may be taken to involve a wide range of issues, but however the question is defined we need data collection tools that can assess all the relevant aspects of it. Such tools need to be user-friendly and concise as well. A questionnaire printed on a single page has a much higher chance of being filled out than one that is printed on multiple pages. Compared to #8, this challenge concentrates on problems in collecting data rather than also problems than in using it.

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Table 1: Preliminary Clarifications of the Challenges in Improving ESRD Patient Safety

22 - Challenge  ENSURING INFORMATION GATHERING AND PROCESSES CROSSES PHYSICAL VENUES.

The salient aspect here is this notion of ‘crossing’: since patients spend time in many venues, from home to intensive care units of hospitals, we need to focus across all these venues and ensure that information and safety-improvement processes flow across them.

23 - Challenge  DIFFICULTY IN INVOLVING OR ACHIEVING BUY-IN BY ALL LOCAL STAKEHOLDERS (THAT IS MANDATORY VS. INCENTIVIZED PROCESSES)

Related to #10 and #13. Assuring ESRD patient safety involves many people doing many different things. It includes, for example, a housekeeping clerk mopping the floor and a truck driver not leaving dialysate outside in cold weather. How do we involve these workers in the process of improving patient care? Any attempt to improve ESRD patient safety will likely result in additional mandatory requirements affecting such workers, and this will reduce “buy-in” by them.

24 - Challenge  ALLOCATING RESOURCES TO REMAIN FOCUSED ON THE MOST CRITICAL AREAS OF CONCERN.

To start with an example, when hospitals are queried on hundreds of areas of patient safety, they want to know which questions ‘are the most important.’ We need to remain focused if we are to be effective.

25 - Challenge  THE NEED FOR FINANCIAL AND OTHER SUPPORT TO REDUCE ERRORS.

Many people have talked about resource and financial issues, for example in collecting data, but this challenge is meant to broaden that. If we as a community strongly believe that patient safety is a priority for us, then resources and money will have to be allotted to our activities. It will take money if we want to improve recruitment and maintenance of staff, for example. If we decide to add computers at point-of-service to improve patient safety, for example, that would have a high price tag too.

26 - Challenge  DIFFERING VIEWS OF THE SEVERITY OF THE PROBLEM OR RECOGNIZING THAT THERE IS A PROBLEM.

2 things strike me. First, most of us recognize clearly those events that dramatically and acutely harm patients; more difficult is discerning delayed harmful effects. Second, even though patients experience very different levels of morbidity, safety is broader than simply whether something had happened to a person; someone who suffers no bad outcome may not have been safe. “Near-misses” therefore are part of safety, but not all.

27 - Challenge  IN A UNIFIED PLAN, BRIDGING THE GAP BETWEEN VARIOUS ISSUES UNIQUE TO CERTAIN MODALITIES OF RENAL REPLACEMENT THERAPIES.

We’re going to have to consider the various modalities of care and differences between them in developing a plan to improve patient safety.

28 - Challenge  NEED FOR COLLABORATIVE PROACTIVE DEVELOPMENT OF REGULATORY POLICIES TO AVOID UNINTENDED ADVERSE CONSEQUENCES TO PATIENTS.

Broadening the concept of ‘safety’, here we wish to touch on the idea that not just individual error impairs safety, but also regulatory actions. For example, the HMA hematocrit audit was not the best policy (with patients’ hematocrit actually falling during the audit), but this took much time and effort to reverse.

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Table 1: Preliminary Clarifications of the Challenges in Improving ESRD Patient Safety

29 - Challenge  **THE EVENT DENOMINATOR FOR ESRD PATIENT SAFETY IS HUGE, HIGHLIGHTING THE NEED TO ESTABLISH ERROR NUMERATOR DATA FOR ESTIMATING MAJOR ERROR RATES.**

Related to #5. The point here is to ask the question of how big the problem is. There is an immense opportunity for errors and near-misses given the size of the ESRD patient population and the amount of care provided. The concern is that ESRD patient data is as good as it gets and making it better may be very costly.

30 - Challenge  **OVERCOMING REGIONAL DIFFERENCES AND RESPONSIBILITIES AND ATTITUDES OF FRONTLINE CAREGIVERS.**

This deals with implementation, specifically within the same discipline (and not tackling the broader problems across disciplines). For example, technicians in the northeast are more career-oriented; those in the southeast are more ‘blue collar’ in their perspective and hence motivational structure.

31 - Challenge  **NEED FOR ACHIEVING AGREEMENT ON THE SCOPE OF THE PROBLEM OF PATIENT SAFETY.**

How far outside the realm of direct ESRD treatment do we go? For example, does patient safety include a case like the following: a patient’s dialysis team is not aware that he is scheduled to undergo surgery that day, and so he receives a medication that requires the postponement of the surgery.

32 - Challenge  **LACK OF LONG-TERM UNDERWRITING OF THERAPY WITH BUILT-IN INCENTIVES.**

Dealing more with the transplant problem here, with incentives both for the patients and the financial underwriters to promote longevity of graft function so that these patients do not revert back to more costly modes of care due to poor post-transplant care.

33 - Challenge  **TO CREATE EXPANDED FUNDING FOR PATIENTS TO SECURE MEDICATIONS AND TO IMPROVE PATIENT MEDICATION EDUCATION PROGRAMS**

One challenge to ESRD patient safety is the fact that many patients can’t afford their medications and don’t get sufficient education in the importance of their taking the medications.

34 - Challenge  **THIS ACTIVITY REPRESENTS A NEW WAY OF THINKING FOR THE ESRD COMMUNITY ABOUT PATIENT PROBLEMS: PATIENT SAFETY IS DIFFERENT OUR HABITUAL PROBLEM SOLVING TECHNIQUES, SUCH AS TQM, QA, ETC.**

There is very little incentive, habit of mind, or experience in seeking out root causes of medical errors. An individual or single act is identified, and the investigation ends there; by contrast, inquiring into the context. To borrow a phrase from the aviation industry, we tend not to go to the ‘second story’ in error analysis. A medication error occurs and the ‘perpetrating’ nurse is identified; the ‘second story’ is what other responsibilities she had, the legibility of the control document, distractions from STAT pages, or other aspects of her work environment that further explain the occurrence of error.
Table 1: Preliminary Clarifications of the Challenges in Improving ESRD Patient Safety

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| 35 - Challenge   | **To develop a reporting system that encourages the full reporting of “errors” and their root causes by achieving the appropriate balance between confidentiality and public accountability.**  
Relates to #7. There has to be confidentiality if errors are going to surface and information necessary to do root cause analysis is to become available. But there also needs to be public accountability of the institutions involved. Have to balance these two needs. Includes the issue of obtaining informed consent, for example as now happens when patients apply for Medicare coverage of their treatment. |
| 36 - Challenge   | **Patient safety issues there is often difficulties in identifying contributing factors, difficulty in identifying the core problem to achieve an affective plan of action.**  
Very often incorrect solutions are applied due to incomplete understanding of the problem. |
| 37 - Challenge   | **Finding and identifying events which are rare and costly to monitor is not likely to lead to cost-effective programs for safety assurance.**  
Many of the safety issues we will identify do not occur on a frequent basis. We may well be attempting to eliminate events that happen very infrequently and thus will be very costly to identify and track. E.g. breast cancer screening for patients 50-60 years old costs $100,000 per year of life saved, and in patients 40-50 years old $200,000 per year of life. Activities we recommend here have to be cost effective if we expect them to be supported. This is a part of the same issue addressed by #24. |
| 38 - Challenge   | **Unsufficient data on ESRD patient safety issues without Medicare eligibility.**  
The USRDS does not capture data during the first 90 days of dialysis, when patients may indeed experience high rates of adverse events. Data after the first 90 days may or may not be sufficient, but clearly this early phase is clearly not monitored. For this particular idea, those patients who after 90 days are on private insurance are not incorporated as the main focus of concern, since their safety is being monitored. All ESRD patients during this interval are the focus of concern. Specifically, without Medicare or HCFA oversight, the safety of these patients is unknown. Too much of our current understanding of ESRD safety ignores these patients or this phase of patients’ experiences. |
| 39 - Challenge   | **On an ongoing basis develop methods to monitor the effects of safety processes on outcomes or results.**  
If we identify a patient safety issue, we have to have a way to track that, hopefully documenting its elimination. We also have to have mechanisms in place to identify new challenges to patient safety as they come up. |
| 40 - Challenge   | **Timely access to ESRD care.**  
Intentionally broad, capturing those patients who are still pre-ESRD, issues of rural health care access, and other general issues of access to health care. |
Table 1: Preliminary Clarifications of the Challenges in Improving ESRD Patient Safety

41 - Challenge SEPARATING SAFETY CONCERNS THAT ARE NOT SIGNIFICANT FROM AN EPIDEMIOLOGICAL STANDPOINT FROM THOSE THAT ARE
We don’t have data to back up any of our ideas about which possible patient safety issues are significant and which aren’t. Related to challenges #5 and #8.

42 - Challenge MISMATCH BETWEEN FUNDING FOR CLINICAL SERVICES AND THE NEED TO UPGRADE OR REPLACE TECHNOLOGY.
Diminishing funding and simultaneous technology and knowledge improvement, with the demand to stay at the cutting edge with less, is challenging.

43 - Challenge LACK OF STRONG PATIENT DEMAND TO MOTIVATE DEMAND TO MOTIVATE CHANGE.
Some patient groups, such as people with AIDS, are strong advocates on their own behalf. ESRD patients tend not to do that, and this is a challenge to improving ESRD patient safety.

44 - Challenge THE CHALLENGE OF DEVELOPING A PROCESS FOR WHO, HOW, WHEN DIFFERENT STAKEHOLDER GROUPS CAN AND SHOULD WORK TOGETHER.
Further down the line, when designing improved safety-enhancing processes, we need to make sure that these details need to be spelled out so as to collaborate.

45 - Challenge (ASSURING RESOURCES AND FINANCES TO DEVELOP AND BENCHMARK SAFETY ISSUES WE DEFINE AS STAKEHOLDERS.)
Deleted.

46 - Challenge ENSURING TIMELY ACCESS TO TRANSPLANTATION.
Given data that there may be a benefit to earlier transplant, perhaps even prior to reaching ESRD and dialysis, moving patients towards transplantation sooner could enhance safety.

47 - Challenge THE NEED TO RECOGNIZE THE RELATIVE IMPORTANCE AND VALUE OF THREE DISTINCT AREAS OF PATIENT SAFETY: 1) DATA COLLECTION, ANALYSIS, AND REPORTING, 2) THE ESTABLISHMENT OF AN APPROPRIATE CULTURE AND PROFESSIONAL ATTITUDE VS 3) TRAINING AND DEVELOPMENT
Here we emphasize the need to balance between the need to get more data and the chance to institute changes recommended by the safety sciences. May not need so much more data to start acting to improve ESRD patient safety. We have to balance any investment between the collection of more data and the institution of changes that can help.

48 - Challenge WE HAVE TO UNDERSTAND THE OPPORTUNITY COSTS OF THIS ACTIVITY RELATIVE TO THE COMPETING PRIORITIES FOR DATA FROM OTHER OVERSIGHT AND REGULATORY BODIES OVER ESRD.
Working with the concept of the ‘forgotten American,’ where A decides that B needs to do something on C’s behalf … someone needs to look out for the total demands that many As may be placing on few Bs, and assist Bs in prioritizing their activities.
Table 1: Preliminary Clarifications of the Challenges in Improving ESRD Patient Safety

49 - Challenge WE HAVE TO ENSURE A FOCUS ON DATA ANALYSIS AND FEEDBACK TO USERS.
   We’ve spent lots of time talking about collecting the data, but providing feedback to users will be very important as well.

50 - Challenge THE EFFICIENT INCORPORATION OF “PATIENT SAFETY THOUGHT PROCESS” INTO WHAT WE DO WITHOUT ADDING REDUNDANCIES.
   This expands on the ideas expressed earlier that we don’t create simply more burdensome workloads and red tape.

51 - Challenge DEVELOPING A SUGGESTED METHOD FOR CORRECTING THESE PROBLEMS.
   We’ve identified lots of problems but not how we’re going to correct them.

52 - Challenge HOW DO YOU INTEGRATE VARIOUS ASPECTS OF PATIENT SAFETY, SUCH AS IDENTIFYING, COLLECTING, AND REPORTING, AND THE EDUCATION OF STAFF AND PATIENTS INTO THE CARE PROCESS TO MAKE IT A DAILY ACTIVITY.
   Implementing a patient safety program into a dialysis unit successfully requires that it work in ‘seamlessly’ and this will requiring education and training of staff.

53 - Challenge PERCEIVED AND REAL REGULATORY IMPEDIMENTS AND COSTS THAT DISCOURAGE INTRODUCTION OF NEW DEVICES AND DRUGS
   One way that we will be able to cope with the rare events discussed here will be through advances in technology. The regulatory approval of new devices in this country is pretty slow and costly, and this is discouraging people who are developing new technologies outside this country from applying to have them approved here. E.g. the development of “closed loop systems” that can automatically make adjustments without requiring the input of an operator. A growing gap may be opening up.

54 - Challenge LACK OF UNDERSTANDING OF DRUG/NUTRIENT INTERACTIONS WHEN MULTIPLE MEDICATIONS ARE USED WITH ESRD PATIENTS.
   Fairly self-explanatory. Some software programs exist for drugs used in general medical patients, but we don’t adequately use our existing knowledge and we don’t know enough specifically about these issues in the ESRD patient population. Patient understanding is also incorporated into this idea.

55 - Challenge TO ENGAGE PATIENTS IN THE PROCESS OF ENSURING SAFETY WE NEED TO BE AWARE OF PATIENT DIVERSITY, I.E. ETHNIC, CULTURE, AND LANGUAGE BARRIERS.
   Language barriers can cause challenges to patient safety by interfering with the patient’s understanding of their care and medical regime.

56 - Challenge TO INSURE THE DISSEMINATION OF DATA RESULTS AND ANALYSIS TO PATIENTS AND MEMBERS OF ALL DISCIPLINES.
   Any work done by this group or other groups should be disseminated beyond simply publication in an isolated journal.
Table 1: Preliminary Clarifications of the Challenges in Improving ESRD Patient Safety

57 - Challenge OVERCOMING CULTURAL BARRIERS IN UNDERSTANDING RISKS AND BENEFITS OF TRANSPLANTATION AND IMMUNOSUPPRESSIVE MEDICATIONS

*Different cultures have varying attitudes toward donating organs and undergoing transplant, as well as varying attitudes about taking medication. We need to understand this diversity in maximizing ESRD care.*

58 - Challenge STAFF BURNOUT.

*Self-explanatory. Staffs are confronted with repetitive tasks that they must perform with the highest level of vigilance; they also are challenged emotionally by the high morbidity and mortality in the patient population they serve.*

59 - Challenge RECOGNITION AND ACCEPTANCE OF ALL RENAL COMMUNITY STAKEHOLDERS THAT PATIENTS ARE THE MOST IMPORTANT STAKEHOLDERS IN IMPROVING ESRD PATIENT SAFETY

*Articulating the moral basis for what we’re doing.*

60 - Challenge IN THE IDENTIFICATION OF PROBLEMS BY PATIENTS, THERE IS A NEED FOR ENSURING THE PROTECTION OF PATIENT RIGHTS.

*Patients claim that they do not ‘speak up’ because they are scared that they would suffer adverse consequences for such behavior. We need to offer firm reassurance that their input will be respected and no adverse consequences will ensue.*
Challenge Clusters
The Clusters of Challenges

Cluster #1: Finding the Right Approach

(Challenge – 1) THE DIFFERING VIEWS OF THOSE FAMILIAR WITH THE MEDICAL MODEL OF MEASUREMENT AND IMPROVEMENT AS COMPARED TO SAFETY AND HUMAN ERROR MEASUREMENT, AVOIDANCE AND IMPROVEMENT

(Challenge – 9) ENSURING THAT ERROR REDUCTION TECHNOLOGIES THAT HAVE ALREADY BEEN DEVELOPED ARE DISSEMINATED AND WIDELY USED

(Challenge – 14) PROVIDING SIMPLE IMPLEMENTATION OF A SOLUTION TO A COMPLEX ISSUE

(Challenge – 19) ACHIEVING A COMPREHENSIVE APPROACH TO PATIENT SAFETY THAT INCLUDES BOTH REGULATORY AND NONREGULATORY APPROACHES

(Challenge – 24) ALLOCATING RESOURCES TO REMAIN FOCUSED ON THE MOST CRITICAL AREAS OF CONCERN

(Challenge – 27) IN A UNIFIED PLAN -- BRIDGING THE GAP BETWEEN VARIOUS ISSUES UNIQUE TO CERTAIN MODALITIES OF RENAL REPLACEMENT THERAPIES

(Challenge – 34) THIS ACTIVITY REPRESENTS A NEW WAY OF THINKING FOR THE ESRD COMMUNITY ABOUT PATIENT PROBLEMS: PATIENT SAFETY IS DIFFERENT FROM OUR HABITUAL, ETC.

(Challenge – 47) THE NEED TO RECOGNIZE THE RELATIVE IMPORTANCE AND VALUE OF THREE DISTINCT ASPECTS OF PATIENT SAFETY; 1) DATA COLLECTION, ANALYSIS AND REPORTING VS 2) THE ESTABLISHMENT OF AN APPROPRIATE CULTURE AND PROFESSIONAL ATTITUDE VS 3) TRAINING AND DEVELOPMENT

Cluster #2: Accommodating Diverse Stakeholder Interests

(Challenge – 2) DEALING WITH DIFFERING CULTURES BE THAT EACH PROVIDER AT THE LOCAL LEVEL, AT THE CORPORATE LEVEL AND INTERDISCIPLINARY

(Challenge – 15) REALIZING EACH OTHER AS EQUAL STAKEHOLDERS BOTH IN THIS ROOM AS WELL AS ACROSS THE BOARD IN THE SAFETY ISSUE

(Challenge – 20) RESISTANCE BY CERTAIN STAKEHOLDER GROUPS TO RECOGNIZE AND POSITIVELY RESOLVE ISSUES OF CONFLICT

(Challenge – 23) DIFFICULTY IN INVOLVING OR ACHIEVING BUY-IN BY ALL LOCAL STAKEHOLDERS (THAT IS MANDATORY VS INCENTIVIZED PROCESSES)

(Challenge – 28) NEED FOR COLLABORATIVE PRO-ACTIVE DEVELOPMENT OF REGULATORY POLICIES TO AVOID AN UNITTENDED ADVERSE CONSEQUENCES TO PATIENTS

(Challenge – 30) OVERCOMING REGIONAL DIFFERENCES AND RESPONSIBILITIES AND ATTITUDES OF FRONT LINE CAREGIVERS

(Challenge – 44) THE CHALLENGE OF DEVELOPING A PROCESS FOR WHO, HOW, WHEN, DIFFERENT STAKEHOLDER GROUPS CAN AND SHOULD WORK TOGETHER

(Challenge – 59) RECOGNITION AND ACCEPTANCE OF ALL RENAL COMMUNITY STAKEHOLDERS THAT PATIENTS ARE THE MOST IMPORTANT STAKEHOLDERS IN IMPROVING ESRD PATIENT SAFETY
The Clusters of Challenges

Cluster #3: Aligning Our Perceptions of the Problem
(Challenge – 3) LACK OF AGREEMENT ON WHAT CONSTITUTES A MEDICAL ERROR A LACK OF A COMMON TAXONOMY
(Challenge – 10) A MISMATCH BETWEEN ACTUAL RESPONSIBILITY FOR PATIENT SAFETY AND THE PERCEPTION OF RESPONSIBILITY FOR PATIENT SAFETY
(Challenge – 26) DIFFERING VIEWS OF THE SEVERITY OF THE PROBLEM OR RECOGNIZING THAT THERE IS A PROBLEM
(Challenge – 31) NEED FOR ACHIEVING AGREEMENT ON THE SCOPE OF THE PROBLEM IN PATIENT SAFETY
(Challenge – 56) TO ENSURE THE DISSEMINATION OF DATA RESULTS AND ANALYSIS TO PATIENTS AND MEMBERS OF ALL DISCIPLINES

Cluster #4: Fostering Exemplary Staff Achievement
(Challenge – 4) CONFLICT BETWEEN FINANCIAL VIABILITY AND APPROPRIATE USE OF RESOURCES TO ACHIEVE EXCELLENCE
(Challenge – 12) MISMATCH BETWEEN THE GROWING NUMBER OF PATIENTS AND THE AVAILABLE WORK FORCE
(Challenge – 13) UNDERSTANDING HOW TO TRAIN AND EDUCATE PATIENT CARE STAFF
(Challenge – 16) LACK OF PROFESSIONAL EDUCATION AND INTERACTION BETWEEN THE PRIMARY AND SPECIALIZED CARE GIVERS
(Challenge – 18) MISMATCH OF KNOWLEDGE AND SKILLS OF CLINICIANS WHO ARE PROMOTED INTO POSITION OF LEADERSHIP WITHOUT APPROPRIATE TRAINING AND/OR EDUCATION
(Challenge – 58) STAFF BURNOUT

Cluster #5: Stepping Up Self-Care
(Challenge – 6) ENGAGING PATIENTS IN THEIR ROLE IN THEIR CARE
(Challenge – 43) LACK OF STRONG PATIENT DEMAND TO MOTIVATE CHANGE
(Challenge – 55) TO ENGAGE PATIENTS IN THE PROCESS OF ENSURING SAFETY WE NEED TO BE AWARE OF PATIENT DIVERSITY I.E., ETHNIC CULTURE AND LANGUAGE BARRIERS
(Challenge – 57) OVERCOMING CULTURAL BARRIERS IN UNDERSTANDING RISKS AND BENEFITS OF TRANSPLANTATION AND IMMUNOSUPPRESSIVE MEDICATIONS
(Challenge – 59) RECOGNITION AND ACCEPTANCE OF ALL RENAL COMMUNITY STAKEHOLDERS THAT PATIENTS ARE THE MOST IMPORTANT STAKEHOLDERS IN IMPROVING ESRD PATIENT SAFETY
(Challenge – 60) IN THE IDENTIFICATION OF PROBLEMS BY PATIENTS, THERE IS A NEED FOR ENSURING THE PROTECTION OF PATIENT RIGHTS
The Clusters of Challenges

Cluster #6: Gauging ESRD Patient Safety

(Challenge – 5) RESOURCES ARE LIMITED -- OUR COMMUNITY SHOULD ONLY PURSUE QUESTIONS THAT ARE LIKELY TO HAVE AN IMPACT ON OUTCOMES -- THE 1ST CHALLENGE IS TO GENERATE ESTIMATES OF THE MAGNITUDE OF THE PROBLEM AND TO ESTIMATE COST OF HOW TO FIX IT

(Challenge – 7) DIFFICULTY IN GATHERING RELEVANT DATA WITHOUT APPROPRIATE LEGAL PROTECTION FROM LITIGATION OR REGULATORY ACTION

(Challenge – 8) OBTAIN ACCURATE DATA TO DETERMINE PROBLEM AREAS AND TO DEVELOPMENT BASELINE MEASUREMENTS OF CURRENT SAFETY

(Challenge – 21) TO DEVELOP DATA COLLECTION TOOLS WHICH COVER THE BROADEST ASPECTS OF PATIENT SAFETY

(Challenge – 22) ENSURING INFORMATION GATHERING AND PROCESSES ACROSS PHYSICAL VENUES

(Challenge – 29) THE EVENT DEMONINATOR FOR ESRD PATIENT SAFETY IS HUGE, HIGHLIGHTING THE NEED TO ESTABLISH ERROR NUMERATOR DATA FOR ESTIMATING MAJOR ERROR RATES

(Challenge – 35) THE IDENTIFICATION OF PROBLEMS THAT REPRESENTS THE BALANCE BETWEEN THE NEED FOR CONFIDENTIALITY AND PUBLIC ACCOUNTABILITY

(Challenge – 38) INSUFFICIENT DATA ON ESRD PATIENT SAFETY ISSUES PRIOR TO MEDICARE ELIGIBILITYC

Cluster #7: Transforming the Culture of the Dialysis Unit

(Challenge – 11) REMOVING THE ELEMENT OF BLAME AND ENDORSING AN ATMOSPHERE OF IMPROVEMENT FOR PROPOSED ACTION

(Challenge – 50) THE EFFICIENT INCORPORATION OF "PATIENT SAFETY THOUGHT PROCESS" INTO WHAT WE DO WITHOUT ADDING REDUNDANCIES

(Challenge – 52) HOW DO YOU INTEGRATE THE VARIOUS ASPECTS OF PATIENT SAFETY SUCH AS IDENTIFYING, COLLECTING AND REPORTING AND THE EDUCATION OF STAFF AND PATIENTS INTO THE CARE PROCESS TO MAKE IT A PART OF THE DAILY ACTIVITY

(Challenge – 60) IN THE IDENTIFICATION OF PROBLEMS BY PATIENTS, THERE IS A NEED FOR ENSURING THE PROTECTION OF PATIENT RIGHTS

Cluster #8: Inferring Specific Correctives

(Challenge – 36) IN PATIENT SAFETY ISSUES THERE IS OFTEN DIFFICULTIES IN IDENTIFYING CONTRIBUTING FACTORS, DIFFICULTY IN IDENTIFYING THE CORE PROBLEM TO ACHIEVE AN EFFECTIVE PLAN OF ACTION

(Challenge – 51) DEVELOPING A SUGGESTED METHOD FOR CORRECTING THESE PROBLEMS

(Challenge – 54) LACK OF UNDERSTANDING OF DRUG / NUTRIENT INTERACTIONS WHEN MULTIPLE MEDICATIONS ARE USED FOR ESRD PATIENTS
The Clusters of Challenges

Cluster #9: Relieving Cost Pressures
(Challenge – 17) THE EXISTENCE OF EXTRAODINARILY COMPLICATED INSURANCE SYSTEM IN OUR COUNTRY
(Challenge – 32) LACK OF LONG-TERM UNDERWRITING OF THERAPY WITH BUILT-IN INCENTIVES
(Challenge – 33) TO CREATE EXPANDED FUNDING FOR PATIENTS TO SECURE MEDICATIONS AND TO IMPROVE PATIENT MEDICATION EDUCATION PROGRAMS

Cluster #10: Ascertaining the Saliency of Safety Events
(Challenge – 37) FINDING AND IDENTIFYING A RARE EVENT IS COSTLY, DIFFICULT AND FRUSTRATING
(Challenge – 41) SEPARATING SAFETY CONCERNS THAT ARE NOT SIGNIFICANT FROM A EPIDEMIOLOGICAL STANDPOINT THAT THOSE THAT ARE WITHOUT DATA

Cluster #11: Intensifying the Allocation of Resources for Improvement
(Challenge – 25) THE NEED FOR FINANCIAL AND OTHER SUPPORT TO REDUCE ERRORS
(Challenge – 42) MISMATCH BETWEEN FUNDING FOR CINICAL SERVICES AND THE NEED TO UPGRADE OR REPLACE TECHNOLOGY
(Challenge – 48) WE HAVE TO UNDERSTAND THE OPPORTUNITY COST OF THIS ACTIVITY RELATIVE TO THE COMPETING PRIORITIES FOR DATA FROM OTHER OVERSIGHT AND REGULATORY BODIES WITH AUTHORITY OVER ESRD
(Challenge – 53) PERCEIVED AND REAL REGULATORY IMPEDIMENTS AND COSTS THAT DISCOURAGE INTRODUCTION OF NEW DEVICES AND DRUGS

Cluster #12: Monitoring Interventions
(Challenge – 39) ON AN ON-GOING BASES DEVELOP METHODS TO MONITOR THE EFFECTS OF SAFETY PROCESSES ON OUTCOMES OR RESULTS
(Challenge – 49) WE HAVE TO ENSURE A FOCUS ON DATA ANALYSIS AND FEEDBACK TO USERS

Cluster #13: Ensuring Timely Access
(Challenge – 40) TIMELY ACCESS TO ESRD CARE
(Challenge – 46) ENSURING TIMELY ACCESS TO TRANSPLANTATION
APPENDIX E

Clarification of Action Options
**Table 2: Preliminary Clarifications of Action Options to Improve ESRD Patient Safety**

1. **CREATE A TASKFORCE OF STAKEHOLDERS AND EXPERTS ON PATIENT SAFETY TO AGREE ON DEFINITIONS OF MEDICAL ERRORS**

   Stakeholders would be a group such as the one assembled today, plus people with knowledge of patient safety from other disciplines. The taskforce could operate in a number of ways, including data collection, surveys, or other activities.

2. **TO DEVELOP A PROCESS FLOW-CHART TO IDENTIFY THE COMPONENTS OF RISK IN THE CONTINUUM OF CARE IN ORDER TO DEFINE THE TAXONOMY.**

   A supplement to the first OPTION, one could march along the daily and weekly travels of a dialysis patient – from home to dialysis center and back, or potentially to the hospital or some other site of care – and see where the risks of harm are located, potentially in the medical setting but also in other settings performing other activities.

3. **IDENTIFY COLLABORATIVE POSSIBILITIES WITH OTHER COMMUNITIES FOR RESEARCH, EDUCATION, AND MONEY**

   After the IOM report on medical errors, many communities are looking at ways to improve patient safety, involving education, research, etc. We should piggyback on such efforts if possible.

4. **DEVELOP UNIFORM EDUCATIONAL MATERIALS/PROGRAMS FOR TRAINING OF STAFF IN SAFETY SCIENCES.**

   The concept here is that there is a cost associated with developing these materials; to the degree that these uniform materials can be jointly-developed and used across many settings, the fixed development costs can be shared and thus lessened on each individual facility. Such standardized curricula already exist for education of technicians and nurses on performing dialysis; the OPTION expressed here would extend these curricular materials into the as-yet underdeveloped safety sciences realm for ESRD specifically. Some general material on patient safety already exists, and this could be used in the interim while more specific material is developed. Examples of safety sciences include how teams communicate among members or how new technologies can be safely introduced into clinical practice.
Table 2: Preliminary Clarifications of Action Options to Improve ESRD Patient Safety

5 DEVELOP A VOCABULARY OF DEFINITIONS AND KEY CONCEPTS BY STAKEHOLDERS

Similar to #1, but this action option is broader, since #1 just involved definitions of medical error. The vocabulary to be developed under this action option would apply to other areas of quality of care as well.

6 ADOPT A FACILITY-BASED, ANNONOMOUS REPORTING SYSTEM THAT TRACKS VARIANCES AND FEEDS THEM BACK TO THE STAFF.

Right at the grass roots level, this immediate feedback will prepare individual units to respond to the challenges to change practices in light of this facility-level information as well as information that will stem from larger data sets. Since this information is gathered and used at the facility level, the data need not be de-identified. This option arises out of the observation that you'll never track the 'near-misses' if the data collection system is not anonymous; people simply will not self-report due to fear of repercussions. The identification of individual 'perpetrators' is not necessary, at a corporate or larger organizational level, to track trends in error types and to investigate further. Concerns about the anonymity were raised, citing concerns about data verification, missing that a particular individual is committing errors repeatedly, etc. The rejoinder is simply that without anonymity, data regarding these near misses simply will never be collected.

7 CONDUCT A SURVEY OF DIALYSIS PATIENTS AND PROFESSIONALS TO LIST ISSUES OF PATIENT SAFETY

We’re trying to develop a taxonomy of patient safety, but current databases are inadequate to do this. This action option proposes carrying out a survey that will elicit experiences of patients and professionals that relate to patient safety. Then we can look at categories and frequencies so we have some initial handle on the scope and the relevance of the problem. "Patient safety" includes medical errors. This would be a survey designed specifically to develop a taxonomy, and would not include things like attitudes to patient safety, for example.

8 PATIENT SAFETY ISSUES BE DIVIDED INTO SENTINEL EVENTS OR NEAR-MISSES

The taxonomy should recognize this distinction, since the tracking the ‘near-misses’ is likely to raise very different and more difficult challenges than the tracking of sentinel events.
Table 2: Preliminary Clarifications of Action Options to Improve ESRD Patient Safety

9. FOCUS LESS ON FORMAL TAXONOMY FOR THE PRESENT AND BEGIN A BROAD BASED ERROR IDENTIFICATION SYSTEM WHICH CAN BE INTERNAL AND/OR EXTERNAL

There’s a danger of getting bogged down by trying to develop a firm definition or taxonomy of patient safety at this point in time. Maybe it would be better to broadly record what are thought to be issues of patient safety and allow useful definitions and taxonomy to arise by natural selection. Institutions such as the VA and many hospitals, for instance, have error-reporting systems in place, reflecting various definitions of patient safety. Maybe we should start there.

10. DEVELOP A SPECIFIC LIST OF WHAT IS CONSIDERED AN ERROR FROM THE IDENTIFIED FLOWCHART

After laying out the continuum of care, one can generate a list of tasks or events that are susceptible to error (and thus enabling the broad definition of ‘errors’ to be advanced).

11. DEVELOP BEST PRACTICE GUIDELINES FOR PROMOTING PATIENT SAFETY

Lots of individual units have already developed ways to prevent bad things from happening. Those ideas can be assembled together to develop best practices for promoting patient safety, whether they involve technology or process. We should give people guidance about what has worked the best. We have data that allow us to know that certain facilities have better outcomes than others, and we can look at their practices and make them available in the form of guidelines to other facilities.

12. DEVELOP A SOFTWARE SYSTEM THAT CAN BE IMPLEMENTED/INSTALLED IN ALL DIALYSIS FACILITIES.

To leverage resources, again the economies of scale regarding development would reduce fixed development costs, as well as promoting uniform data collection, collation, transmission, and analysis across sites and within networks. HCFA may or may not be in this chain of information; that decision would take further considerations regarding the pros and cons of HCFA inclusion on the quality and quantity of captured data.
13 IDENTIFY THE CHARACTERISTICS OF MEDICAL ERRORS IN
CONTRAST TO QUALITY OF CARE ISSUES

In many discussions, examples of poor quality of care seem to be treated as
cases of medical error. We should characterize and define the differences
between medical error and other issues in quality of care. From the legal
perspective, medical errors carry legal culpability and legal responsibility, while
quality of care issues may or may not have legal culpability.

14 CREATE A DATA BASE OF MEDICAL ERRORS AND NEAR-MISSES
MAINTAINED BY A NON-REGULATORY GROUP AND PROTECTED
FROM LEGAL DISCLOSURE.

Fairly self-explanatory. If there is a mechanism that would protect a privately-held
data-base from being accessed through legal inquiry, which does exist for
governmental data-bases, then such a data-base would enhance trust level.

15 INTEGRATE CURRENT WORK ON PATIENT SAFETY TAXONOMY
FROM OTHERS, E.G. ANESTHESIA AND PHARMACOLOGY INTO ESRD

Taxonomy systems in these areas exist and may be useful in thinking about these
issues in ESRD.

16 SURVEY OF PATIENTS AND PROFESSIONALS ON WHAT
CONSTITUTES HUMAN AND TECHNOLOGICAL MEDICAL ERRORS IN
ESRD CARE; THEIR IMPORTANCE AND FREQUENCY.

OPTION #7 really covers this option, so it is withdrawn.

17 CONDUCT EDUCATION AND TRAINING FOR THE ESRD PROGRAM
LEADERSHIP ON THE NATURE OF THE PROBLEM AND IN THE
SAFETY SCIENCES

The focus here is on the leadership: without leadership buy-in we can't succeed.
Leadership includes people such as those in this room: leadership of payers,
individual units, networks, etc.

18 USING A DEFINED LIST OF MEDICAL ERRORS, IDENTIFY
STAKEHOLDERS AND THEIR RESPONSIBILITIES IN RESPONDING TO
A MEDICAL ERROR.

This is in the process of defining of medical errors and then defining stakeholder
roles and responsibilities.
Table 2: Preliminary Clarifications of Action Options to Improve ESRD Patient Safety

19  GAIN COMMITMENT FROM INDUSTRY TO PROVIDE PATIENT SAFETY FUNDS AND TECHNOLOGIES AS PART OF CONTRACTS

   It's in the best interest of industry that their products and devices be used safely. We should begin a dialogue with vendors to improve the use of their products and devices and thus improve patient safety.

20  ESTABLISH A CENTRAL CLEARINGHOUSE FOR PATIENT SAFETY FOR ESRD, INCLUDING DEFINITIONS, PROGRAMS, REAL-TIME ERROR TRACKING, THAT WOULD BE AVAILABLE AT NO CHARGE TO DIALYSIS FACILITIES.

   Similar to the previous concept (OPTION #12) of a central data repository, but with the caveat that access to the data would be free for individual facilities.

21  ESTABLISH A PLAN TO EDUCATE THE RENAL COMMUNITY ON WHAT PATIENT SAFETY IS

   We have to have a plan to educate the people who will ensure that the action to improve patient safety occurs. This would involve education in safety science, including medical error.

22  ARCHIVE DATA CENTRALLY BY PATIENT WITHOUT PROVIDER IDENTIFICATION.

   To overcome the difficult of obtaining or collecting relevant data, here the idea is that data regarding individual patients could be entered by providers, with provider willingness to do so enhanced by the protection of their anonymity. Patients could access their own data. The data might be accessible by a Web-based portal, with patient confidentiality protected through various measures.

23  PROVIDE TOOLBOX TO DIALYSIS UNITS TO HELP IDENTIFY AND CHARACTERIZE ISSUES IN PATIENT SAFETY

   It will be helpful to give specific guidance to end users on how to identify and classify patient safety issues. This will could be the form of a "toolbox" that gives specific guidance in many areas, for example in distinguishing between sentinel events vs. near misses. PRO's have used such "toolboxes" to enable end-users to follow guidelines and record events clearly. These toolboxes include data collection forms, definitions for categories, and flow charts for analyzing data. Want to enable and empower end users to understand what we are talking about here and record data in a meaningful way. The idea of establishing a clearinghouse (in action option #20) might include providing such tools, but this action option (#23) concentrates on providing such tools.
Table 2: Preliminary Clarifications of Action Options to Improve ESRD Patient Safety

24 IDENTIFY AND ANALYZE EXISTING DATA ON ERRORS IN ESRD CARE WITHIN A PROTECTED ENVIRONMENT.

Although we have not comprehensive data base on ESRD, we do have smaller existing data sets. If in a protected environment, these data bases could be analyzed to generate “top five” lists of adverse events or medical errors, or other preliminary but helpful analyses while we develop these larger & more comprehensive data sets.

25 CONDUCT RESEARCH INTO MEDICAL ERROR IDENTIFICATION AND ITS IMPORTANCE IN REGARDS TO FUTURE SYSTEM FAILURES AND NEGATIVE PATIENT OUTCOMES

The focus here is on research into what kind of error-identification and reporting systems we need to implement improvements in patient safety.

26 DEVELOP FORMAL PRACTICE GUIDELINES TO AVOID THE OCCURRENCE OF PREVIOUSLY IDENTIFIED MEDICAL ERRORS.

OPTION #11 captures this option, so this option is withdrawn.

27 ENCOURAGE ADAPTATION

Many action items involve adapting existing ideas and methods from other areas to improve ESRD patient safety.

28 MAKE PATIENT SAFETY A HIGH PRIORITY FOR ESRD NETWORKS AND P-R-Os TO LEVERAGE CURRENT FUNDING FOR THESE ORGANIZATIONS AS WELL AS STATE HEALTH DEPARTMENTS.

Clear.

29 CONDUCT LITERATURE SEARCH OF PATIENT SAFETY DEFINITIONS USED IN OTHER HEALTH CARE SETTINGS

Similar to #15. The idea is to expand our knowledge of terms and definitions used in other health care systems to see if they could be adopted in ESRD.

30 EXEMPT DATA FROM ADMISSIBILITY VIA FEDERAL LEGISLATION.

Just a dream, perhaps, that if we accomplished this option, data collection would facilitated and the quality enhanced. This protection extends probably just to civil suits and not criminal charges.
### Table 2: Preliminary Clarifications of Action Options to Improve ESRD Patient Safety

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Produced by the participants at the NPSF/ RPA/Forum Workshop – 31st October 2000

CWA, Ltd. Interactive Management Consultants
Table 2: Preliminary Clarifications of Action Options to Improve ESRD Patient Safety

37 IDENTIFY POSSIBLE/PROBABLE OUTCOME CRITERIA OF MEDICAL ERRORS AND NEAR MISSES AND CONSTRUCT ROOT CAUSE ANALYSIS OF THE MAJOR CATEGORIES

Once possible / probable outcome criteria are developed, it would be a good use of time to sit down and do root cause analysis of the major categories. This information could then be provided to facilities to give them a place to start in addressing these issues.

38 STUDY PRESENT BUDGET ALLOCATIONS FOR ESRD AND REDISTRIBUTE MONIES MORE APPROPRIATELY TO INCLUDE ISSUES OF PATIENT SAFETY.

Although in an ideal world, more money would be appropriated to ESRD patient safety, but more realistically, reallocation of a fixed sum of money may be what is required. Although similar to OPTION #34, this idea is broader, looking beyond individual facility reimbursement.

39 DEVELOP A PROFORMA TO DETERMINE THE SYSTEM "ROI" OF A BROAD BASED SAFETY PROGRAM

There are many possible ways to measure a return on investment (ROI) in enhancing patient safety, ranging far beyond just measures of money saved.

40 LEVERAGE EXISTING ANALYTICAL ORGANIZATIONS, eg USRDS, TO ANALYZE DATA AND REPORT ON PATIENT SAFETY OUTCOMES.

Clear.

41 PROVIDE PATIENTS INFORMATION ABOUT THEIR ROLE AND ABILITY TO ACCESS ERROR REPORTING SYSTEMS

The patients are intimately involved in all venues and in all care provided, and they need to be included in any improvement.

42 DEVELOP A PATIENT ACUITY TOOL STANDARDIZING STAFFING RATIOS TO MEET PATIENT NEEDS AND ENSURE PATIENT SAFETY.

OPTION #37 captures this idea, so it is withdrawn.

43 PROMOTE INCLUSION OF PATIENT SAFETY SCIENCE IN DIRECT CARE STAFF CORE CURRICULUM

Much like #4, but not identical. "Direct care staff" includes doctors and nurses.
Table 2: Preliminary Clarifications of Action Options to Improve ESRD Patient Safety

44 REQUEST ANALYSIS FROM CDC, FDA, AND ESRD NETWORKS OF MEDICAL ERRORS AND ADVERSE EVENT REPORTS FOR THE PAST THREE YEARS.

*Complements OPTION #24, but identifies the particular organizations that would do the work.*

45 ENLIST ESTABLISHED SAFETY EXPERTS AND TECHNIQUES TO ANALYZE, EVALUATE, AND RECOMMEND CHANGE FOR CURRENT SAFETY PROBLEMS.

*Make sure we don’t reinvent the wheel. We need to utilize any available experts from outside the ESRD industry.*

46 PUBLISH CLINICAL OUTCOMES OF MEDICAL ERRORS ANNUALLY.

*Similar to how mortality rates are reported, this would allow comparison across units.*

47 SUPPORT EXISTING LEGISLATIVE EFFORTS TO HAVE A POT OF MONEY IN MEDICARE DESIGNATED FOR NEW TECHNOLOGIES THAT CAN ENHANCE PATIENT SAFETY

*This provides another way to get some money in the system, recognizing how difficult it is to change reimbursement rates. The idea is for there to be a pot of money available, and facilities could apply for it if they purchase technology that enhances patient-safety. This proposal is currently on Capitol Hill, so there’s some chance of it occurring.*
APPENDIX F

DELPHI Survey Cover Letter
MEMORANDUM

Date: November 20, 2000
To: ESRD Patient Safety Workshop Participants
From: Diane Conaway and Mitch Dvorak
Subject: DELPHI Study and Additional Workshop Products

The Facilitation Team would like to thank all of the participants for their extremely hard work, perseverance and good humor during the ESRD Patient Safety Workshop on “Designing an Action Agenda for Improving ESRD Patient Safety.” The purpose of this document, (which we refer to as a DELPHI Study or questionnaire) is:

- to reflect on our collective and individual learning;
- to further cultivate collective leadership in this initiative;
- to self-identify the perceived roles, with respect to specific actions, appropriate for your organization to engage;
- to offer commentary on the consensus actions to which you are committed; and
- to set the stage to enlarge the number of organizations involved.

The responses to this DELPHI will be integrated with the Final Report. Your responses will also guide near term action. This is the primary vehicle in which you should articulate what you perceive to be your organization’s role with respect to this initiative on improving ESRD Patient Safety.

In the culminating stage of the workshop, the boundary-spanning teams achieved a one-half or greater majority (four to eight of eight teams) on 10 proposed action options. A key finding of the workshop is a unanimous call among the small teams of participants to:

- **Create a task force of stakeholders and experts on patient safety to agree on definitions of medical errors.** (Action Option #1 in Cluster #1 Defining and Identifying the Problem) which is clarified as meaning:

  *Stakeholders would be a group such as the one assembled today, plus people with knowledge of patient safety from other disciplines. The taskforce could operate in a number of ways, including data collection, surveys, or other activities.*

- **Conduct education and training for the ESRD program leadership on the nature of the problem and in the safety sciences.** (Action Option #17 in Cluster #4 Leaders) which is clarified as meaning:

  *The focus here is on the leadership: without leadership buy-in we can’t succeed. Leadership includes people such as those in this room: leadership of payers, individual units, networks, etc.*

The Workshop of October 30 & 31 represents a highly leveraging step towards achieving these ends. The hosts of the workshop, namely the Renal Physicians Association, the Forum of ESRD Networks, and the National Patient Safety Foundation expressed their long-term commitment as well as their desire for collaborative action in launching and implementing the Workshop findings and recommendations.
The resulting Consensus Action Scenario appears graphically in Figure 2. This scenario is based on:

(a) A preliminary focus on the three highly leveraging challenges to address. The structure of challenges was completed on Day One of the workshop and appears as Figure 1: Influence Pattern among Most Important Challenges in your workbooks. This structure included every challenge that four or more individuals identified as their top five priorities. The influence relationship among the challenges was generated by a series of assertions, by the participants, regarding the influence of making progress on one challenge with respect to addressing another challenge. Figure 1 represents a collective judgment on over thirty decisions determined by the strong majority of two thirds or more of the participants. As you’ll recall many of these decisions were unanimous, and most were nearly unanimous.

(b) The Action Options identified by individual participant selection (using dots) of the five options of higher relative importance. This resulted in 12 Action Options that received four individual votes or more from the entire group of participants.

(c) The Action Options selected by four or more of the eight small teams for inclusion in their team action scenario. This resulted in a focus on 10 Action Options.

Table 3 displays results b and c in a summary form. You will see that the Action Options included in the Consensus Action Scenario and connected to the TIE LINE in Figure 2 are the same ten. Table 3 and Figure 2 are for the “Choice” portion of your workbooks.

These ten consensus action options are presented in Attachment A for the purpose of asking you to provide additional information on collective leadership in this initiative.

During the Workshop we completed a first round of inquiries concerning Definition and Design. The DELPHI Study moves us into the Choice and Action stages of the overall project. This stage of our project should be considered as an opportunity to revisit and reflect on the issues, challenges, opportunities and next steps, the broader set of stakeholders, our individual and collective learning, and your role and leadership on the ESRD Patient Safety Initiative.

The RPA/NPSF partners consider it essential to conduct every step of the process in an open and transparent fashion and to reflect the “bottom-up” emergence of focus and collaboration. We realize that this format is unusual for many of you. If you have any questions about the tasks requested, please feel free to contact Diane Conaway at 610-651-0414. Thank you in advance for your help and cooperation in completing this DELPHI questionnaire.

Please fax your responses included in Attachment A and B of the DELPHI Study no later than December 4th to Mitch Dvorak at 312-464-4154.

Attachment: DELPHI Study
APPENDIX G

DELPHI Survey Responses
**DELPHI Responses to Next Steps and Follow-Up Including Leadership Roles on selected Consensus Action Options**

**(1 - ACTION OPTION): CREATE A TASK FORCE OF STAKEHOLDERS AND EXPERTS ON PATIENT SAFETY TO AGREE ON DEFINITIONS OF MEDICAL ERRORS**

Stakeholders would be a group such as the one assembled today, plus people with knowledge of patient safety from other disciplines. The taskforce could operate in a number of ways, including data collection, surveys, or other activities.

(Cluster #1)

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<th>Organization:</th>
<th>Workshop Participant:</th>
<th>Perceived Role &amp; Comments:</th>
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<tr>
<td>National Assoc. of Nephrology Technicians</td>
<td>Joe Mazilli</td>
<td>Role: To ensure representation from front line caregivers.</td>
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<tr>
<td>Centers for Disease Control</td>
<td>Jerry Tokars</td>
<td>Role: Serve on group. Liaison to groups at CDC.</td>
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<td>Comments: Many other groups are working on this issue. Similar work from several groups could be combined to avoid repeating others’ work.</td>
</tr>
<tr>
<td>American Society of Pediatric Nephrology</td>
<td>Barbara Fivush</td>
<td>Role: Pediatric representation is critical to ensure that all segments of the ESRD Population are considered in regards to “Patient Safety”.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comments: Consideration of the uniqueness of the pediatric population must be taken into account before data collection initiated. Surveys and other activities must be appropriate for pediatric patients. Safety issues are likely to be view differently by patients and parents.</td>
</tr>
<tr>
<td>American Association of Kidney Patients Forum of ESRD Networks</td>
<td>Peter Lundin</td>
<td>Role: Patient input.</td>
</tr>
<tr>
<td></td>
<td>Peter DeOreo</td>
<td>Role: Participate.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comments: Much preparation needed before meeting similar to last meeting. Also incorporate experts from NOW – ESRD to improve taxonomy.</td>
</tr>
<tr>
<td>American Society of Transplant Surgeons</td>
<td>Joshua Miller</td>
<td>Role: No input submitted.</td>
</tr>
<tr>
<td>American Hospital Association</td>
<td>Kirsten Anderson</td>
<td>Role: A stakeholder with expertise in safety as well as experience with surveys, etc., from the hospital perspective.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comments: AHA suggests that the group first look to the National Quality Forum and its work in defining medical error before creating a new set of definitions. One of our physician executives to whom I will be turning over my efforts in this project is a member of that work group.</td>
</tr>
<tr>
<td>Health Care Financing Administration</td>
<td>Freund, Sarisits, Frederick &amp; Frankenfield</td>
<td>Role: Participate / member.</td>
</tr>
<tr>
<td>U of Wisconsin, Prof. Of Pharmacy &amp; Medicine</td>
<td>Curtis Johnson</td>
<td>Role: Assist in creation. Willing to serve on task force.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comments: Very high priority.</td>
</tr>
<tr>
<td>Texas Dept. of Health, State Surveyor</td>
<td>Glenda Payne</td>
<td>Role: Participation.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comments: Provide copies of primary seminal articles / chapters from safety sciences prior to this talk force meeting &amp; facilitation common starting point.</td>
</tr>
<tr>
<td>Renal Physicians Association</td>
<td>Allen Nissenson</td>
<td>Role: RPA would play a major role in organizing &amp; leading this task force.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comments: Current steering group of RPA/Forum/NPSF would be obvious group to develop this.</td>
</tr>
<tr>
<td>Renaissance Healthcare</td>
<td>Coleman Mosley</td>
<td>Role: Collaboration / participate is task force.</td>
</tr>
<tr>
<td>Fresenius Medical Care</td>
<td>J. Michael Lazarus</td>
<td>Role: Participating &amp; source for experts in patient care in ESRD facilities.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comments: Careful definition of errors – which are measurable &amp; correctable, is key.</td>
</tr>
<tr>
<td>American Nephrology Nurses Association</td>
<td>Jean Nardini</td>
<td>Role: Clearly in defining medical errors in the ESRD arena.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comments: This is the most important action. Without an agreement on what is going to be defined as a medical error – all else is meaningless.</td>
</tr>
<tr>
<td>National Patient Safety Foundation</td>
<td>Lou Diamond</td>
<td>Role: Could convene &amp; provide both administration and/or a staff support.</td>
</tr>
<tr>
<td>Nephrology Nursing Certification Commission</td>
<td>Janel Parker</td>
<td>Role: Expertise in testing / certifying nephrology nurses &amp; hemodialysis patient care technicians.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comments: Interaction with state regulatory boards to provide initial testing for patient care technicians and dialysis nurses. Provide nationally recognized examination to test for competency levels / public safety is the purpose of the testing.</td>
</tr>
<tr>
<td>Association for the Advancement of Medical Instrumentation</td>
<td>Richard Ward</td>
<td>Role: Clear definitions will be important for successful pursuit of many of the Action Options, in my experience, writing definitions by committee is very difficult. Therefore, I suggest the core task force be kept small. Can other definition sets (Institute of Medicine?) be co-opted? Use of an existing set of definitions would help minimize confusion.</td>
</tr>
<tr>
<td>Renal Disease Management, Inc.</td>
<td>Chester Amedia</td>
<td>Role: CMO of a Disease Management Company which interfaces with payors.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Comments: Representation of all levels of providers, patients, industry AND payors (not only HCFA).</td>
</tr>
</tbody>
</table>
## DELPHI Responses to Next Steps and Follow-Up Including Leadership Roles on selected Consensus Action Options

<table>
<thead>
<tr>
<th>Organization</th>
<th>Individuals</th>
<th>Role:</th>
<th>Comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal Physicians Association</td>
<td>Robert Kossmann</td>
<td>Participating in meetings, discussions, e-mails, conference calls.</td>
<td></td>
</tr>
<tr>
<td>Renal Administrators Association</td>
<td>Patricia Hansen</td>
<td>Participate in collecting data on perceived issues, checking accuracy, and implementing methods of prevention. <strong>Comments:</strong> Careful differentiation between “perceived” and “actual” patient safety issues from both patients and professionals is critical.</td>
<td></td>
</tr>
</tbody>
</table>
DELPHI Responses to Next Steps and Follow-Up Including Leadership Roles on selected Consensus Action Options

(7 - ACTION OPTION): CONDUCT A SURVEY OF DIALYSIS PATIENTS AND PROFESSIONALS TO LIST ISSUES OF PATIENT SAFETY

We’re trying to develop a taxonomy of patient safety, but current databases are inadequate to do this. This action option proposes carrying out a survey that will elicit experiences of patients and professionals that relate to patient safety. Then we can look at categories and frequencies so we have some initial handle on the scope and the relevance of the problem. “Patient safety” includes medical errors. This would be a survey designed specifically to develop a taxonomy, and would not include things like attitudes to patient safety, for example.

(Cluster #1)

<table>
<thead>
<tr>
<th>Organization:</th>
<th>Workshop Participant:</th>
<th>Role: You have advice on infectious issues to be surveyed. Have some prototype survey questions.</th>
<th>Perceived Role &amp; Comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centers for Disease Control</td>
<td>Jerry Tokars</td>
<td>Offer advice on infectious issues to be surveyed. Have some prototype survey questions.</td>
<td></td>
</tr>
<tr>
<td>American Society of Pediatric Nephrology</td>
<td>Barbara Fivush</td>
<td>Pediatric representation is necessary to ensure that a survey is appropriate for pediatric patients. Comments: It is likely that a survey of pediatric dialysis patients will need to involve parents in order to successfully list and define pediatric patient safety issues.</td>
<td></td>
</tr>
<tr>
<td>American Association of Kidney Patients</td>
<td>Peter Lundin</td>
<td>Survey of AAKY population knowledgeable about patient safety. Comments: Most patients are well aware of what makes them feel unsafe in dialysis unit. What they are not aware of is mistakes they don’t observe.</td>
<td></td>
</tr>
<tr>
<td>Forum of ESRD Networks</td>
<td>Peter DeOreo</td>
<td>Review and comment.</td>
<td></td>
</tr>
<tr>
<td>Health Care Financing Administration</td>
<td>Freund, Sarsitis,</td>
<td>Would be willing to advice &amp; comment, but would recommend against our sponsoring, funding, etc. in large part because of administration issues. Comments: Maybe there is a role (i.e. special study) for the USRDS. Would not want this to be a prerequisite for other steps (clusters, etc.)</td>
<td></td>
</tr>
<tr>
<td>U of Wisconsin, Prof. Of Pharmacy &amp; Medicine</td>
<td>Curtis Johnson</td>
<td>Review of instrument pre survey. Review &amp; comment on results. Comments: Survey itself would need to be somewhat structured to guide respondent to our questions, get sufficiently open ended to get answers from broader perspective.</td>
<td></td>
</tr>
<tr>
<td>Texas Dept. of Health, State Surveyor</td>
<td>Glenda Payne</td>
<td>Review of instrument pre survey. Review &amp; comment on results. Comments: Survey itself would need to be somewhat structured to guide respondent to our questions, get sufficiently open ended to get answers from broader perspective.</td>
<td></td>
</tr>
<tr>
<td>Renal Physicians Association</td>
<td>Allen Nissenson</td>
<td>Review of instrument pre survey. Review &amp; comment on results. Comments: Survey itself would need to be somewhat structured to guide respondent to our questions, get sufficiently open ended to get answers from broader perspective.</td>
<td></td>
</tr>
<tr>
<td>National Kidney Foundation, Council of Nephrology Social Work</td>
<td>Wendy Funk-Schrag</td>
<td>RPA would work to develop the questions focused on physicians. Comments: Need outside advice on the best way to structure &amp; carry out such a survey, incl. a rev. of similar work already done.</td>
<td></td>
</tr>
<tr>
<td>Renaissance Healthcare</td>
<td>Coleman Mosley</td>
<td>Assist in developing survey, careful of literacy level of survey, pt. Education about importance of pt. Input in completing survey. Comments: It is very important to get the patients’ input and see what safety issues they are concerned about and what constitutes error to them. Frequent staff turnover is often cited by pts. as a concern they have r/t pt. safety.</td>
<td></td>
</tr>
<tr>
<td>Fresenius Medical Care</td>
<td>J. Michael Lazarus</td>
<td>Participate in the development of survey tools for patients &amp; professionals. Comments: If survey is to develop taxonomy, once should be enough. Who supports? Where do resources come from?</td>
<td></td>
</tr>
<tr>
<td>Am. Nephrology Nurses Association</td>
<td>Jean Nardini</td>
<td>Participate in the development of survey tools for patients &amp; professionals. Comments: If survey is to develop taxonomy, once should be enough. Who supports? Where do resources come from?</td>
<td></td>
</tr>
<tr>
<td>National Patient Safety Foundation</td>
<td>Lou Diamond</td>
<td>Would be willing to advice &amp; comment, but would recommend against our sponsoring, funding, etc. in large part because of administration issues. Comments: Maybe there is a role (i.e. special study) for the USRDS. Would not want this to be a prerequisite for other steps (clusters, etc.)</td>
<td></td>
</tr>
<tr>
<td>Nephrology Nursing Certification Commission</td>
<td>Janel Parker</td>
<td>Review of instrument pre survey. Review &amp; comment on results. Comments: Survey itself would need to be somewhat structured to guide respondent to our questions, get sufficiently open ended to get answers from broader perspective.</td>
<td></td>
</tr>
<tr>
<td>Renal Disease Management, Inc.</td>
<td>Chester Arnedia</td>
<td>Review of instrument pre survey. Review &amp; comment on results. Comments: Survey itself would need to be somewhat structured to guide respondent to our questions, get sufficiently open ended to get answers from broader perspective.</td>
<td></td>
</tr>
<tr>
<td>Renal Physicians Association</td>
<td>Robert Kossmann</td>
<td>Participate in the development of survey tools for patients &amp; professionals. Comments: If survey is to develop taxonomy, once should be enough. Who supports? Where do resources come from?</td>
<td></td>
</tr>
<tr>
<td>National Renal Administrators Association</td>
<td>Patricia Hansen</td>
<td>Participate in the development of survey tools for patients &amp; professionals. Comments: If survey is to develop taxonomy, once should be enough. Who supports? Where do resources come from?</td>
<td></td>
</tr>
</tbody>
</table>

Appendix G - Page 3
(14 - ACTION OPTION): CREATE A DATA BASE OF MEDICAL ERRORS AND NEAR-MISSES MAINTAINED BY A NON-REGULATORY GROUPS AND PROTECTED FROM LEGAL DISCLOSURE

Fairy self-explanatory. If there is a mechanism that would protect a privately-held data-base from being accessed through legal inquiry, which does exist for governmental data-bases, then such a data-base would enhance trust level.

<table>
<thead>
<tr>
<th>Organization</th>
<th>Workshop Participant</th>
<th>Perceived Role &amp; Comments</th>
</tr>
</thead>
</table>
| Centers for Disease Control | Jerry Tokars | **Role:** We currently have a functioning, secure, internet-based reporting system. Extend this system and/or assist in developing others.  
**Comments:** Our group at CDC is interested in building such a database and so resources could be pooled. |
| American Society of Pediatric Nephrology | Barbara Fivush | **Role:** Pediatric input needed to ensure data is collected and evaluated in a fashion appropriate for children.  
**Comments:** It is imperative that “trust” between patients and caregivers exists as a database is created. A "No-Blame" environment is needed for successful collection of accurate data |
| Forum of ESRD Networks | Peter DeOreo | **Role:** Define, data dictionary, co-operate a pilot project  
**Comments:** Likely use Web technology. |
| American Hospital Association | Kirsten Anderson | **Role:** Can advise on setting up database.  
**Comments:** The database would need to address all of the issues such as voluntary vs. mandatory reporting to the database, confidentiality, discoverability, near misses vs. actual errors, definitions, etc. The other aspect is to be sure that any manipulations to the database are actually uses – who evaluates, who provides the analysis, feedback, etc. |
| Health Care Financing Administration | Freund, Sarsitis, Frederick & Frankenfield | **Role:** Development of elements and contributing to development of mechanism. |
| Renaissance Healthcare Fresenius Medical Care | Coleman Mosley | **Role:** Would participate in the formation and maintenance. |
| National Patient Safety Foundation | J. Michael Lazarus | **Role:** Source of ESRD staff to assist. |
| Nephrology Nursing Certification Commission | Lou Diamond | **Role:** Could convene & provide both administration and/or a staff support.  
**Comments:** Also included in Action Option #20. Will require legal protection. |
| Renal Disease Management, Inc. | Janel Parker | **Role:** No input submitted. |
| Renal Physicians Association | Chester Amedia | **Role:** CMO of DM Company.  
**Comments:** Action Option #1 have significant interests in systems development. I do not have computer expertise. This group needs to interact with definition group (Action Option #20). |
| National Renal Administrators Association | Robert Kossman | **Role:** Participate in the formulation process of database.  
**Comments:** Assist with establishing and promoting collection of existing data.  
**Comments:** Including professional legal participation in developing. Who will fund? Who maintains where housed? HIPPA – new rules on disclosure, sharing of information. May create limits on what is possible. Needs research before proceeding. |
| | Patricia Hansen | |

(Cluster #2)
DELPHI Responses to Next Steps and Follow-Up Including Leadership Roles on selected Consensus Action Options

(20 - ACTION OPTION): ESTABLISH A CENTRAL CLEARINGHOUSE FOR PATIENT SAFETY FOR ESRD, INCLUDING DEFINITIONS, PROGRAMS, REAL-TIME ERROR TRACKING, THAT WOULD BE AVAILBLE AT NO CHARGE TO DIALYSIS FACILITIES

It's in the best interest of industry that their products and devices be used safely. We should begin a dialogue with vendors to improve the use of their products and devices and thus improve patient safety. (Cluster #2)

<table>
<thead>
<tr>
<th>Organization:</th>
<th>Workshop Participant:</th>
<th>Perceived Role &amp; Comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Association of Nephrology Technicians</td>
<td>Joe Mazilli</td>
<td>Role: To have technical input.</td>
</tr>
<tr>
<td>Centers for Disease Control</td>
<td>Jerry Tokars</td>
<td>Role: Assist in developing definitions for infectious events.</td>
</tr>
<tr>
<td>American Society of Pediatric Nephrology</td>
<td>Barbara Fivush</td>
<td>Role: Pediatric input is needed to make certain that products and devices are safe for children. Comments: Since the pediatric ESRD population is small, most often industry is not focused on children's dialysis needs in regards to devices. Size and decreased blood volume in children may result in safety issues unique to this population.</td>
</tr>
<tr>
<td>Forum of ESRD Networks</td>
<td>Peter DeOreo</td>
<td>Role: Participate. Comments: Likely will need broader participation for networks.</td>
</tr>
<tr>
<td>American Society of Transplant Surgeons</td>
<td>Joshua Miller</td>
<td>Role: No input submitted.</td>
</tr>
<tr>
<td>American Hospital Association</td>
<td>Kirsten Anderson</td>
<td>Role: Can advise on project and use our experience collaborating with many safety experts, however the AHA should not be the locus of the clearinghouse.</td>
</tr>
<tr>
<td>Health Care Financing Administration</td>
<td>Freund, Sarsitis, Frederick &amp; Frankenfield</td>
<td>Role: Contingent upon availability of funding could employ HCFA contractors in this role. Comments: NIDDK, FDA, NPSC &amp; other existing clearinghouses may be options.</td>
</tr>
<tr>
<td>Renal Physicians Association</td>
<td>Allen Nissenson</td>
<td>Role: Work with other organizations to develop web-based clearinghouse. Comments: Need a central repository perhaps linked to this item above (Action Option #14).</td>
</tr>
<tr>
<td>Renaissance Healthcare</td>
<td>Coleman Mosley</td>
<td>Role: Would participate in the formation and maintenance.</td>
</tr>
<tr>
<td>Fresenius Medical Care</td>
<td>J. Michael Lazarus</td>
<td>Role: Oversight. Comments: HCFA / Government must work with dialysis industry to allow our input &amp; equal partnership.</td>
</tr>
<tr>
<td>National Patient Safety Foundation</td>
<td>Lou Diamond</td>
<td>Role: Could convene &amp; provide both administration and/or a staff support. Comments: Some features of Action Option #14.</td>
</tr>
<tr>
<td>Nephrology Nursing Certification Commission</td>
<td>Janel Parker</td>
<td>Role: No input submitted.</td>
</tr>
<tr>
<td>Renal Physicians Association</td>
<td>Robert Kossmann</td>
<td>Role: Participate in discussion and planning for establishment of such a clearinghouse.</td>
</tr>
<tr>
<td>National Renal Adm. Assoc.</td>
<td>Patricia Hansen</td>
<td>Role: Utilize the NRAA website to facilitate the dissemination of information.</td>
</tr>
</tbody>
</table>

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DELPHI Responses to Next Steps and Follow-Up Including Leadership Roles on selected Consensus Action Options

(23 - ACTION OPTION): PROVIDE TOOLBOX TO DIALYSIS UNITS TO HELP IDENTIFY AND CHARACTERIZE ISSUES IN PATIENT SAFETY

It will be helpful to give specific guidance to end users on how to identify and classify patient safety issues. This could be the form of a "toolbox" that gives specific guidance in many areas, for example in distinguishing between sentinel events vs. near misses. PRO's have used such "toolboxes" to enable end-users to follow guidelines and record events clearly. These toolboxes include data collection forms, definitions for categories, and flow charts for analyzing data. Want to enable and empower end users to understand what we are talking about here and record data in a meaningful way. The idea of establishing a clearinghouse (in action option #20) might include providing such tools, but this action option (#23) concentrates on providing such tools.

<table>
<thead>
<tr>
<th>Organization: / Workshop Participant:</th>
<th>Perceived Role &amp; Comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Association of Nephrology Technicians</td>
<td>Joe Mazilli</td>
</tr>
<tr>
<td>Centers for Disease Control</td>
<td>Jerry Tokars</td>
</tr>
<tr>
<td>American Society of Pediatric Nephrology</td>
<td>Barbara Fivush</td>
</tr>
<tr>
<td>Forum of ESRD Networks</td>
<td>Peter DeOreo</td>
</tr>
<tr>
<td>American Society of Transplant Surgeons</td>
<td>Joshua Miller</td>
</tr>
<tr>
<td>Health Care Financing Administration</td>
<td>Freund, Sarisits, Frederick &amp; Frankenfield</td>
</tr>
<tr>
<td>U of Wisconsin, Prof. Of Pharmacy &amp; Medicine</td>
<td>Curtis Johnson</td>
</tr>
<tr>
<td>Texas Dept. of Health, State Surveyor</td>
<td>Glenda Payne</td>
</tr>
<tr>
<td>Renal Physicians Association</td>
<td>Allen Nissenson</td>
</tr>
<tr>
<td>National Kidney Foundation, Council of Nephrology Social Work</td>
<td>Wendy Funk-Schrag</td>
</tr>
<tr>
<td>Fresenius Medical Care</td>
<td>J. Michael Lazarus</td>
</tr>
<tr>
<td>American Nephrology Nurses Association</td>
<td>Jean Nardini</td>
</tr>
<tr>
<td>National Patient Safety Foundation</td>
<td>Lou Diamond</td>
</tr>
<tr>
<td>Nephrology Nursing Certification Commission</td>
<td>Janel Parker</td>
</tr>
<tr>
<td>Renal Disease Management, Inc.</td>
<td>Chester Amedia</td>
</tr>
<tr>
<td>Renal Physicians Association</td>
<td>Robert Kossmann</td>
</tr>
<tr>
<td>National Renal Administrators Association</td>
<td>Patricia Hansen</td>
</tr>
</tbody>
</table>
**DELPHI Responses to Next Steps and Follow-Up Including Leadership Roles on selected Consensus Action Options**

**11 - ACTION OPTION:** DEVELOP BEST PRACTICE GUIDELINES FOR PROMOTING PATIENT SAFETY

Lots of individual units have already developed ways to prevent bad things from happening. Those ideas can be assembled together to develop best practices for promoting patient safety, whether they involve technology or process. We should give people guidance about what has worked the best. We have data that allow us to know that certain facilities have better outcomes than others, and we can look at their practices and make them available in the form of guidelines to other facilities. (Cluster #3)

<table>
<thead>
<tr>
<th>Organization</th>
<th>Workshop Participant</th>
<th>Perceived Role &amp; Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Association of Nephrology Technicians</td>
<td>Joe Mazilli</td>
<td>Role: Provide input from front line caregiver.</td>
</tr>
<tr>
<td>Centers for Disease Control</td>
<td>Jerry Tokars</td>
<td>Role: Assist in planning and/or implementation for infectious outcomes.</td>
</tr>
<tr>
<td>American Society of Pediatric Nephrology</td>
<td>Barbara Fivush</td>
<td>Role: Best practice guidelines will be different for adult and pediatric patients.</td>
</tr>
<tr>
<td>Forum of ESRD Networks</td>
<td>Peter DeOreo</td>
<td>Role: Review &amp; comment.</td>
</tr>
<tr>
<td>American Hospital Association</td>
<td>Kirsten Anderson</td>
<td>Role: Help analyze difference practices.</td>
</tr>
<tr>
<td>Health Care Financing Administration</td>
<td>Freund, Sarsitis, Frederick &amp; Frankenfield</td>
<td>Role: Review &amp; comment.</td>
</tr>
<tr>
<td>Renal Physicians Association</td>
<td>Allen Nissenson</td>
<td>Role: Develop physician BDPs in this area.</td>
</tr>
<tr>
<td>Fresenius Medical Care</td>
<td>J. Michael Lazarus</td>
<td>Role: Chain / facility input.</td>
</tr>
<tr>
<td>American Nephrology Nurses Association</td>
<td>Jean Nardini</td>
<td>Role: Nursing would &amp; should help define guidelines.</td>
</tr>
<tr>
<td>National Patient Safety Foundation</td>
<td>Lou Diamond</td>
<td>Role: Could convene &amp; provide both administration and/or a staff support. Have early experience within NPSF call for solutions program.</td>
</tr>
<tr>
<td>Association for the Advancement of Medical Instrumentation</td>
<td>Richard Ward</td>
<td>Role: Participate in the preparation of best practice guidelines in technical areas. To some extent, AAMI is already working in this area through its Recommended Practice documents.</td>
</tr>
<tr>
<td>Renal Physicians Association</td>
<td>Robert Kossmann</td>
<td>Role: Participate in development &amp; adaptations of guidelines.</td>
</tr>
<tr>
<td>National Renal Administrators Association</td>
<td>Patricia Hansen</td>
<td>Role: Contributions from administrative perspective, clinical knowledge of patient safety issues and assist with insuring implementation.</td>
</tr>
</tbody>
</table>

**Comments:** Collaborate efforts to compile “best practice guidelines” with all professional modalities.
(4 - ACTION OPTION): DEVELOP UNIFORM EDUCATION MATERIALS / PROGRAMS FOR TRAINING OF STAFF IN SAFETY SCIENCES

The concept here is that there is a cost associated with developing these materials; to the degree that these uniform materials can be jointly-developed and used across many settings, the fixed development costs can be shared and thus lessened on each individual facility. Such standardized curricula already exist for education of technicians and nurses on performing dialysis; the OPTION expressed here would extend these curricular materials into the as-yet underdeveloped safety sciences realm for ESRD specifically. Some general material on patient safety already exists, and this could be used in the interim while more specific material is developed. Examples of safety sciences include how teams communicate among members or how new technologies can be safely introduced into clinical practice.

<table>
<thead>
<tr>
<th>Organization:</th>
<th>Workshop Participant:</th>
<th>Perceived Role &amp; Comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Association of Nephrology Technicians</td>
<td>Joe Mazilli</td>
<td>Role: No input submitted.</td>
</tr>
<tr>
<td>American Society of Pediatric Nephrology Forum of ESRD Networks</td>
<td>Barbara Fivush</td>
<td>Role: Pediatric input is needed.</td>
</tr>
<tr>
<td></td>
<td>Peter DeOreo</td>
<td>Role: Review &amp; comment. Comments: Although it is likely that for the most part staff education would be similar, it is probably that some pediatric issues might require additional staff training.</td>
</tr>
<tr>
<td>American Hospital Association</td>
<td>Kirsten Anderson</td>
<td>Role: Provide expertise in patient safety.</td>
</tr>
<tr>
<td>Health Care Financing Administration</td>
<td>Freund, Sarris, Frederick &amp; Frankenfield</td>
<td>Role: Review, comment, potential avenues for distribution.</td>
</tr>
<tr>
<td>U of Wisconsin, Prof. Of Pharmacy &amp; Medicine</td>
<td>Curtis Johnson</td>
<td>Role: I believe I can contribute to the development of these tools especially in the area of medications</td>
</tr>
<tr>
<td>Texas Dept. of Health, State Surveyor</td>
<td>Glenda Payne</td>
<td>Role: Review &amp; edit. Provide educational sessions for surveyors &amp; nephrology issues. Comments: Echo this comment. Suggest use of Medical Media or similar group &amp; seeking funding from industry – i.e. drug companies for training in avoiding med. Errors.</td>
</tr>
<tr>
<td>Renal Physicians Association</td>
<td>Allen Nissenson</td>
<td>Role: Develop such materials for participating MDs &amp; those in training. Comments: Work with ASN program Directors to get to renal fellows during training.</td>
</tr>
<tr>
<td>National Kidney Foundation, Council of Nephrology Social Work</td>
<td>Wendy Funk-Schrag</td>
<td>Role: Staff education on pt. psychosocial issues r/t safety.</td>
</tr>
<tr>
<td>Fresenius Medical Care</td>
<td>J. Michael Lazarus</td>
<td>Role: Provide experts staff.</td>
</tr>
<tr>
<td>National Patient Safety Foundation Nephrology Nursing Certification Commission</td>
<td>Lou Diamond</td>
<td>Role: Could convened &amp; provide both administration and/or a staff support. Comments: ANNA has developed technician and nursing education programs that could be endorsed by a committee.</td>
</tr>
<tr>
<td></td>
<td>Janel Parker</td>
<td></td>
</tr>
<tr>
<td>Renal Physicians Association</td>
<td>Robert Kossmann</td>
<td>Role: Participate in development, review &amp; modification of uniform educational materials.</td>
</tr>
<tr>
<td>National Renal Administrators Association</td>
<td>Patricia Hansen</td>
<td>Role: To assist in establish “cost effective” training materials utilizing the expertise of administrators with broad financial background. Comments: Carefully review existing material to avoid the unnecessary expense of “reinventing the wheel”. How can developmental costs be imposed on facilities? What if facilities refuse – e.g. the big chains? Group has no legal mandate. Who is funding this activity?</td>
</tr>
</tbody>
</table>
## DELPHI Responses to Next Steps and Follow-Up Including Leadership Roles on selected Consensus Action Options

**17 - ACTION OPTION**: CONDUCT EDUCATION AND TRAINING FOR THE ESRD PROGRAM LEADERSHIP ON THE NATURE OF THE PROBLEM AND IN THE SAFETY SCIENCES

*The focus here is on the leadership: without leadership buy-in we can't succeed. Leadership includes people such as those in this room: leadership of payers, individual units, networks, etc.*

(Cluster #4)

<table>
<thead>
<tr>
<th>Organization: -</th>
<th>Workshop Participant: -</th>
<th>Perceived Role &amp; Comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Association of Nephrology Technicians</td>
<td>Joe Mazilli</td>
<td><strong>Role</strong>: As part of the “Technician” leadership, help create these programs.</td>
</tr>
</tbody>
</table>
| Centers for Disease Control | Jerry Tokars | **Role**: Consult, assist in developing education items.  
**Comments**: Education & teaching to prevent dialysis-associated infections would be a natural outgrowth of our guidelines & best-practices study. Have been planning to do a video. |
| American Society of Pediatric Nephrology Forum of ESRD Networks | Barbara Fivush, Peter DeOreo | **Role**: Pediatric leadership needs to be included.  
**Comments**: HCFA grant has been requested to start this. |
| American Society of Transplant Surgeons | Joshua Miller | **Role**: Willing to be part of “faculty” & work in design.  
**Comments**: |
| American Hospital Association Health Care Financing Administration | Kirsten Anderson, Freund, Sarisits, Frederick & Frankenfield | **Role**: Use the AHA Medication Safety Initiative template to participate in education & training of leaders.  
**Role**: Currently plan to fund a contribution to this effort, focused on Network Leadership. Details as available (pending funding decisions).  
**Role**: Willing to help design & deliver such programs.  
**Comments**: |
| U of Wisconsin, Prof. Of Pharmacy & Medicine | Curtis Johnson | **Role**: Participate in training.  
**Comments**: Seek to learn more about safety sciences.  
**Role**: Identify and educate physician leaders.  
**Comments**: Work with ESRD Network MRBS, HMO MCD Directors; other MD leaders.  
**Role**: Would be willing to Participate.  
**Role**: Support to get government provider & patient leadership buy-in.  
**Role**: Lecture at management workshops.  
**Role**: No input submitted.  
**Role**: Assist when appropriate in development.  
**Comments**: Consider the development of videos and on-line materials.  
**Role**: Participate in the education of ESRD leadership & further my own education.  
**Role**: Contribute to development of corrective action or practice guidelines to improve patient safety.  
**Comments**: Work in conjunction with other participating organizations to provide educational workshops. |
DELPHI Responses to Next Steps and Follow-Up Including Leadership Roles on selected Consensus Action Options

(36 - ACTION OPTION): SUPPORT INCORPORATION OF PATIENT SAFETY ACTIVITIES INTO THE CONDITIONS OF COVERAGE FOR ESRD

Self-explanatory. To encourage universal engagement in patient safety participation, these regulatory requirements would help.

<table>
<thead>
<tr>
<th>Organization</th>
<th>Workshop Participant</th>
<th>Perceived Role &amp; Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centers for Disease Control</td>
<td>Jerry Tokars</td>
<td>Role: Consult on infectious disease matters.</td>
</tr>
<tr>
<td>American Society of Pediatric Nephrology</td>
<td>Barbara Fivush</td>
<td>Comments: CDC has worked with HCFA/NIH on dialysis-associated infections for many years.</td>
</tr>
<tr>
<td>American Association of Kidney Patients</td>
<td>Peter Lundin</td>
<td>Role: Pediatric input needed.</td>
</tr>
<tr>
<td>Forum of ESRD Networks</td>
<td>Peter DeOreo</td>
<td>Comments: ESRD codes are different for adult and pediatric patients.</td>
</tr>
<tr>
<td>Health Care Financing Administration</td>
<td>Freund, Sarsitis,</td>
<td>Role: Support from patients. Sr. Congressional action is needed.</td>
</tr>
<tr>
<td>Texas Dept. of Health, State Surveyor</td>
<td>Glenda Payne</td>
<td>Role: Review &amp; Comment.</td>
</tr>
<tr>
<td>Renaissance Healthcare</td>
<td>Coleman Mosley</td>
<td>Role: Press HCFA to include in revised C of C.</td>
</tr>
<tr>
<td>American Nephrology Nurses Association</td>
<td>Jean Nardini</td>
<td>Comments: Who can oppose patient safety? Support of this option from all parties participating in this workgroup will enhance the likelihood of acceptance by HCFA.</td>
</tr>
<tr>
<td>National Patient Safety Foundation</td>
<td>Lou Diamond</td>
<td>Role: Would be willing to participate.</td>
</tr>
<tr>
<td>Nephrology Nursing Certification Commission</td>
<td>Janel Parker</td>
<td>Role: Have our legislative consultant support these regulations.</td>
</tr>
<tr>
<td>Renal Physicians Association</td>
<td>Robert Kossmann</td>
<td>Role: Can provide advice about how to proceed.</td>
</tr>
<tr>
<td>National Renal Administrators Association</td>
<td>Patricia Hansen</td>
<td>Comments: RPA should lead to advocate with other organizations.</td>
</tr>
</tbody>
</table>

(Cluster #6)
DELPHI Responses to Next Steps and Follow-Up Including Leadership Roles on selected Consensus Action Options

(37 - ACTION OPTION): IDENTIFY POSSIBLE/PROBABLE OUTCOME CRITERIA OF MEDICAL ERRORS AND NEAR MISSES AND CONSTRUCT ROOT CAUSE ANALYSIS OF THE MAJOR CATEGORIES

Once possible / probable outcome criteria are developed, it would be a good use of time to sit down and do root cause analysis of the major categories. This information could then be provided to facilities to give them a place to start in addressing these issues.

(Cluster #8)

<table>
<thead>
<tr>
<th>Organization:</th>
<th>Workshop Participant:</th>
<th>Perceived Role &amp; Comments:</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Association of Nephrology Technicians</td>
<td>Joe Mazilli</td>
<td>Role: No input submitted.</td>
</tr>
<tr>
<td>American Society of Pediatric Nephrology Forum</td>
<td>Barbara Fivush</td>
<td>Role: Outcome criteria are likely to be different in pediatric patients.</td>
</tr>
<tr>
<td>ESRD Networks</td>
<td>Peter DeOreo</td>
<td>Role: Review &amp; Comment.</td>
</tr>
<tr>
<td>American Society of Transplant Surgeons</td>
<td>Joshua Miller</td>
<td>Comments: This could follow from the leadership training.</td>
</tr>
<tr>
<td>Health Care Financing Administration</td>
<td>Freund, Sarsitis, Frederick &amp; Frankenfield</td>
<td>Role: No input submitted.</td>
</tr>
<tr>
<td>U of Wisconsin, Prof. Of Pharmacy &amp; Medicine</td>
<td>Curtis Johnson</td>
<td>Role: Participate.</td>
</tr>
<tr>
<td>Texas Dept. of Health, State Surveyor Renal Physicians Association</td>
<td>Glenda Payne</td>
<td>Comments: My time for this would be limited I'm afraid. Think we need more data to base this on.</td>
</tr>
<tr>
<td>Renal Physicians Association</td>
<td>Allen Nissenson</td>
<td>Role: Participate in identifying and involvement via root cause analysis.</td>
</tr>
<tr>
<td>Renaissance Healthcare</td>
<td>Coleman Mosley</td>
<td>Comments: Must be multidisciplinary and includes technical experts in root cause analysis.</td>
</tr>
<tr>
<td>Fresenius Medical Care</td>
<td>J. Michael Lazarus</td>
<td>Role: Would be willing to participate.</td>
</tr>
<tr>
<td>National Patient Safety Foundation</td>
<td>Lou Diamond</td>
<td>Role: Work with team to do analyses.</td>
</tr>
<tr>
<td>Nephrology Nursing Certification Commission</td>
<td>Janel Parker</td>
<td>Role: Needs to be undertaken carefully.</td>
</tr>
<tr>
<td>Association for the Advancement of Medical Instrumentation</td>
<td>Richard Ward</td>
<td>Role: No input submitted.</td>
</tr>
<tr>
<td>Renal Physicians Association</td>
<td>Robert Kossmann</td>
<td>Role: Participate in analysis of categories involving events with a technical basis.</td>
</tr>
<tr>
<td>National Renal Administrators Association</td>
<td>Patricia Hansen</td>
<td>Comments: This type of analysis could prove useful in identifying areas where new or improved device standards are needed. This potential benefit may help create a basis for AAMI's ongoing involvement in the project.</td>
</tr>
</tbody>
</table>

Administrators have "first hand" available issues and errors for identification purposes, and through unit CQI can determine root cause analys.
APPENDIX H

Bibliography Relevant to the Methodology
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