ESRD Special Study

Developing Dialysis Facility-Specific Kidney Transplant Referral Clinical Performance Measures

Final Project Report
July 1, 2004 – June 30, 2005

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ESRD Special Study: Developing Dialysis Facility-Specific Kidney Transplant Referral Clinical Performance Measures

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Executive Summary

The Centers for Medicare & Medicaid Services (CMS) contracted with End Stage Renal Disease (ESRD) Network 9 for a special study between July 1, 2004 and June 30, 2005 to develop kidney transplant referral measures at the dialysis facility level. These measures will track steps in the transplant referral process and may be used for quality improvement and public reporting. CMS chose to develop quality measures in this area because of the Department of Health and Human Services interest in increasing organ donation and transplantation and because not all ESRD patients are offered the opportunity for transplantation, despite being the treatment modality of choice.

The contract specified seven key tasks to be completed within the 12-month timeframe.

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Literature Review and Identify Potential Measures

A literature review of all articles relevant to the development of kidney transplant referral measures over the last 20 years in six major journals was completed. From this review, articles were selected that dealt with access to kidney transplantation, steps in the kidney transplant process, practice guidelines, clinical performance measures, and quality improvement. The reference lists of these articles were also reviewed to identify additional articles. All articles, abstracts, and notes on relevance to this project were entered into a customized database.

A summary report of literature reviewed and potential clinical performance measures was prepared and submitted to Pamela Frederick, CMS Government Task Leader (GTL) and Deborah Read, Project Officer (PO) on September 30, 2004. A table of relevant articles was constructed for the report and for use by TEP members.

Convene Technical Expert Panel (TEP)

A Technical Expert Panel (TEP) was convened to assist the contractor in developing transplant referral measures. TEP members, including patients and professionals, were sought to represent various ESRD stakeholders involved in or impacted by the transplant referral process. National renal organizations were invited to circulate a notice requesting nominations for membership on the TEP to their constituents. Members were chosen by the contractor based on their area of expertise, location and knowledge of the subject area. Individual TEP members were approved by CMS. The final TEP membership included transplant surgeons; dialysis facility representatives, including those from large dialysis organizations; transplant recipients; a transplant coordinator; representatives from a kidney patient organization, a managed care organization, a quality improvement organization, and the Scientific Registry of Transplant Recipients; and CMS representatives. Alan Leichtman, MD from University Renal Research & Education Association (URREA) and Jonathan Sugarman, MD, MPH from Qualis Health were contracted to provide technical consultant services for the project. Observers included additional CMS staffers and representatives from eSource.

The first TEP meeting was held in Baltimore on October 21 and 22, 2004. The purpose of the meeting was to obtain input from experts on the development of dialysis facility-specific kidney
transplant referral measures. Findings from the literature search and the challenges of developing clinical performance measures (CPMs) without existing practice guidelines were discussed. Proposed transplant referral measures were presented. Common barriers to completion of the referral to kidney transplantation and modifications to the proposed measures were discussed at length.

Following the meeting, a summary report of the meeting was prepared and sent to CMS on November 11, 2004. The draft Clinical Performance Measures document was revised based on TEP member input at the October 20 and 21 meeting. The draft was sent to CMS for approval on December 6, 2004 and further edited based on CMS input.

Obtain Input from Renal Community on Potential Measures and Convene Second TEP Meeting

The draft Clinical Performance Measures were posted on The Renal Network, Inc. (ESRD Networks 9 & 10) Web site (www.therenalnetwork.org) from January 11, 2005 until January 28, 2005 for public comment. An email announcing the posting was distributed to renal organizations and ESRD networks, requesting review and comment. Comments received through the Web site were returned to the Network anonymously. Both organizations and individuals responded using this mechanism. Additional identifiable responses were received by email or mail from organizations and individuals.

On February 9 and 10, 2005 a second TEP meeting was convened in Baltimore. The goals of the TEP at this meeting were to review public comments obtained regarding the draft CPMs and to refine the draft measures and supporting information for presentation and discussion at the Stakeholders meeting scheduled for April 14, 2005. The majority of meeting time was focused on extensive discussion relating to each draft CPM, including the specific measure, choices (e.g., Yes/No), numerator, denominator, data source, feasibility of data collection, and use of the measures for public reporting. Public comments collated from the circulated draft Clinical Performance Measures document were reviewed, discussed, and incorporated into the TEP recommendations.

A summary report of the meeting was sent to CMS on March 8, 2005. The draft Clinical Performance Measures document was modified based on the meeting discussion.

Coordinate ESRD Stakeholders Meeting and Convene Third TEP Meeting

An ESRD Stakeholders meeting was held by CMS on April 14, 2005 to disseminate information on the progress of ESRD special studies, including the kidney transplant referral measures project. A presentation of draft Clinical Performance Measures was followed by a question and answer session with the Stakeholders.

On April 15, 2005, the TEP convened for a third meeting to refine the dialysis facility-specific kidney transplant referral measures, to discuss public comments received at the Stakeholders meeting on April 14, 2005, and to formulate a plan for pilot testing the proposed measures. The draft proposed measures and descriptors, a description of a proposed pilot project, and issues relating to the proposed pilot project were discussed. Draft data collection forms were presented and reviewed with TEP members.

Prepare List of Recommended Kidney Transplant Referral Measures and Compose Final Project Report

The draft Clinical Performance Measures were further refined based on discussion from the ESRD Stakeholders and third TEP meetings. The list of recommended dialysis facility-specific kidney transplant referral measures was sent to CMS on June 1, 2005. The Final Project Report was sent on June 30, 2005.
Recommended Dialysis Facility-Specific Kidney Transplant Referral Measures

A table of five recommended dialysis facility-specific measures is below.

<table>
<thead>
<tr>
<th>CPM/Descriptor</th>
<th>Measure</th>
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<tr>
<td>CPM A</td>
<td>Incident Patient Discussion</td>
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<td>CPM B</td>
<td>Prevalent Patient Discussion</td>
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<tr>
<td>Descriptor</td>
<td>Interest Descriptor</td>
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<td>Descriptor</td>
<td>Contraindication Descriptor</td>
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<tr>
<td>CPM C</td>
<td>Referral to Transplant Center</td>
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Three of the measures meet the definition of clinical performance measure, i.e. indicators that assess processes and outcomes of health care and can be used for quality improvement activities. Two items are descriptors. Descriptors are not clinical performance measures per se, but are necessary to calculate the proposed clinical performance measures. A measure name, short description, data collection question, literature source, medical review criteria, numerator, denominator, applicable exclusions, data elements, potential data sources, applicable setting, purpose of the measure, and supporting rationale were provided for each measure.

The three proposed clinical performance measures, Incident Patient Discussion, Prevalent Patient Discussion, and Referral to Transplant Center, and two descriptors, Interest and Contraindication, may be obtained by the dialysis facility. Modification of the patient long term care program required by the Conditions for Coverage may allow facilities to capture this data, at least annually.

Proposed Pilot Testing

Because several of the proposed CPMs and descriptors involve tasks not currently monitored or documented by dialysis providers, it will be important to pilot test the items before they are implemented nationally. Pilot testing will help identify and correct unclear items or instructions and will provide standardized choice options for items that are currently open-ended. Pilot testing will also help to determine the validity of submitted information by comparison with chart abstraction and patient interviews. A suggested pilot testing plan is included in the full report.

Use of Measures for Quality Improvement and Public Reporting

Monitoring the steps in the transplant referral process is likely to lead to quality improvement efforts that will enhance transplantation access. For example, dialysis facilities and transplant centers may develop methods to enhance communication of information about patients and thereby speed up the referral and evaluation of transplant candidates. Moreover, public reporting of clinical performance measures may assist patients in choosing dialysis facilities.

Proposed Conditions for Coverage

Proposed Conditions for Coverage for dialysis facilities and Conditions of Participation for transplant centers support the recommended Kidney Transplant Referral CPMs by requiring patients to be informed of the option of transplantation, requiring transplant centers to use written selection criteria for waitlisting or declining transplantation for patients, requiring dialysis facilities and transplant centers to communicate about transplant status of patients, and requiring transplant referral tracking by dialysis facilities. Adoption of these key aspects into the final Conditions for Coverage/Participation will facilitate the implementation of the recommended Kidney Transplant Referral CPMs.

Recommended Transplant Center-Specific Measures

The steps to kidney transplantation encompass activities at both hemodialysis facility and transplant center levels. The TEP and Contractor strongly believe that attention and measurement of the dialysis facility side of process, without equal attention and measurement of the transplant center side of the process is shortsighted. Ensuring all appropriate dialysis patients are referred to a transplant center is
important, but equally critical is what happens between the time of referral and time of waitlisting for deceased donor transplantation or live donor transplantation. Many patients experience challenges during this interim that prevent timely movement through the steps to transplantation. Therefore, two additional transplant center-specific measures are recommended.

<table>
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<tr>
<th>CPM/Descriptor</th>
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<tr>
<td>CPM D Waiting List/Living Donor Transplant</td>
<td>Deceased Donor Transplant Descriptor</td>
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The data elements for CPM D: Waiting List/Living Donor Transplant, and Deceased Donor Transplant Descriptor, may be obtained from the Scientific Registry of Transplant Recipients (SRTR) or the Organ Procurement Transplant Network (OPTN). If the proposed Conditions for Coverage for dialysis facilities and Conditions of Participation for transplant centers are adopted as written, dialysis facilities will be required to track the results of each transplant referral. Measuring these endpoints (waitlisting and live donor transplantation) relative to the date transplant referral was made may reveal opportunities for quality improvement activities aimed at helping to move patients through all the steps in the transplant process and thus reduce disparities in transplantation. Public reporting of this clinical performance measure may assist patients in choosing transplant centers.

Lessons Learned
Discussion at TEP and Stakeholder meetings highlighted the following common barriers to completion of the referral to kidney transplantation:

- No consistent coordination or communication exists between dialysis facilities and transplant centers.
- No standardized process is in place to inform a dialysis facility that a referral to transplant center has taken place, or that the patient has been accepted/rejected for further evaluation by the transplant center.
- There are few agreed-upon standard criteria regarding which patients are medically unsuitable to be referred to a transplant center for evaluation.
- There is a concern that transplant centers will be unable to handle the load of patients referred by dialysis facilities if this project is successful in increasing referrals.
- Several steps in the transplant process are not under the control of dialysis facilities. Additional monitoring at the transplant center level would be beneficial.
- The role of the transplant surgeon designee is not clearly defined.
- There are multiple, uncoordinated data sources.
- Patient education regarding transplantation needs to be improved.

Recommendations to CMS
There are four key recommendations resulting from discussions at the TEP meetings:

- National implementation of the recommended Kidney Transplant Referral Measures will require dialysis facilities to begin tracking and documenting the transplant referral process of their patients. It is anticipated that limited documentation of this process is currently in dialysis medical records. We foresee that facilities will most efficiently track the data necessary for reporting in concert with the annual completion of each patient’s long term care program. Given sufficient notice, this CPM data could then be collected along with the annual national CPM data collection that already occurs.
- Although the scope of work for this project was limited to dialysis facility-specific kidney transplant referral measures, the TEP and Contractor urge CMS to consider the measurement and evaluation of the time period between
referral and waitlisting or transplantation. Two transplant center-specific measures are proposed to allow evaluation of all of the steps in the transplant process.

- One challenge identified by the TEP is poor communication between dialysis facilities and transplant centers regarding both transplant referral and workup processes. The TEP recommended development of a standardized referral form for use between dialysis facilities and transplant centers, with the goal of an electronic-based referral system. ESRD Networks may be able to serve as a conduit for the exchange of this information.

- To complete the CPM data collection, dialysis facilities must obtain a list of contraindications to transplantation from each transplant center where their patients are referred. The TEP recommended that transplant center inclusion/exclusion criteria for transplantation be available on an internet-based system that is readily available to both patients and dialysis providers. ESRD Networks may be able to serve as centralized clearinghouses for these data.

Conclusion
We are confident that the recommended Dialysis-Facility Specific Kidney Transplant Referral Measures will be invaluable for studying regional differences in referral for kidney transplantation, identifying possible interventions, and determining the impact of interventions. It is likely that pilot testing will reveal additional recommendations for national implementation of the CPM data collection. Lastly, we encourage CMS to evaluate all steps in the transplant process and to consider the addition of transplant center-specific measures in the future.
Description of Project Activities

The Centers for Medicare & Medicaid Services (CMS) contracted with End Stage Renal Disease (ESRD) Network 9 for a special study between July 1, 2004 and June 30, 2005 to develop kidney transplant referral measures at the dialysis facility level. These measures will track steps in the transplant referral process and may be used for quality improvement and public reporting. CMS chose to develop quality measures in this area because of the Department of Health and Human Service interest in increasing organ donation and transplantation and because not all ESRD patients are offered the opportunity for transplantation, despite being the treatment modality of choice.

Measures Development Process

Scope of Work

The table below lists the seven specific tasks required by the Scope of Work for this special project. The subsections that follow detail work completed to meet the task requirements.

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Task 1. Literature Review and Identify Potential Measures

Initially MEDLINE searches were performed to review relevant literature for the development of kidney transplant referral measures but search terms were not found with sufficient sensitivity and specificity. As a result, a review of all articles over the last 20 years in six major journals was completed (American Journal of Kidney Diseases; Journal of the American Society of Nephrology; Kidney International; Nephrology, Dialysis, and Transplantation; Transplantation; Transplant Proceedings). From this review, articles were selected that dealt with access to kidney transplantation, steps in the kidney transplant process, practice guidelines, clinical performance measures, and quality improvement. The reference lists of these articles were also reviewed to identify additional articles. All articles, abstracts, and notes on relevance to this project were entered into a customized database.

A summary report of literature reviewed and potential clinical performance measures was prepared and submitted to Pamela Frederick, CMS Government Task Leader (GTL) and Deborah Read, Project Officer (PO) on September 30, 2004. A table of relevant articles was constructed for the report and for use by TEP members (see Appendix A). A CD containing PDF files of all relevant articles was also prepared for TEP members.

Task 2. Convene Technical Expert Panel (TEP)

A Technical Expert Panel (TEP) was convened to assist the contractor (ESRD Network 9) in developing transplant referral measures. TEP members, including patients and professionals, were sought to represent various ESRD stakeholders involved in or impacted by the transplant referral process. National renal organizations were invited to circulate a notice requesting nominations for membership on the TEP to their constituents. Members were chosen by the contractor based on their area of expertise, location and knowledge of the subject area. Individual TEP members were approved by CMS. The final TEP membership included
transplant surgeons; dialysis facility representatives, including from the large dialysis organizations; transplant recipients; a transplant coordinator; representatives from a kidney patient organization, managed care organization, quality improvement organization, and the Scientific Registry of Transplant Recipients; and CMS representatives. Observers included additional CMS staffers and representatives from eSource. See page 28 for a list of TEP members.

The first TEP meeting was held in Baltimore on October 21 and 22, 2004. A summary report of the meeting is included as Appendix B. The purpose of the meeting was to obtain input from experts on the development of dialysis facility-specific kidney transplant referral measures. At the meeting, Ashwini Sehgal, MD, Clinical Coordinator, reviewed project goals and specific tasks required. Findings from the literature search and the challenges of developing clinical performance measures (CPMs) without existing practice guidelines were discussed. Proposed transplant referral measures were presented. Common barriers to completion of the referral to kidney transplantation and modifications to the proposed measures were discussed at length.

Following the meeting, a summary report of the meeting was prepared and sent to CMS on November 11, 2004. The draft Clinical Performance Measures document was revised based on TEP member input at the October 20 and 21 meeting. The draft was sent to CMS for approval on December 6, 2004 and further edited based on CMS input.

Task 3. Obtain Input from Renal Community on Potential Measures and Convene Second TEP Meeting

The draft Clinical Performance Measures were posted on The Renal Network, Inc. (ESRD Networks 9 & 10) Web site (www.therenalnetwork.org) from January 11, 2005 until January 28, 2005 for public comment. An email announcing the posting was distributed to renal organizations and ESRD networks, requesting review and comment. Comments received through the Web site were returned to the Network anonymously. Both organizations and individuals responded using this mechanism. Additional identifiable responses were received by email or mail from organizations and individuals. A total of 35 public responses were obtained. Appendix C contains a collation of the anonymous responses received.

On February 9 and 10, 2005 a second Technical Expert Panel (TEP) meeting was convened in Baltimore. The goals of the TEP at this meeting were to review public comments obtained regarding the draft CPMs and to refine the draft measures and supporting information for presentation and discussion at the Stakeholders meeting scheduled for April 14, 2005. The majority of meeting time was focused on extensive discussion relating to each draft CPM, including the specific measure, choices (e.g., Yes/No), numerator, denominator, and data source. Public comments collated from the circulated draft Clinical Performance Measures document were reviewed, discussed, and incorporated into the TEP recommendations.

On day 2, revised measures were presented to the TEP for further discussion. TEP and Observer input was solicited in the areas of specific measure, choices, numerator, denominator, data source, feasibility of data collection and use of the measures for public reporting. The next steps in the process of fulfilling the contract were discussed. This was followed by a discussion of relevant comments for TEP members to provide to CMS related to Conditions for Coverage for End Stage Renal Disease Facilities and Conditions of Participation for Transplant Centers.

A summary report of the meeting was sent to CMS on March 8, 2005 and is attached as Appendix D. The draft Clinical Performance Measures document was modified based on the meeting discussion.
Task 4. Obtain Technical Consultant Services for Assistance
Alan Leichtman, MD from University Renal Research & Education Association (URREA) and Jonathan Sugarman, MD, MPH from Qualis Health were contracted to provide technical consultant services for the project. They each participated in all three Technical Expert Panel meetings in Baltimore.

Task 5. Coordinate ESRD Stakeholders Meeting and Convene Third TEP Meeting
An ESRD Stakeholders meeting was held by CMS on April 14, 2005 to disseminate information on the progress of ESRD special studies, including the kidney transplant referral measures project. Dr. Sehgal presented the draft Clinical Performance Measures and fielded questions from the audience. Questions and comments raised at the Stakeholders Meeting are attached in Appendix E.

On April 15, 2005, the TEP convened for a third meeting to refine the dialysis facility-specific kidney transplant referral measures, to discuss public comments received at the Stakeholders meeting on April 14, 2005, and to formulate a plan for pilot testing the proposed measures. Dr. Sehgal, gave a presentation outlining the draft proposed measures and descriptors, a description of a proposed pilot project, and issues relating to the proposed pilot project. Following that discussion, draft data collection forms were reviewed and discussed by Susan Stark, Executive Director of The Renal Network, Inc. Comments were solicited from TEP members and observers and final steps in fulfilling the contract were discussed. A summary of the meeting was forwarded to CMS and is attached as Appendix F.

Task 6. Prepare List of Recommended Kidney Transplant Referral Measures
The draft Clinical Performance Measures were further refined based on discussion from the ESRD Stakeholders and third TEP meetings. The list of recommended dialysis facility-specific kidney transplant referral measures was sent to CMS on June 1, 2005. A table of the recommended measures submitted is found on page 9.

Task 7. Prepare Final Project Report
Additional comments were obtained from CMS and incorporated into this Final Report.

Literature Review Findings
The table in Appendix A lists relevant literature sources used to develop the recommended dialysis facility-specific clinical performance measures. The following subsections summarize key literature review findings.

Background on End Stage Renal Disease
Approximately 450,000 Americans receive treatment for End Stage Renal Disease (also referred to as Chronic Kidney Disease Stage 5). Medicare covers virtually all individuals with End Stage Renal Disease regardless of age. About one-third of patients are black, 13% are Hispanic, and 45% are female. Of all patients, 72% receive chronic dialysis treatment while 28% have a functioning kidney.1 In the year 2002, 8000 new transplants were from deceased donors while 6000 were from living donors.2

Advantages of Transplantation
Compared with long-term dialysis, kidney transplantation generally offers a longer life span, a better quality of life, and lower health care costs.3-9 For example, transplant recipients have a 50-80% lower long-term mortality rate than patients awaiting transplant.10
Steps in the Transplant Process

Obtaining a kidney transplant involves a series of steps: 10-14

1. Patient medical suitability to undergo transplantation.
2. Patient interest in receiving a transplant.
3. Completion of pre-transplant workup, i.e. referral to transplant surgeon, evaluation and treatment of medical conditions, and laboratory studies such as tissue typing. 15, 16
4. Movement up deceased donor waiting list or receipt of organ from suitable living donor.

Completion of these steps may take anywhere from a few weeks to several years. Blacks, women, the poor, and the elderly are slowed at multiple steps in the transplant process. 17

Sociodemographic Correlation of Transplant Access

Sociodemographic factors associated with decreased transplant access include black race, female gender, low socioeconomic status, and advanced age. 18-32 For example, black dialysis patients have a 40% lower deceased donor transplant rate and a 70% lower living donor transplant rate than white dialysis patients. 1

Barriers to Receiving a Kidney Transplant

Barriers at multiple levels may act as impediments to receiving a kidney transplant. Barriers at the patient level may include active medical conditions, lack of knowledge about transplantation, comfort with continuing dialysis and concerns about surgery, adverse effects of medications, and health care costs. Barriers at the dialysis provider level may include a lack of time and reimbursement for educating patients about transplantation and potential loss of revenue if patients are transplanted. Barriers at the transplant center level include the distance patients must travel to get to the center, limited resources and personnel for evaluation, and inadequate coordination with patients and referring nephrologists. Barriers at the health care system level include the limited funding for pre-transplant counseling and post-transplant care, the need for culturally sensitive interactions with minority patients, and the extreme shortage of deceased donor organs. 18, 23-26, 33-39

Unique Features of Living Donor Transplants

Living donor transplantation involves identifying a potential donor, evaluating the donor’s medical suitability, and performing a transplant. 40-42 These tasks can usually be performed much more quickly than moving up a deceased donor waiting list. However, barriers to living donor transplantation include reluctance to ask potential donors to be evaluated and lack of a medically suitable donor. 43

Recent Trends in Access to Transplantation

From 1993 to 2002, the number of deceased donor kidney transplants increased 10% from 7400 to 8300 while the number of individuals on the deceased donor kidney transplant waiting list doubled from 24,000 to 51,000. During this time, the percentage of black recipients increased from 24% to 30% while the percentage of female recipients remained steady at 40%. From 1993 to 2002, the number of living donor transplants doubled from 2900 to 6200. During this time, the percentage of black recipients was 14% while the percentage of female recipients was 40%. 2

Medicare Quality Improvement Efforts in End Stage Renal Disease

Medicare quality improvement efforts in End Stage Renal Disease have involved (a) identification of key outcome and process indicators by expert workgroups, (b) mandatory reporting of indicators by providers, (c) distribution of performance data to providers, and (d) education and supervision of providers by ESRD Networks. These efforts were associated with two-fold improvements in the proportion of patients with adequate hemodialysis doses and three-fold improvements in the proportion of patients with adequate
hemoglobin levels. Moreover, improvements in quality were associated with declines in race and sex disparities in dialysis dose.

**Need for Clinical Performance Measures**

As a condition for Medicare coverage, dialysis providers are required to annually re-evaluate each patient’s treatment modality (dialysis vs. transplant), to include each patient’s preferences in the evaluation, and to record the results in a written long-term program. In completing this evaluation, providers generally review each of the steps in the transplant process (suitability, interest, pre-transplant workup, waiting list). However, providers differ greatly in how they code this information. Moreover, there is no registry to collect this transplant process information. Having a mandatory registry with standardized indicators would be invaluable for studying regional differences in access to transplantation, identifying possible interventions, and determining the impact of interventions. Indicators that assess processes and outcomes of health care as part of quality improvement activities are referred to as clinical performance measures.

**Challenges in Using Clinical Performance Measures**

There are several challenges in using clinical performance measures to assess access to kidney transplantation across dialysis providers. First, already overburdened dialysis facility staff will need to do additional work to collect and submit the information. Second, the reliability and validity of the information submitted will need to be monitored, perhaps by performing chart abstractions and patient interviews for a random subset of patients. Such abstractions and interviews could be used to confirm submitted information such as patient interest and medical suitability. Third, factors beyond the control of dialysis providers are likely to affect completion of specific steps in the transplant process. For example, organ donation rates will affect movement up the deceased donor waiting list. Fourth, deciding which patient characteristics to adjust for can be difficult. For example, race may reflect both biologic differences (e.g. tissue types) and process of care (e.g. under-referral to transplant centers). In this case, adjusting for race risks the possibility of inappropriately adjusting for process of care. However, not adjusting for race, risks the possibility of not adjusting for biological differences that may account for differences in outcomes.

**Recommended Dialysis Facility-Specific Measures**

A table of five recommended dialysis facility-specific measures is below. Three of the measures meet the definition of clinical performance measure, i.e., indicators that assess processes and outcomes of health care and can be used for quality improvement activities. Two items are descriptors. Descriptors are not clinical performance measures per se, but are necessary to calculate the proposed clinical performance measures.

<table>
<thead>
<tr>
<th>CPM/Descriptor</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPM A</td>
<td>Incident Patient Discussion</td>
</tr>
<tr>
<td>CPM B</td>
<td>Prevalent Patient Discussion</td>
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<tr>
<td>Descriptor</td>
<td>Interest Descriptor</td>
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<tr>
<td>Descriptor</td>
<td>Contraindication Descriptor</td>
</tr>
<tr>
<td>CPM C</td>
<td>Referral to Transplant Center</td>
</tr>
</tbody>
</table>

The tables on the following pages provide the measure name, short description, the measure, data collection question, literature source, medical review criteria, numerator, denominator, applicable exclusions, data elements (see also Appendix G), potential data sources, applicable setting and purpose of the measure. Supporting rationale follows each measure table.

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### Dialysis Facility-Specific Clinical Performance Measure A – Incident Patient Discussion

<table>
<thead>
<tr>
<th>Name: Clinical Performance Measure A – Incident Patient Discussion</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Short Description:</strong> This measure indicates percentage of facility incident patients informed of the option of kidney transplantation within 90 days of starting dialysis at the current facility.</td>
</tr>
<tr>
<td><strong>Measure:</strong> Percentage of patients and/or patient representatives who acknowledge that nephrologist or dialysis team has discussed, within 90 days of initiation of dialysis at the current facility, the option of kidney transplantation.</td>
</tr>
<tr>
<td><strong>Data Collection Question:</strong> Patient and/or representative acknowledge that nephrologist or dialysis team has discussed, within 90 days of initiation of dialysis at the current facility, the option of kidney transplantation.</td>
</tr>
<tr>
<td>a. Yes</td>
</tr>
<tr>
<td>b. No</td>
</tr>
<tr>
<td><strong>Medical Review Criteria:</strong> Patient acknowledged discussion of option of kidney transplantation occurred within 90 days of initiating dialysis at current facility.</td>
</tr>
<tr>
<td><strong>Numerator:</strong> Yes response</td>
</tr>
<tr>
<td><strong>Denominator:</strong> All incident patients of dialysis facility (i.e. &lt; 90 days at current facility)</td>
</tr>
<tr>
<td><strong>Applicable Exclusions:</strong> None</td>
</tr>
<tr>
<td><strong>Data Elements (see Appendix G):</strong></td>
</tr>
<tr>
<td>Date of first dialysis at current facility</td>
</tr>
<tr>
<td>Patient acknowledgement that discussion of kidney transplantation option occurred within 90 days of first dialysis at current facility (yes, no, unknown)</td>
</tr>
<tr>
<td>Number of incident patients of dialysis facility (i.e. &lt; 90 days at current facility)</td>
</tr>
<tr>
<td><strong>Potential Data Sources:</strong> Long term care plan, other parts of the dialysis facility medical record</td>
</tr>
<tr>
<td><strong>Applicable Setting:</strong> Dialysis facility</td>
</tr>
<tr>
<td><strong>Literature Source (see Appendix A):</strong> 12, 21, 22, 26, 27, 42, 49, 55, 80, 84, 92, 96, 104, 128, 129, 136</td>
</tr>
<tr>
<td><strong>Evidence or Opinion:</strong> Both</td>
</tr>
<tr>
<td><strong>Purpose of Measure:</strong> Quality improvement and public reporting</td>
</tr>
<tr>
<td><strong>Name:</strong></td>
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<tr>
<td>-----------</td>
</tr>
<tr>
<td><strong>Short Description:</strong></td>
</tr>
<tr>
<td><strong>Measure:</strong></td>
</tr>
</tbody>
</table>
| **Data Collection Question:** | Patient and/or representative acknowledge that nephrologist or dialysis team has discussed, within the last 12 months, the option of kidney transplantation.  
 a. Yes  
 b. No |
| **Medical Review Criteria:** | Patient acknowledged discussion of option of kidney transplantation occurred within past 12 months. |
| **Numerator:** | Yes response |
| **Denominator:** | Varies  
 **Denominator 1:** All prevalent patients of dialysis facility (i.e. ≥ 90 days at current facility).  
 **Denominator 2:** All prevalent patients of dialysis facility (i.e. ≥ 90 days at current facility) minus patients with permanent contraindications to kidney transplantation. |
| **Applicable Exclusions:** | Varies based on denominator  
 **Denominator 1:** Exclude patients at dialysis facility < 90 days  
 **Denominator 2:** Exclude patients at dialysis facility < 90 days or with permanent contraindications to kidney transplantation |
| **Data Elements (see Appendix G):** | Date of first dialysis at current facility  
 Patient acknowledgement that discussion of kidney transplant option occurred within past 12 months (yes, no, unknown)  
 Number of prevalent patients of dialysis facility (i.e. ≥ 90 days at current facility)  
 Number of prevalent patients with permanent contraindications to kidney transplantation |
| **Potential Data Sources:** | Long term care plan, other parts of the dialysis facility medical record |
| **Applicable Setting:** | Dialysis facility |
| **Literature Source (see Appendix A):** | 12, 21, 22, 26, 27, 42, 49, 55, 80, 84, 92, 96, 104, 128, 129, 136 |
| **Evidence or Opinion:** | Both |
| **Purpose of Measure:** | Quality improvement for both denominators. Public reporting for incident patients of dialysis facility (i.e. < 90 days at current facility) |
Rationale for CPMs A and B

Educated patients are more likely to make informed decisions about transplantation. Involvement of patients and physicians in decision-making about treatment modality is also consistent with Medicare Conditions for Coverage of dialysis facilities. The Conditions for Coverage of dialysis facilities require patients to be informed of their suitability for transplantation.

Ideally, patients and providers will discuss treatment modalities well before the onset of End Stage Renal Disease. However, such discussions often don’t occur because of lack of awareness of renal disease, poor access to medical care, or uncertainty about the irreversibility of renal failure. Discussion about transplantation as a treatment modality should take place within 90 days of starting dialysis at the current facility and then at least annually thereafter, as required by the Conditions for Coverage. If a prevalent patient has a permanent contraindication to transplantation then it may not be necessary to have further discussions about transplantation.

Each dialysis facility should have a written policy regarding (a) who has primary responsibility for discussing the option of transplantation with patients, (b) who else may contribute to such discussions, (c) what the components of discussion should be, (d) how the discussion will be documented, and (e) the role of the medical director in ensuring compliance. Ideally, the primary nephrologist will lead the patient education discussion about transplantation. Other members of the dialysis team, under the direction of the primary nephrologist (e.g. nurses, social workers, dietitians), should contribute to the education discussion. Components of the discussion may include the referral and evaluation process, selection criteria, living vs. deceased donors, deceased donor waiting list, surgery, success rates, complications, financial implications, and psychological issues. Several conversations may be necessary to adequately cover these issues. Providers should verify patients’ understanding, e.g. by asking them to restate what has been discussed.

Written information can help supplement verbal discussions. It may be helpful for dialysis facilities to develop a standardized written information packet in collaboration with the local transplant center(s) that is appropriate to the educational, cultural, and linguistic background of their patients. Each patient’s acknowledgement of the discussion should be documented in the dialysis facility medical record. Dialysis facilities may consider including this item in the written long term care plan that is required under the Conditions for Coverage. The written form should specify the date this item was completed as well as the names of the providers involved in discussion. As with other CPMs (e.g. dialysis dose, hemoglobin), the medical director should monitor outcomes of this CPM. The medical director may need to intervene with specific primary nephrologists and/or patients if discussion about transplantation does not occur in a timely fashion.

Family members or guardians should be included if patients are children or are mentally incompetent. However, even competent adults may benefit from having family members present when the option of transplantation is discussed. The age and developmental status of pediatric patients should be considered when involving them in discussions. Useful suggestions for addressing the needs of pediatric patients are available on the United Network for Organ Sharing (UNOS) Web site.

Proposed Revision of Conditions for Coverage

If implemented, new proposed Conditions for Coverage (CMS-3818-P) will require evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s) as part of the initial and annual assessment of patients. If patients are not suitable for transplantation referral, the basis for nonreferral must also be documented.
Proposed Revision of 2728 Form
A proposed revised version of the End Stage Renal Disease Medical Evidence Report (2728 form) includes the following question:

*Has patient been informed of kidney transplant options?*
  a. Yes
  b. No

If not, please check all that apply:
  * Medically unfit
  * Unsuitable due to age
  * Psychologically unfit
  * Patient declines information
  * Patient has not been assessed
  * Other

Once implemented, this may provide additional information about discussions with incident patients. However, this question is not suitable for use as a clinical performance measure for dialysis facilities for two reasons. First, it often reflects pre-End Stage Renal Disease (Chronic Kidney Disease Stage 4) care as opposed to care provided by a dialysis facility. Second, while the denominator should be all patients, the appropriate numerator is questionable. The response “yes” clearly belongs in the numerator. The response “no” combined with the reason “patient declines information” may also belong in the numerator. However, it is not clear if the response “no” combined with the reason “other” belongs in the numerator or not.
# Interest Descriptor

**Name:** Interest Descriptor

**Short Description:** This is a descriptor, not a clinical performance measure. The descriptor denotes patients’ willingness to be evaluated for kidney transplantation. This descriptor is needed to calculate Clinical Performance Measure C - Referral to Transplant Center.

**Measure:** Number of patients who are undecided or do not want to be evaluated for kidney transplantation.

**Data Collection Question:** Does patient want to be evaluated for kidney transplantation?
- a. Yes
- b. Undecided (specify why)
- c. No (specify why)

**Medical Review Criteria:** Patient is undecided or not interested in kidney transplantation.

**Numerator:** Not applicable

**Denominator:** Not applicable

**Applicable Exclusions:** None

**Data Elements (see Appendix G):**
- Patient interest in kidney transplantation (yes, undecided, no, unknown)
- Reason(s) patient undecided in transplantation (if applicable) (free text)
- Reason(s) patient uninterested in transplantation (if applicable) (financial burden, medical complication, age, satisfied with dialysis, other (specify))

**Potential Data Sources:** Long term care plan, other parts of the dialysis facility medical record

**Applicable Setting:** Dialysis facility

**Literature Source (see Appendix A):** 5, 6, 7, 21, 22, 27, 49, 56, 60, 76, 88, 92, 93, 112, 114

**Evidence or Opinion:** Both

**Purpose of Measure:** To calculate denominator for Clinical Performance Measure C - Referral to Transplant Center
Rationale for Interest Descriptor
Willingness to undergo a formal evaluation at a transplant center is a concrete expression of a patient’s interest in transplantation. Reasons for lack of interest in transplantation include medical limitations, fear of surgery or complications, financial concerns, religious/ethical reasons, and feeling fine on dialysis. Because patients’ interest in transplantation may evolve over time, it is important to reassess their interest on a regular basis. According to current Conditions for Coverage, patients should be reassessed at least every 12 months.

Patient interest in transplantation should be documented in the dialysis facility medical record. Dialysis facilities may want to list this item in each patient’s written long term care plan and update it at least every 12 months. The written form should specify the date this item was completed and name of the person completing the item.

All interested patients should be listed as a "yes" response, even if they may not be medically suitable for transplantation. Patients already waitlisted or in the midst of a pre-transplant workup should also be listed as a "yes" response. Reasons for being undecided or not interested may be collected in an open-response manner during pilot testing. This information can then be used to develop standardized choice options for use when CPMs are implemented.

Proposed Revision of Conditions for Coverage:
Proposed Conditions for Coverage §494.90(a)(5) Patient Plan of Care: Transplantation Status specifies that when the patient is a transplantation referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient’s plan of care must include documentation of the-- (i) Plan for transplantation, if the patient accepts transplantation referral; (ii) Patient’s decision, if the patient is a transplantation referral candidate but declines the transplantation referral; or (iii) Reasons(s) for the patient’s nonreferral as a transplantation candidate as documented in accordance with §494.80(a)(10).
**Contraindication Descriptor**

<table>
<thead>
<tr>
<th><strong>Name</strong>: Contraindication Descriptor</th>
</tr>
</thead>
</table>

**Short Description**: This is a descriptor, not a clinical performance measure. The descriptor denotes patients with contraindications to referral for kidney transplant evaluation. This descriptor is needed to calculate Clinical Performance Measure C - Referral to Transplant Center.

**Measure**: Number of patients with contraindications to referral for kidney transplant evaluation.

**Data Collection Question**: Are there any contraindications to referring patient for kidney transplant evaluation?
   a. Yes (specify contraindication)
   b. No

**Medical Review Criteria**: Patient has a contraindication to referral for kidney transplant evaluation.

**Numerator**: Not applicable

**Denominator**: Not applicable

**Applicable Exclusions**: None

**Data Elements (see Appendix G)**:
- Presence of contraindication to kidney transplantation (yes, no, unknown)
- Contraindication identifier (transplant center, dialysis facility)
- Contraindication reason (severe cardiovascular disease, severe peripheral occlusive vascular disease, active non-skin cancer, dementia, psychosis, noncompliance, severe obesity, other (specify))

**Potential Data Sources**: Long term care plan, other parts of the dialysis facility medical record

**Applicable Setting**: Dialysis facility

**Literature Source (see Appendix A)**: 2, 5, 6, 7, 12, 21, 22, 31, 32, 43, 49, 60, 73, 88, 103, 107, 114

**Evidence or Opinion**: Both

**Purpose of Measure**: To calculate denominator for Clinical Performance Measure C - Referral to Transplant Center
Rationale for Contraindication Descriptor

While the option of transplantation should be considered for all patients, not all patients need to be referred to a transplant center for a formal evaluation. In particular, referring patients with absolute contraindications to transplantation would burden both patients and transplant centers without any obvious benefit. There are very few generally agreed upon absolute contraindications to kidney transplantation. These include active or recent cancer, active systemic infections, and a life expectancy of less than two years.73, 74 In general, patients with active or recent cancer have an increased risk of recurrence and metastasis with immunosuppressive therapy.75 However, these risks are minimal for patients with incidentally discovered renal cell carcinomas, in situ carcinomas, and basal cell skin cancers.75 Patients with active systemic infections such as sepsis or tuberculosis should not be transplanted because such infections can worsen and become life threatening in the presence of immunosuppressive therapy.71, 74 For patients with limited life expectancy, renal transplantation may not offer any advantage and may instead accelerate death.73 National transplant societies should develop and promulgate guidelines on contraindications to referral.

Individual transplant centers may have additional absolute contraindications and are likely to vary in what they consider to be contraindications.76-78 For example, a survey of European transplant centers found that two-thirds would automatically exclude patients with symptomatic heart failure from renal transplantation while one third would not.77 Non-adherence with treatment, lack of insurance coverage, and drug abuse may be additional absolute contraindications at a local transplant center.79 Dialysis facilities should obtain each local transplant center’s list of absolute contraindications. Patients and nephrologists will need to consider any differences in absolute contraindications among transplant centers in their region when deciding about referrals.

ESRD Networks may wish to obtain and make available these lists for all the transplant centers in each Network.

Several caveats should be kept in mind when applying these contraindications. First, they should be tailored to the circumstances of individual patients, and there may be patients who should be referred in spite of having a seemingly absolute contraindication to transplantation. For example, a patient with recently treated breast cancer who has exhausted all vascular and peritoneal access sites may warrant transplant evaluation. Second, patients should be re-evaluated periodically to determine if absolute contraindications are still present. Patients with no evidence of cancer for a number of years (depending on the type of cancer) or with an adequately treated systemic infection should be reconsidered for transplant evaluation.73, 74 Third, contraindications may change over time. National transplant societies and local transplant centers should maintain up-to-date guidelines that dialysis facilities can refer to.

Dialysis facilities may want to list any absolute medical contraindications in each patient’s written long term care plan and update it at least every 12 months. The written form should specify the date this item was completed and name of the person completing the item. Current Medicare Conditions for Coverage specify that a transplant surgeon or designee be involved in decisions about treatment modality.52 Dialysis facilities should specify the individual who will be the designee.

Proposed Revision of Conditions for Coverage

The new proposed Conditions for Coverage §494.80(a)(10) Assessment Criteria requires the evaluation of suitability for a transplantation referral, based on criteria developed by the prospective transplantation center and its surgeon(s). If a patient is not suitable for transplantation referral, the basis for nonreferral must be documented in the patient’s medical record.65 If implemented as proposed, dialysis facilities will be required to obtain specific
inclusion/exclusion criteria for transplantation referral from transplant centers.

Proposed Conditions for Coverage §494.90(a)(5) Patient Plan of Care: Transplantation Status specify that when a patient is a transplantation referral candidate, the interdisciplinary team must develop plans for pursuing transplantation. The patient’s plan of care must include documentation of the—(i) Plan for transplantation, if the patient accepts transplantation referral; (ii) Patient’s decision, if the patient is a transplantation referral candidate but declines the transplantation referral; or (iii) Reasons(s) for the patient’s nonreferral as a transplantation candidate as documented in accordance with §494.80(a)(10).72

Proposed Revision of 2728 Form

A proposed revised version of the End Stage Renal Disease Medical Evidence Report (2728 form) includes the following question:

Has patient been informed of kidney transplant options?
   a. Yes
   b. No

If not, please check all that apply:
   - Medically unfit
   - Unsuitable due to age
   - Psychologically unfit
   - Patient declines information
   - Patient has not been assessed
   - Other

Once implemented, this may provide additional information about contraindications for transplantation. However, this question is not suitable for use as a contraindication descriptor for two reasons. First, it is not limited to absolute contraindications and includes relative contraindications. Second, medical contraindications are specified only if the response to the first question is “no.” Patients with absolute medical contraindications who are informed of (the lack of) kidney transplant options will not be captured by this item.
# Dialysis Facility-Specific Clinical Performance Measure C - Referral to Transplant Center

<table>
<thead>
<tr>
<th><strong>Name</strong></th>
<th>Clinical Performance Measure C - Referral to Transplant Center</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Short Description</strong></td>
<td>This measure tracks percent of facility patients referred to a transplant center.</td>
</tr>
<tr>
<td><strong>Measure</strong></td>
<td>Percentage of patients referred to a transplant center for evaluation.</td>
</tr>
</tbody>
</table>
| **Data Collection Question** | Has patient been referred to a transplant center for an evaluation?  
  a. Yes (specify who referred, how referred, name of transplant center, and date)  
  b. No (specify reasons for not referring) |
| **Medical Review Criteria** | Patient was referred to a transplant center. |
| **Numerator** | Yes response |
| **Denominator** | Varies  
  Denominator 1: All patients  
  Denominator 2: Exclude patients with contraindications  
  Denominator 3: Exclude uninterested/undecided patients  
  Denominator 4: Exclude patients with contraindications, uninterested/undecided patients |
| **Applicable Exclusions** | Varies based on denominator  
  Denominator 1: None  
  Denominator 2: Exclude patients with contraindications  
  Denominator 3: Exclude uninterested/undecided patients  
  Denominator 4: Exclude patients with contraindications and uninterested/undecided patients |
| **Data Elements (see Appendix G)** | Patient referred to transplant center (yes, no, unknown)  
  Date patient referred to transplant center (if applicable) (mm/dd/yyyy)  
  Who referred patient (if applicable) (nephrologist, patient, nurse, social worker, secretary, other (specify))  
  How patient referred (if applicable) (written communication, phone call, other (specify))  
  Reason for nonreferral (if applicable) (contraindication, physician judgment, patient uninterested/undecided, patient already on waitlist, other (specify))  
  Total number of patients in dialysis facility  
  Number of patients with contraindication to kidney transplantation  
  Number of patients uninterested in kidney transplantation  
  Number of patients undecided about kidney transplantation |
| **Potential Data Sources** | Long term care plan, other parts of the dialysis facility medical record |
| **Applicable Setting** | Dialysis facility |
| **Literature Source (see Appendix A)** | 5, 6, 7, 12, 49, 88, 92, 114 |
| **Evidence or Opinion** | Both |
| **Purpose of Measure** | Quality improvement for all denominators. Public reporting for denominator 4. |
Rationale for CPM C

Because of the expertise of transplant center personnel, all appropriate patients should be referred to a transplant center for evaluation. Appropriate patients are those without absolute contraindications who want to be evaluated for kidney transplantation.

Dialysis facilities and transplant centers vary in how referrals occur. In general, nephrologists initiate referrals, but other dialysis facility personnel may also initiate referrals. Moreover, some transplant centers may expect patients to make the initial contact. In other cases, patients may self-refer, even if their primary nephrologists think they are not transplant candidates.

The Technical Expert Panel identified communication between dialysis facilities and transplant centers as a major impediment to timely access to transplantation. Transplant centers should provide a written acknowledgement that a referral has been received and should also provide periodic updates about the status and results of the evaluation to both the dialysis facility and primary nephrologist. Utilizing a national, standardized referral form, preferably electronic, may improve communication and documentation between dialysis facilities and transplant centers.

Referrals should be documented in the dialysis facility medical record. The person making the referral, method of referral, the date of the referral, and the name of transplant center should be specified. Dialysis facilities may want to list this item in each patient’s written long term care plan and update it at least every 12 months.

Standardized response options for the Data Collection Question may include:
- Who made the referral: patient, nephrologist, nurse, social worker, secretary, or other
- How the referral was made: standardized form, letter, e mail, phone call, or other
- Reasons for not referring: contraindications specified by transplant center, physician judgment or refuses to refer, patient not interested, patient already on waiting list, or other.

Four denominators were created for more detailed description of this step in the transplantation process. Denominator 1 includes all patients, denominator 2 excludes patients with contraindications, denominator 3 excludes uninterested patients, and denominator 4 excludes patients with contraindications and or uninterested patients. Only denominator 4 results should be publicly reported because these results are the most actionable. Results using denominators 1-3 should be reported back to dialysis facilities.

Feasibility Of Collecting Data

Three proposed clinical performance measures, Incident Patient Discussion, Prevalent Patient Discussion, and Referral to Transplant Center, and two descriptors, Interest and Contraindication, may be obtained by the dialysis facility. Modification of the patient long term care program required by the Conditions for Coverage may allow facilities to capture this data at least annually.

Note that several items currently include open-ended questions. For example, Interest Descriptor asks for reasons for not wanting to be evaluated for a kidney transplant. It will be useful to include a list of common responses for these items, while still allowing the option of writing in another response. Pilot testing of these proposed measures will help to develop and refine lists of common responses to each item.
Use of Measures for Quality Improvement and Public Reporting

Monitoring the steps in the transplant process is likely to lead to quality improvement efforts that will enhance access to transplantation. For example, dialysis facilities and transplant centers may develop methods to enhance communication of information about patients and thereby speed up the referral and evaluation of transplant candidates. Moreover, public reporting of clinical performance measures may assist patients in choosing dialysis facilities and transplant centers.

Because race, gender, and socioeconomic disparities in access to transplantation are of special concern, it will be useful for facilities to monitor clinical performance measures not just for their patients as a whole, but also for specific subgroups of patients.

Implementing these clinical performance measures is likely to add to the demands placed on dialysis facilities, including new data reporting requirements, increased evaluation of patients, and larger numbers of living donor transplants. Dialysis and transplant providers, policy makers, and payors will need to consider the best ways to respond to these demands.

Proposed Pilot Testing

Overview

Because several of the recommended CPMs and descriptors involve tasks not currently monitored or documented by dialysis providers, it will be important to pilot test the items before they are implemented nationally. Pilot testing will help identify and correct unclear items or instructions and will provide standardized choice options for items that are currently open-ended. Pilot testing will also help to determine the validity of submitted information by comparison with chart abstraction and patient interviews.

Dialysis facilities participating in piloting will need to be educated about the pilot project and will need to modify their current practices regarding monitoring access to transplantation. As a result, it will be more efficient to carry out pilot testing on many patients from a modest number of facilities (as opposed to a few patients each from a very large number of facilities). The need for facility education also means that piloting must be performed prospectively. Facility educational activities performed for pilot testing may be used to develop educational activities for later national implementation.

The following recommended approach take these considerations into account.

Proposed Pilot Test Timeline Overview

The pilot process will begin with a meeting of the Technical Expert Panel to review steps to be taken in conducting the pilot and obtain the recommendations of these experts. The table below provides an overview of the proposed pilot test timeline. In month 1 dialysis facilities will be recruited, the facility education program will be developed, and the pilot data collection form will be tested (Appendix H). In months 2 and 3, volunteering facilities will be educated on how to collect data for the pilot project. Facility data will be collected in months 4 through 9. In months 7-9, the Network will validate facility data. Pilot study results will be evaluated in months 10 and 11. The TEP will be convened in month 11. The final report to CMS will be due in month 12. Details regarding dialysis facility selection and methods follow.
Dialysis Facility Selection
Facility selection will be achieved by recruiting 20 volunteer dialysis facilities from two to three ESRD Networks, including urban, suburban, and non-urban areas. This will include regions with multiple transplant centers as well as regions with a single transplant center. The pilot sample will also include facilities representing a mix of large, medium, and small size; profit and non-profit; and freestanding and hospital-based (all facilities selected will have a minimum of 30 patients). Additionally, URREA data could be used to draw the sample from low, medium, and high wait-listing rate facilities. Facilities will be clustered in regions to allow data validation by network staff for a 5% subset of patients.

Patient Selection
Patients will be selected by requesting that the volunteer facilities provide list of patients for whom the long-term care plan is due within the next six months. This list, plus new patients starting dialysis at the facility, will comprise the patient sample. We estimate an average of 50 patients per participating facility, making a total patient sample of 1000 (50 patients/facility x 20 facilities).

Methods
Prior to implementing the pilot, the forms must be tested. As a preliminary step we suggest that five facilities complete the Pilot Data Collection Form (Appendix H) for two patients and return completed forms to the Network office for review. Forms will be reviewed by Network staff to ensure intended data is being collected. Network staff will log any questions that arise from facilities completing the forms and use the information to modify form if necessary.

Before the actual data collection begins, Network staff will educate volunteer facilities on the project and use of the Pilot Data Collection form through use of Webex conference calls. One facility will be selected to also utilize the optional draft Care Planning Supplement form (Appendix I).

Over a six-month time period, facilities will collect data on the Pilot Data Collection form, with one facility using the suggested Care Planning Supplement form, in concert with completing patient long-term care plans. Facilities will submit the completed data forms on a monthly basis. Network staff will monitor submissions and assist as needed. During the last three months of the six-month data collection period, network staff will validate a 5% subset of completed Pilot Data Collection forms by comparison with patient interviews and chart abstraction.

Network staff will evaluate results of the pilot, including availability of information needed for the Pilot Data Collection Form; completeness,
timeliness, and validity of submitted information; usefulness of the suggested Care Planning Supplement forms, and quality of educational activities. Participating dialysis facilities will be debriefed to learn their perspective of the process.

Following results evaluation, the Network will convene the Technical Expert Panel to review results and recommend modifications to CPM content and process, Data Collection form, suggested Care Planning Supplement form, and facility educational activities. After the TEP meeting, a final report for CMS will be developed to include final recommendations for CPMs, modified data collection tools, and recommended facility educational activities for national implementation.

Recommended Transplant Center-Specific Measures

The steps to kidney transplantation encompass activities at both hemodialysis facility and transplant center levels. The TEP and Contractor strongly believe that attention and measurement of the dialysis facility side of process, without equal attention and measurement of the transplant center side of the process is shortsighted. Ensuring all appropriate dialysis patients are referred to a transplant center is important, but equally critical is what happens between the time of referral and time of waitlisting for deceased donor transplantation or live donor transplantation. Many patients experience challenges during this interim that prevent timely movement through the steps to transplantation. Therefore, two additional transplant center-specific measures are recommended.

<table>
<thead>
<tr>
<th>CPM/Descriptor</th>
<th>Measure</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPM D</td>
<td>Waiting List/Living Donor Transplant</td>
</tr>
<tr>
<td>Descriptor</td>
<td>Deceased Donor Transplant Descriptor</td>
</tr>
</tbody>
</table>

The data elements for CPM D: Waiting List/Living Donor Transplant and Deceased Donor Transplant Descriptor, may be obtained from the Scientific Registry of Transplant Recipients (SRTR) or the Organ Procurement Transplant Network (OPTN). If the proposed Conditions for Coverage for dialysis facilities and Conditions of Participation for transplant centers are adopted as written, dialysis facilities will be required to track the results of each transplant referral. Measuring these endpoints (waitlisting and live donor transplantation) relative to the date transplant referral was made may reveal opportunities for quality improvement activities aimed at helping to move patients through all the steps in the transplant process and thus reduce disparities in transplantation. Public reporting of this clinical performance measure may assist patients in choosing transplant centers.
# Transplant Center-Specific Clinical Performance Measure D-
Waiting List/Living Donor Transplant

<table>
<thead>
<tr>
<th><strong>Name:</strong></th>
<th>Clinical Performance Measure D: Waiting List/Living Donor Transplant</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Short Description:</strong></td>
<td>This is an indicator for transplant centers, not a clinical performance measure for dialysis facilities. This indicates percentage of facility patients referred to a transplant center that were placed as active status (Status 1) on deceased donor transplant waiting list or received a living donor transplant within 12 months of referral.</td>
</tr>
<tr>
<td><strong>Measure:</strong></td>
<td>Percentage of referred patients who were placed on deceased donor waiting list or received a living donor transplant within 12 months after referral to transplant center.</td>
</tr>
</tbody>
</table>
| **Data Collection Question:** | Was patient placed as active status (Status 1) on deceased donor waiting list or did patient receive living donor transplant within 12 months after referral to transplant center?  
   a. Yes, active status (Status 1) on waiting list (specify date placed)  
   b. Yes, received living donor transplant (specify date)  
   c. Both a and b  
   d. No (specify reasons) |
| **Medical Review Criteria:** | Within 12 months of referral patient was placed on deceased donor waiting list as active status (Status 1) or received a living donor transplant. |
| **Numerator:** | Any yes response |
| **Denominator:** | Varies  
   **Denominator 1:** All patients referred to transplant center  
   **Denominator 2:** Exclude patients who are not transplant candidates after workup |
| **Applicable Exclusions:** | Varies based on denominator  
   **Denominator 1:** Patients not referred to transplant center  
   **Denominator 2:** Patients not referred to transplant center and patients not transplant candidates after pre-transplant workup |
| **Data Elements (see Appendix G):** | Date patient placed as Active Status (status 1) (mm/dd/yyyy)  
   Date patient received living donor transplant (mm/dd/yyyy)  
   Reason not Active Status (status 1) or did not receive living donor transplant within 12 months of referral to transplant center  
   Number of patients not referred to transplant center  
   Number of patients not transplant candidates after pre-transplant workup |
| **Potential Data Sources:** | Hemodialysis facilities, transplant centers, Organ Procurement Transplant Network, Scientific Registry of Transplant Recipients |
| **Applicable Setting:** | Transplant Center |
| **Literature Source (see Appendix A):** | 5, 6, 7, 23, 49, 66, 88, 90, 91, 114 |
| **Evidence or Opinion:** | Both |
| **Purpose of Measure:** | Quality improvement and public reporting |
Rationale for CPM D

After completing the pre-transplant workup, patients who are considered transplant candidates are placed on the deceased donor waiting list or will receive a living donor transplant. It is possible that patients on deceased donor waiting list may also be in the process of awaiting a living donor transplantation. In general, little time elapses between completion of workup and waitlisting or living donor transplantation. As a result, waitlisting or living donor transplantation may be used as proxies for completion of the pre-transplant workup. Information about placement on the deceased donor waiting list or receipt of a living donor transplant is available from the Scientific Registry of Transplant Recipients (SRTR) or the Organ Procurement Transplant Network (OPTN). This clinical performance measure reflects the process of care at the transplant center rather than the dialysis facility.

The pre-transplant workup includes a medical and surgical history, physical examination, tissue typing, and other tests such as blood typing and an electrocardiogram. This workup is generally carried out by the transplant center but the patient's dialysis facility and nephrologist may assist with specific tasks. Many patients take more than a year to complete the pre-transplant workup, and this step acts as an important impediment to timely access to kidney transplantation. Examples of reasons a pre-transplant workup may extend beyond 12 months include treatment of active medical conditions, long waits for appointments for necessary testing, and patients missing appointments. There is currently no standard process in place for communication between transplant centers and dialysis facilities regarding transplant work-up results, wait listing status, or change in medical status affecting transplant suitability.

A “yes” response should be generated only when patients are listed as active status (Status 1) and ready for transplantation. Patients placed on active status who are subsequently removed from the list without receiving a transplant should still be categorized as "yes" responses for this CPM. It may be necessary to modify this item to specify that only patients who are on the active waiting list for at least a specified period of time are categorized as "yes" responses. This will help exclude patients placed in active status without actually completing the pre-transplant workup. Reasons for “no” response should be collected in an open-response manner from transplant centers in the pilot testing phase to help determine standardized choice options for use when these CPMs are implemented.

Two denominators are proposed. Data for the numerator may be obtained from SRTR/OPTN. Data for denominator 1 may be obtained from dialysis facilities. Data for denominator 2 would require additional information on results of the pre-transplant workup from transplant centers. The TEP recommended that the pilot testing phase explore reasons for a "no" answer for this CPM. This information is available only from transplant centers. It is important information to track because this is an area where patients may get lost to follow-up or otherwise not progress through the work-up process and therefore never become waitlisted for transplant.

Proposed Revision of Conditions for Coverage

Data for denominator 2 could be more easily obtained if the new Conditions for Coverage are implemented as proposed. §494.90(c) Patient Plan of Care: Transplantation Referral Tracking specifies that an interdisciplinary team must track the results of each kidney transplant center referral.
## Deceased Donor Transplant Descriptor

<table>
<thead>
<tr>
<th><strong>Name:</strong></th>
<th>Deceased Donor Transplant Descriptor</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Short Description:</strong></td>
<td>This is a descriptor, not a performance measure for dialysis facilities. This descriptor tracks patients who have received a deceased donor kidney transplant.</td>
</tr>
<tr>
<td><strong>Measure:</strong></td>
<td>Number of patients who have received a deceased donor kidney transplant.</td>
</tr>
</tbody>
</table>
| **Data Collection Question:** | Has patient received a deceased donor kidney transplant?  
 a. Yes (specify date)  
 b. No |
| **Medical Review Criteria:** | Patient received a deceased donor kidney transplant. |
| **Numerator:** | Not applicable |
| **Denominator:** | Not applicable |
| **Applicable Exclusions:** | Patients not on deceased donor waiting list |
| **Data Elements (see Appendix G):** | Date patient received deceased donor transplant (mm/dd/yyyy) |
| **Potential Data Sources:** | SRTR/OPTN |
| **Applicable Setting:** | Transplant center |
| **Literature Source (see Appendix A):** | 5, 6, 7, 36, 49, 66, 88, 90, 91, 110 |
| **Evidence or Opinion:** | Evidence |
| **Purpose of Measure:** | Quality improvement and public reporting |
Rationale Deceased Donor Transplant Descriptor

This item represents the final step in access to deceased donor kidney transplantation and is influenced by the availability of deceased donor kidneys. This information is readily available from SRTR or OPTN.

Alternate Dialysis Facility and Transplant Center Pilot Testing Approach

A comprehensive pilot study to evaluate all steps in the transplant project is feasible with the additional collection of SRTR/OPTN data in months 9 and 10 to calculate CPM D: Waiting List/Living Donor Transplant and the Deceased Donor Transplant Descriptor. Since information for CPM D: Waiting List/Living Donor Transplant “no” response is only available from transplant centers, an alternate approach is to include both volunteer dialysis facilities and their local transplant centers in the pilot project. Transplant centers could be contacted by either dialysis facilities or the contractor to provide information necessary to answer CPM D. Additionally, since dialysis facilities to date have not monitored or documented the transplant referral process, transplant centers may be able to provide information regarding the date of referral, how referral occurred, and if contraindication to transplantation was found for referred patients.

Lessons Learned

Discussion at TEP and Stakeholder meetings highlighted the following common barriers to completion of the referral to kidney transplantation:

- No consistent coordination or communication exists between dialysis facilities and transplant centers.
- No standardized process is in place to inform a dialysis facility that a referral to transplant center has taken place, or that the patient has been accepted/rejected for further evaluation by the transplant center.
- There are few agreed-upon standard criteria regarding which patients are medically unsuitable to be referred to a transplant center for evaluation.
- There is a concern that transplant centers will be unable to handle the load of patients referred by dialysis facilities if this project is successful in increasing referrals.
- Several steps in the transplant process are not under the control of dialysis facilities. Additional monitoring at the transplant center level would be beneficial.
- The role of the transplant surgeon designee is not clearly defined.
- There are multiple, uncoordinated data sources.
- Patient education regarding transplantation needs to be improved.

Recommendations to CMS

National Implementation of Dialysis Facility-Specific Kidney Transplant Referral Measures

National implementation of Kidney Transplant Referral Measures will require dialysis facilities to begin tracking and documenting the transplant referral process of their patients. It is anticipated that limited documentation of this process is currently in dialysis medical records. As a result, facilities will need to be informed in advance of the reporting requirements for these CPMs to allow sufficient time to gather and record data. We foresee that facilities will most efficiently track the data necessary for reporting in concert with the annual completion of each patient’s long term care program. Given sufficient notice, this CPM data could then be collected along with the annual national CPM data collection that already occurs.
Evaluate All Steps of the Transplant Process
Although the scope of work for this project was limited to dialysis facility-specific kidney transplant referral measures, the TEP and Contractor urge CMS to consider the measurement and evaluation of the time period between referral and waitlisting or transplantation. Two transplant center-specific measures are proposed to allow evaluation of all of the steps in the transplant process.

Improve Communication Between Dialysis Facilities and Transplant Centers
One challenge identified by the TEP is poor communication between dialysis facilities and transplant centers regarding both transplant referral and workup processes. The TEP recommended developing a standardized referral form for use between dialysis facilities and transplant centers, with the goal of eventually making this an electronic-based referral system. ESRD Networks may be able to serve as a conduit for the exchange of this information.

Disseminate Inclusion/Exclusion Criteria for Kidney Transplantation
To complete the CPM data collection, it will be necessary for dialysis facilities to obtain a list of contraindications to transplantation from each transplant center where their patients are referred. The TEP recommended that transplant center inclusion/exclusion criteria for transplantation be available on an internet-based system that is readily available to both patients and dialysis providers. ESRD Networks may be able to serve as centralized clearinghouses for this data.

Proposed Conditions for Coverage
Proposed Conditions for Coverage for dialysis facilities and Conditions of Participation for transplant centers support the recommended Kidney Transplant Referral CPMs by requiring patients be informed of the option of transplantation, requiring transplant centers to use written selection criteria for waitlisting or declining transplantation for patients, requiring dialysis facilities and transplant centers to communicate about transplant status of patients, and requiring transplant referral tracking by dialysis facilities. Adoption of these key aspects into the final Conditions for Coverage/Participation will facilitate the implementation of the recommended Kidney Transplant Referral CPMs.

Conclusion
We are confident that the recommended Dialysis-Facility Specific Kidney Transplant Referral Measures will be invaluable for studying regional differences in access to transplantation, identifying possible interventions, and determining the impact of interventions. However, it is likely that pilot testing will reveal additional recommendations for national implementation of the CPM data collection. Lastly, we encourage CMS to evaluate all steps in the transplant process and to consider the addition of transplant center-specific measures in the future.
Technical Expert Panel Meeting Attendees

Technical Expert Panel:
Teri Arthur, MSW, LSW, University of Chicago
Francis Delmonico, MD, Harvard University
Erick B. Edwards, Ph.D., United Network for Organ Sharing
Jens Goebel, MD, Cincinnati Children’s Hospital Medical Center
Richard Goldman, MD, Renal Physicians Association, Forum of ESRD Networks
Bonita Balkcom Guilford, Transplant Recipient, ESRD Network 6
Lawrence G. Hunsicker, MD, University of Iowa Health Care
Mysore S. Anil Kumar, MD, Drexel University College of Medicine
J. Michael Lazarus, MD, Fresenius Medical Care-North America
Keith Mentz, Chief Executive Officer, Nephrology, Inc.
Kim E. Phillips, MSN, RN, CCTC, Univ. of Utah Solid Organ Transplant Services
Kris Robinson, American Association of Kidney Patients
Marlon Yu, RN, Kaiser Permanente

Project Consultants:
Alan Leichtman, MD, University Renal Research & Education Association
Jonathan Sugarman, MD, MPH, Qualis Health

URREA Observer:
Valarie Ashby, Kidney Epidemiology and Cost Center, University of Michigan

CMS Representatives:
Brady Augustine
James Bowman, MD
Pamela Frederick, MSB
Jayne Hammen
Kathy Hudson
Deborah Read
Barry Straube, MD

CMS Observers:
Teresa Casey, RD, LD
Gina Clemons
Diane L. Frankenfield, DrPH
Eva Fung
Heather Grimsley
Judith Kari
Mathew Leipold
Condict Martak
Siddhartha Mazumdar
Marcia Newton
Eileen Zerhusen

eSource/CSC Representatives:
Andy Hanks, MBBS, Computer Sciences Corporation
Shannon Wright, BSW, PMP, Computer Sciences Corporation
Contractor (ESRD Network 9):
Ashwini Sehgal, MD, MetroHealth Medical Center, Clinical Coordinator
Janeen Leon, MS, RD, LD, MetroHealth Medical Center, Project Coordinator
Melissa Aulisio, MNO, Project Assistant
Jay W. Wish, MD, President
George Aronoff, MD, Medical Review Board Chair
Susan A. Stark, Executive Director
Bridget Carson, Assistant Director
Raynel Kinney, RN, CNN, CPHQ, Quality Improvement Director
References


72. Proposed Conditions for Coverage for End Stage Renal Disease Facilities; Patient Plan of Care section 494.90 published on February 4, 2005 (70 FR 6250).
## Appendix A
### Literature Review – Kidney Transplant Referral Clinical Performance Measures

<table>
<thead>
<tr>
<th>Lead Author, Year, Citation</th>
<th>Title</th>
<th>Relevance for CPMs</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. Alexander (1998) JAMA 280: 1148-1152</td>
<td>Barriers to cadaveric renal transplantation among blacks, women, and the poor</td>
<td>Outlines the steps that patients must go through in order to receive a cadaveric kidney transplant.</td>
</tr>
<tr>
<td>8. Arthur (2002) Am J Kidney Dis 40: 678-681</td>
<td>The role of social networks: a novel hypothesis to explain the phenomenon of racial disparity in kidney transplantation</td>
<td>Getting a kidney transplant may be a social phenomenon potentially dependent upon access to information from social networks. African Americans may be less likely to gain information on transplants from their social networks (family, friends, etc.).</td>
</tr>
<tr>
<td>10.</td>
<td>Ayanian (1999) N Engl J Med 341: 1661-1669</td>
<td>The effect of patients’ preferences on racial differences in access to renal transplantation</td>
</tr>
<tr>
<td>15.</td>
<td>Bloembergen (1997) Am J Kidney Dis 30: 733-738</td>
<td>Association of gender and access to cadaveric renal transplantation.</td>
</tr>
<tr>
<td>16.</td>
<td>Bloembergen (1996) J Am Soc Nephrol 7: 1139-1144</td>
<td>Gender discrepancies in living related renal transplant donors and recipients</td>
</tr>
</tbody>
</table>
N Engl J Med 325: 442-444 | Donors but not living related donors. There is a need for culturally sensitive education to enhance family discussions regarding living related transplantation. | Organ donation and blacks. A critical frontier.  
A report communicating progress in early 1990’s of increasing black donor pool via grassroots educational campaign. |
Transplant Proc 29: 1482-1483 | A national minority transplant program for increasing donation rates | Must use culturally/ethnically tailored approach to increase/sustain increases in donation rates of minorities. Minorities must stay involved in the planning and implementation processes. |
Transplant Proc 21: 1976-1978 | Psychologic factors related to dialysis in kidney transplant decisions | Females, older aged and lower educated individuals more likely to refuse transplant. Those who refuse transplant seem to “grow comfortable” with the dialysis process and get social reinforcement from dialysis. High anxiety at the beginning of ESRD may be a barrier to learning about transplant and other information from care providers. |
42CFR405.2137 | Subpart U - Conditions for Coverage of Suppliers of End-Stage Renal Disease (ESRD) Services. Condition: Patient long-term program and patient care plan | Conditions for Coverage outline that the long term program be reviewed at least every 12 months, patients be fully informed of their suitability for transplantation and the physician-director is responsible for participating in the selection of treatment modality including transplantation. |
494.80(a)(10) published on February 4, 2005 (70FR6249) | Proposed Conditions for Coverage for End Stage Renal Disease Facilities; Patient assessment | Proposal requires initial and annual evaluation of suitability for transplantation referral based on transplant center criteria. Reasons for referral must also be documented. |
494.90 published on February 4, 2005 (70FR6250) | Proposed Conditions for Coverage for End Stage Renal Disease Facilities; Patient plan of care | Proposal requires dialysis team to document plan for transplantation, patient decision or reasons for non-referral. Dialysis facilities must also track results of each transplant center referral. |
J Am Soc Nephrol 16: 269-277 | Influence of race on kidney transplant outcomes within and outside the Department of Veterans Affairs | Racial disparities in transplant persist in Veterans Affairs system despite access to care. |
| 25. | Chertow (2001)  
Am J Kidney Dis 37: 435-437 | Gridlock on the road to kidney transplantation | If barriers are successfully removed, access to transplant list will not decrease waiting time for blacks; it will increase wait time and only marginally increase likelihood of transplantation. Must make policy changes in how organs |
<table>
<thead>
<tr>
<th></th>
<th>Author (Year)</th>
<th>Reference</th>
<th>Abstract</th>
</tr>
</thead>
<tbody>
<tr>
<td>27.</td>
<td>Coombs (1993)</td>
<td>Transplant Proc 25: 2503-2504</td>
<td>Treatment options for end-stage renal disease: patient perceptions and factors influencing choice of modality. Patients may not fully understand the information presented to them about modality, possibly due to the stress of initial diagnosis or depression. Need repeated education.</td>
</tr>
<tr>
<td>29.</td>
<td>Davidson (1991)</td>
<td>Transplant Proc 23: 2531-253</td>
<td>Attitudinal barriers to organ donation among black Americans. 2500 black Americans from 5 churches surveyed. Willingness to donate was influenced by religious concepts of death and mistrust of health-care professions.</td>
</tr>
<tr>
<td>32.</td>
<td>Dobbels (2001)</td>
<td>Prog Transplant 11: 121-30</td>
<td>Psychosocial and behavioral selection criteria for solid organ transplantation. Addresses lack of data regarding how psychosocial and behavioral factors affect the outcomes to solid organ transplantation. Cannot develop evidence-based selection criteria for transplants due to this limitation. A few studies show that social support networks play a large role in outcome success and compliance in individuals with psychiatric disorders. Need intervention to address lack of</td>
</tr>
<tr>
<td>33.</td>
<td>Eggers (1992)</td>
<td>Social support, etc.</td>
<td>Comparison of treatment costs between dialysis and transplantation.</td>
</tr>
<tr>
<td>34.</td>
<td>Eggers (1988)</td>
<td></td>
<td>Effect of transplantation on the Medicare end-stage renal disease program.</td>
</tr>
<tr>
<td>35.</td>
<td>Eggers (1995)</td>
<td></td>
<td>Racial differences in access to kidney transplantation</td>
</tr>
<tr>
<td>36.</td>
<td>Ellison (2003)</td>
<td></td>
<td>Geographic differences in access to transplantation in the United States</td>
</tr>
<tr>
<td>37.</td>
<td>Epstein (2000)</td>
<td></td>
<td>Racial disparities in access to renal transplantation—clinically appropriate or due to underuse or overuse?</td>
</tr>
<tr>
<td>38.</td>
<td>Evans (1985)</td>
<td></td>
<td>The quality of life of patients with end-stage renal disease</td>
</tr>
<tr>
<td>39.</td>
<td>Fabrizii (2004)</td>
<td></td>
<td>Patient and graft survival in older kidney transplant recipients: does age matter?</td>
</tr>
<tr>
<td>41.</td>
<td>Fishbane (2002)</td>
<td></td>
<td>Quality outcomes and obstacles to their achievement in end-stage renal disease</td>
</tr>
<tr>
<td>No.</td>
<td>Author (Year)</td>
<td>Journal/Citation</td>
<td>Summary</td>
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<tr>
<td>43.</td>
<td>Fritsche (2000)</td>
<td>Transplantation 70: 1492-7</td>
<td>Practice variations in the evaluation of adult candidates for cadaveric kidney transplantation: a survey of the European Transplant Centers</td>
</tr>
<tr>
<td>44.</td>
<td>Furth (2000)</td>
<td>Pediatrics 106: 756-761</td>
<td>Racial differences in access to the kidney transplant waiting list for children and adolescents with end-stage renal disease</td>
</tr>
<tr>
<td>45.</td>
<td>Garg (2001)</td>
<td>Am J Kidney Dis 37: 921-931</td>
<td>Reducing racial disparities in transplant activation: whom should we target?</td>
</tr>
<tr>
<td>47.</td>
<td>Garg (2000)</td>
<td>J Am Soc Nephrol 11: 958-964</td>
<td>Impact of gender on access to the renal transplant waiting list for pediatric and adult patients</td>
</tr>
<tr>
<td>50.</td>
<td>Gaylin (1993)</td>
<td>The impact of comorbid and</td>
<td>Nonwhites, older patients, women, diabetics and lower</td>
</tr>
<tr>
<td>JAMA 269: 603-608</td>
<td>sociodemographic factors on access to renal transplantation</td>
<td>income patients show reduced transplant rates. Introducing comorbid factors to sociodemographic analysis of who gets transplants did not change the results.</td>
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<td>------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>52. Goldfarb-Rumyantzev (2005) Nephrol Dial Transplant 20: 167-175</td>
<td>Duration of end-stage renal disease and kidney transplant outcome</td>
<td>Reviewed all transplants in 1990's. Short dialysis course less than 6 months has no detrimental effect on graft or patient survival.</td>
<td></td>
</tr>
<tr>
<td>55. Gordon (2000) Adv Ren Replace Ther 7: 177-183</td>
<td>Patient-nephrologist discussions about kidney transplantation as a treatment option</td>
<td>Suggests that discussions between patients and nephrologists are an important determinant of access to kidney transplantation.</td>
<td></td>
</tr>
<tr>
<td>57. Hadorn (1996) Jt Comm J Qual Improv 22: 265-276</td>
<td>Phase II of the AHCPR-sponsored heart failure guideline: translating practice recommendations into review criteria</td>
<td>Panelists pointed out (a) potential for misuse of CPMs by payers, (b) recommendations can't cover every conceivable circumstance, and (c) hassle involved for providers to comply with documentation requirements.</td>
<td></td>
</tr>
<tr>
<td>58. Hata (1998) Transplantation 65: 208-212</td>
<td>Effects of changes in the criteria for nationally shared kidney transplants for HLA-matched patients</td>
<td>Changes to the algorithm regarding HLA-matching increased transplantation rates in minorities. Graft survival rates were not diminished by the change.</td>
<td></td>
</tr>
<tr>
<td>60. Holley (1996)</td>
<td>Patients' views in the choice of renal</td>
<td>Describes reasons patients don't want to be listed,</td>
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<td></td>
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<tr>
<td>Kidney Int 49: 494-498</td>
<td>transplant</td>
<td>including religious beliefs, risk of transplant, seeing what happened to themselves or others with failed transplants, and feeling better staying off dialysis. Unclear how much patients were informed about transplantation.</td>
<td></td>
</tr>
<tr>
<td>63. Isaacs (2000) Am J Kidney Dis 36: 526-533</td>
<td>Racial disparities in access to simultaneous pancreas-kidney transplantation in the United States</td>
<td>Large racial disparity in simultaneous pancreas kidney transplantation (SPK). Whites are 6-35 times more likely to have SPK than all other racial groups.</td>
<td></td>
</tr>
<tr>
<td>66. Kallich (1993) RAND</td>
<td>Access to Cadaveric Kidney Transplantation</td>
<td>Blacks much less likely to be listed. Also found large geographic variability in black and white access to waiting list. Age, hospitalizations, cause of kidney failure and geographic differences do not fully explain the differences in access to listing.</td>
<td></td>
</tr>
</tbody>
</table>
| 70. Kasiske (1991) | The effect of race on access and outcome | Risk of end-stage renal disease is four time higher for
<table>
<thead>
<tr>
<th>Source</th>
<th>Reference</th>
<th>Title</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>N Eng J Med 324: 302-307</td>
<td></td>
<td>in transplantation</td>
<td>blacks vs. whites. Racial differences in cadaveric and living transplants may be due in part to differences in ABO blood groups and matching MHC antigens. Blacks less likely to donate organs. Blacks have lower allograft survival rates than whites.</td>
</tr>
<tr>
<td>Reference</td>
<td>Journal/Publication Details</td>
<td>Abstract/Summary</td>
<td></td>
</tr>
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<td></td>
</tr>
<tr>
<td>83.</td>
<td>Louis (1997) J Gen Intern Med 12: 478-484</td>
<td>Kidney transplant candidates' views of the transplant allocation system. Patients waiting for transplant have misconceptions about the system. Patients thought antigen matching is best way to allocate organs, but reasons for this opinion varied by race.</td>
<td></td>
</tr>
<tr>
<td>84.</td>
<td>Loxton (2003) Topics in Advanced Practice Nursing eJournal 3</td>
<td>Patient Education: The Nurse as Source of Actionable Information. Provides list of actions to improve patient education. Discusses alternate sources of information potentially used by patients. These alternate sources may provide incorrect information.</td>
<td></td>
</tr>
<tr>
<td>87.</td>
<td>Matas (2002) Transplantation 73: 811-812</td>
<td>Proposed guidelines for re-evaluation of patients on the waiting list for renal Increase in waiting time for cadaveric kidneys have increased the need for continuing evaluation of wait-listed</td>
<td></td>
</tr>
<tr>
<td>Reference</td>
<td>Title</td>
<td>Description</td>
<td></td>
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<tr>
<td>Meier-Kriesche (2002) Transplantation 74: 1377-1381</td>
<td>Waiting time on dialysis as the strongest modifiable risk factor for renal transplant outcomes: a paired donor kidney analysis.</td>
<td>Patients with ESRD &gt; 2 years have worse 5 and 10-year graft survival rates than patients with ESRD &lt; 6 months prior to transplantation. Part of the advantage of living related transplantation may be the reduced time on dialysis. A survival benefit still remains with later transplant vs. dialysis.</td>
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<tr>
<td>Ohler (2000) Prog Transplant 10: 138-140</td>
<td>Educating patients and families about solid organ transplantation</td>
<td>Editorial. Discusses need for patient and family education, but from the perspective of after they are already referred to transplant center. Discusses need to clear misconceptions patients have.</td>
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<tr>
<td>Ojo (1994)</td>
<td>Comparative mortality risks of chronic</td>
<td>Transplant confers survival benefit in black ESRD</td>
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<td>Reference</td>
<td>Details</td>
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<tr>
<td>Am J Kidney Dis 24: 59-64</td>
<td>dialysis and cadaveric transplantation in black end-stage renal disease patients</td>
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<tr>
<td>Ozminkowski (1998) Med Care 36: 1398-1406</td>
<td>What if socioeconomics made no difference?: access to a cadaver kidney transplant as an example.</td>
<td>Simulation study. A redistribution of waiting list spots and transplants to disadvantaged persons would occur if socioeconomic factors were eliminated.</td>
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<tr>
<td>Penn (1993) Transplantation 55: 742-747</td>
<td>The effect of immunosuppression on pre-existing cancers</td>
<td>Increased risk of reoccurrence and metastasis with immunosuppressive therapy. Minimal risk if cancer is in situ, basal cell skin cancer or incidentally discovered renal cell carcinoma.</td>
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<td>Port (1993) JAMA 270: 1339-1343</td>
<td>Comparison of survival probabilities for dialysis patients vs. cadaveric renal transplant recipients</td>
<td>Mortality risk was initially higher after transplant surgery, but there was a long-term survival benefit (&gt;325 days post-transplant). Lower long-term risk was greatest for diabetic patients.</td>
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<tr>
<td>Pradel (2003) Am J Kidney Dis 41: 849-858</td>
<td>Patients' attitudes about living donor transplantation and living donor</td>
<td>Only 17% of potential recipients obtained information regarding living related donor transplantation from</td>
<td></td>
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<td>Article</td>
<td>Reference</td>
<td>Summary</td>
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<tr>
<td>Ramos (1994)</td>
<td>Transplantation 57: 490-497</td>
<td>The evaluation of candidates for renal transplantation. The current practice of U.S. transplant centers. Wide variation in evaluating candidates for transplantation in early 1990's. Different centers use different criteria to determine eligibility. For example, some centers use age limits or treat HBsAg or HCV status differently than other centers.</td>
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<tr>
<td>Robertson (1989)</td>
<td>Transplant Proc 21: 3397-3402; discussion 3413-3398</td>
<td>Patient selection for organ transplantation: age, incarceration, family support, and other social factors Discusses medical and social factors in determining access to transplantation. Author agrees with current use of medical criteria to determine suitability for listing. Disputes arguments for inclusion of social factors in this determination since most do not correlate with medical success.</td>
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<tr>
<td>Sanfilippo (1992)</td>
<td>JAMA 267: 247-252</td>
<td>Factors affecting the waiting time of cadaveric kidney transplant candidates in the United States Two overriding factors affecting waiting list time include immunologic compatibility and success of local organ recovery rates relative to potential recipients. Other factors include multiple center listing, age, and race.</td>
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<tr>
<td>Schutte (1997)</td>
<td>Transplant Proc 29: 3746-3747</td>
<td>Barriers to donation in minority, low-income, and rural populations Focus groups consisting of minority, low income and rural participants were questioned regarding transplant and donation issues. Concerns included misinformation about donation process, wait list, allocation, and donor cards.</td>
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<tr>
<td>Sehgal (2003)</td>
<td>JAMA 289: 996-1000</td>
<td>Impact of quality improvement efforts on race and sex disparities in hemodialysis Quality improvement efforts have the potential to reduce disparities in health outcomes.</td>
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<td>Author (Year)</td>
<td>Journal</td>
<td>Title</td>
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<td>117.</td>
<td>Spital (2000)</td>
<td>Transplantation 69: 1728-1731</td>
<td>Evolution of attitudes at U.S. transplant centers toward kidney donation by friends and altruistic strangers</td>
</tr>
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<td>120.</td>
<td>Thamer (2001)</td>
<td>Transplantation 71: 281-288</td>
<td>U.S. nephrologists’ attitudes towards renal transplantation: results from a national survey</td>
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<td>121.</td>
<td>Turenne (1996)</td>
<td>J Am Soc Nephrol 7: 1926</td>
<td>The Use of Standardized Transplant Ratios (STRs) to Measure Access to Kidney Transplantation (abstr)</td>
</tr>
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<td>122.</td>
<td>The University of Michigan Kidney Epidemiology and Cost Center (2004)</td>
<td>2004 Dialysis Facility Report</td>
<td>Sample of the Dialysis Facility Report (DFR) form used to provide data back to facilities from CMS. This data is used for the Dialysis Facility Compare website. Expect that this reporting mechanism would likely be used to disseminate results of transplant CPMs.</td>
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<td>126.</td>
<td>Walter (2004)</td>
<td>Pitfalls of converting practice guidelines into quality measures: lessons learned from a VA performance measure.</td>
<td>Important to create denominators for CPMs that take into account patient medical suitability and preference for transplant so that CPM results are meaningful.</td>
</tr>
<tr>
<td>127.</td>
<td>Ward (2000)</td>
<td>Access to renal transplantation among patients with end-stage renal disease due to lupus nephritis</td>
<td>Lupus nephritis patients are disadvantaged for receiving cadaveric transplant despite increased likelihood of being wait listed. No difference seen in living related transplant. Regional differences were noted (possible center effect).</td>
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<tr>
<td>128.</td>
<td>Webber (1990)</td>
<td>Patient education. A review of the issues</td>
<td>Patient education needs to be interactive. Questions if patient education exists to serve the needs of the health care professional or to empower the patient.</td>
</tr>
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<td>129.</td>
<td>Weinman (1990)</td>
<td>Providing written information for patients: psychological considerations</td>
<td>Written educational information increases patient knowledge and level of adherence; however having the knowledge is not strongly related to clinical outcome in the chronically ill.</td>
</tr>
<tr>
<td>130.</td>
<td>Weng (2003)</td>
<td>A comparison of persons who present for preemptive and nonpreemptive kidney transplantation</td>
<td>Lack of communication regarding transplantation between physicians and patients is evident. Good discussion of possible reasons why patients delayed transplant evaluation - including complexity of medical care, proper diagnosis of renal disease, comprehension by patient of their disease, referral to nephrologist and then to a transplant center.</td>
</tr>
<tr>
<td>132.</td>
<td>Winkelmayer (2002)</td>
<td>Late nephrologist referral and access to</td>
<td>Suggests late nephrologist referral before renal</td>
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<td>Am J Kidney Dis 37: 431-434</td>
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<td>134. Wolfe (2000)</td>
<td>Differences in access to cadaveric renal transplantation in the United States</td>
<td>Number of patients waitlisted increased by 16%/yr 1993 to 1996, yet cadaveric donated organs increased by only 1.6%/yr. Female and blacks had lower rates of waitlisting than males and whites. PRA levels from pregnancy influence female rates. Adjusting for PRA nearly eliminates the differences. Black and Native American (34% lower) and Asian American (17% lower) differences in transplantation rate after waitlisting remain after adjustment.</td>
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<td>Am J Kidney Dis 36: 1025-1033</td>
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<tr>
<td>135. Wolfe (1999)</td>
<td>Comparison of mortality in all patients on dialysis, patients on dialysis awaiting transplantation, and recipients of a first cadaveric transplant</td>
<td>National comparison of relative risk of mortality in patients on waiting list for transplant vs. those receiving transplant. Mortality risk was higher initially post-transplant, but there was a cumulative survival benefit beginning 244 days post-transplant. Long-term risk of death reduction averaged 66%.</td>
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<td>N Engl J Med 341: 1725-1730</td>
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<td>136. Wolooshin (1999)</td>
<td>How can we help people make sense of medical data?</td>
<td>Need to prepare patients to understand the facts that will be presented. Discusses the issue of risk.</td>
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<td>Eff Clin Pract 2: 176-183</td>
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<td>Am J Kidney Dis 44: 1083-1089</td>
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<td>N Engl J Med 343: 1545-1552</td>
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<td>Transplantation 63: 669-674</td>
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<tr>
<td>141. Zenios (1999)</td>
<td>Evidence-based organ allocation</td>
<td>It is possible to create a simulated model that improves equity (wait time and likelihood of transplant) and efficiency</td>
<td></td>
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<td>Am J Med 107: 52-61</td>
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(survival and quality-adjusted life expectancy) compared to the current UNOS model. However creating an effective and fair allocation policy requires tough choices and any policy will disadvantage some patients.
Appendix B

Developing Dialysis Facility-Specific Kidney Transplant Referral Measures

Technical Expert Panel - Meeting 1 Summary
October 20 and 21, 2004

Contents:

I. Purpose
II. Overview
III. Meeting Highlights
IV. Background Presentation
V. Implicit Guidelines
VI. Clinical Performance Measures
VII. Next Steps
VIII. Panel Members & Observers

On October 20 and 21, 2004, a Technical Expert Panel (TEP) was convened to assist the contractor (ESRD Network 9/10) in developing dialysis facility-specific kidney transplant referral measures. TEP members include transplant surgeons; facility representatives (including large dialysis organizations (LDOs); a transplant recipient; a transplant coordinator; representatives from a kidney patient organization, managed care organization, quality improvement organization and the Scientific Registry of Transplant Recipients; and CMS representatives. Observers included additional CMS staffers and representatives from Computer Science Corporation. A complete listing of those in attendance is on page 19.

I. Purpose.

The goal of the meeting was to obtain input from experts on the development of dialysis facility-specific kidney transplant referral measures. These measures will assess and track steps in access to transplantation and will be used for quality improvement interventions and for public reporting at the dialysis facility level.

This project was chosen by CMS due to its interest in increasing kidney transplantation and concerns about disparities and discrimination in access to transplantation.

This meeting was the first of three TEP meetings. This project will result in a formal document with recommended transplant referral measures to CMS in June 2005.
II. Overview.

Day One:
The meeting began with introductions of all TEP members and observers. Susan Stark, Executive Director of Network 9/10 (contractor), gave an overview of the ESRD networks and the challenges of developing clinical performance measures (CPMs) when there are no existing explicit practice guidelines.

Pamela Frederick, Government Task Leader (GTL) for this project, discussed CMS’s interest in this project and the role of the TEP in providing guidance in developing the measures.

Following Ms. Frederick’s comments, Ashwini Sehgal, MD, Clinical Coordinator, gave a presentation, outlining the need for developing CPMs and what should be considered when developing these measures. Project goals and specific tasks were reviewed. Findings from the literature search were reviewed. Challenges of developing CPMs were discussed, followed by an overview of implicit practice guidelines and draft CPMs.

The afternoon session focused on extensive discussion relating to each draft CPM, including the specific measure, choices (e.g., Yes/No), numerator, denominator and data source.

Day Two:
Revised measures were presented to the TEP for further discussion. Observer input was solicited. Next steps in the process of fulfilling the contract were discussed. This was followed by a review of transplant data by Valarie Ashby, TEP observer and Senior Research Associate with the Kidney Epidemiology and Cost Center (KECC) at the University of Michigan.

III. Meeting Highlights.

Discussion centered on common barriers to completion of the referral to kidney transplantation. The following barriers were named:

- No consistent coordination or communication exists between dialysis facilities and transplant centers.

- No standardized process is in place to inform a dialysis facility that a referral to transplant center has taken place, or that the patient has been accepted/rejected for further evaluation by the transplant center.

- There are few agreed-upon standard criteria regarding which patients are medically unsuitable to be referred to a transplant center for evaluation.
• There is a concern that transplant centers will be unable to handle the load of patients referred by dialysis facilities if this project is successful in increasing referrals.

• Several steps in the transplant process are not under the control of dialysis facilities. Monitoring will also need to occur at the transplant center level.

• The role of the transplant surgeon designee is not clearly defined. A designee is often not identified for facilities.

• There are multiple, uncoordinated data sources.

• Patient education on transplantation needs to be improved.

IV. Background Presentation.

Project Goals: Dr. Sehgal used the Super Bowl trophy as a metaphor to describe the various ways scarce kidneys could be allocated: need, equal chance, wait time, utility, merit, social worth, market, etc. Dr. Sehgal added that assessment should be based on something other than “need.” He stated that the current system allocates organs based on utility and wait time. There is a need to develop these CPMs for quality improvement purposes. One panelist stated that “systems” issues are part of the problem. He felt it is important to consider who controls the decision to refer a patient: the doctor or the dialysis center.

The goals of the project were reviewed:

1. Develop measures for quality improvement and for public reporting at the dialysis facility level
2. Should be based on evidence and conditions for coverage
3. Should be minimally burdensome to providers
4. Should be based on as much consensus as possible

Dr. Sehgal solicited panelist input. Comments included the need to define where the transplant process starts for the purpose of the project, the impact physicians and caregivers can have on patient interest, the need to address both biological and systematic issues that lead to unequal distribution of kidneys without over-burdening the system and the use of “virtual” vs. “full” transplant work evaluation.

The specific tasks for fulfilling the CMS scope of work were reviewed.

1. Literature review, draft potential measures
2. Technical Expert Meetings (TEP)
Developing Dialysis Facility Specific Kidney Transplant Referral Measures
TEP Meeting Summary
Meeting 1: October 20 & 21, 2004

3. Present findings to renal community and technical consultants for comment
4. TEP meeting #2 to draft measures incorporating community input
5. ESRD stakeholders meeting, TEP meeting #3
6. Final recommended measures

Literature Review Method: Dr. Sehgal discussed the methodology and results of the literature search. The initial plan was to use a Medline search, but there were no good “key words.” For example, “kidney transplant referral measures” yielded 0 articles; “access to kidney transplantation” yielded 43 articles; and “kidney transplantation” yielded 116,000 articles. An alternative search method was used and all article titles from six major journals over last 20 years were reviewed. Journals included the American Journal of Kidney Disease; the Journal of the American Society of Nephrology; Kidney International; Nephrology, Dialysis and Transplantation; Transplantation; and Transplantation Proceedings.

Relevant articles were retrieved and abstracted. References from each retrieved article were reviewed for relevancy, articles retrieved and those references were reviewed and articles retrieved. Additionally, personal files were reviewed and expert opinions were sought to seek out additional articles. Additional resources will be added as they are identified by members of the TEP.

Literature Results:
Four key points were reviewed from the literature search:

1. A large and growing gap exists between need and supply of organs.
2. Several steps are involved in access to transplantation. This is more than just a waiting list problem.
3. Facility variation suggests process of care can be improved.
4. Standardized reporting of indicators have been part of successful quality improvement initiatives.

Need vs. supply:
The number of those living with ESRD is projected to grow from 400,000 currently to over 1.5 million over the next 20 years. Kidney transplants have increased at a much slower rate compared to incident ESRD rates. There is a growing gap between those who need transplantation and the number of kidneys available. Transplantation offers a survival advantage, a better quality of life and lower health care costs compared to other treatment modalities.

Steps to transplantation:
Dr. Sehgal reviewed the steps in the transplant process for deceased donor transplants: Interest and medical suitability lead to pre-transplant work-up, then waiting list, and then to transplantation.

TEP comments followed:
Panelists stated that education needs to be added as an early step, with education occurring both before the start of dialysis and once on dialysis. One member expressed concern that some nephrologists do not offer transplantation as an option prior to starting dialysis. A member said that interest is a function of environmental impacts. If patients are told they aren’t suitable, then they don’t express interest. Another panelist stated that insurance considerations affect interest. Ms. Frederick reminded panelists to focus on measures at the dialysis facility level. Dr. Sugarman pointed out that Quality Improvement Organization (QIO) programs are transitioning from “measures” to “global issues.” He recommended bundling measures. Ms. Stark pointed out that many entities have a stake in this process, and that TEP recommendations can point this out and possibly have a ripple effect to broader issues.

Data on sociodemographic correlates of transplantation were presented. The most common reason for not moving through the process was patient lack of interest. Second most common reason was patients felt they were “doing fine on dialysis”. Those who fail to get onto the wait list tend to get stuck at the transplant work-up step when comparing black and white populations. The comparison of rich vs. poor was based on ZIP Code data. All study data were adjusted for age and are independent of race.

**Facility Variation**

Dr. Sehgal discussed the wide variation across dialysis facilities. Some facilities had overwhelming success at the “interest step,” but others were well below the norm. Wide variation at various steps suggests the process of care can be improved.

**Quality Improvement Efforts**

Recent trends from 1993 to 2002 were reviewed. Deceased donor transplants increased from 7,400 to 8,300; living donor transplants increased from 2,900 to 6,200, but the deceased donor waiting list increased from 24,000 to 51,000. Over 70,000 individuals are currently on the waiting list. Given the large organ shortage, there is an ethical obligation to distribute the scarce resource (organs) fairly. Quality improvement (QI) efforts may increase living organ transplants.

Past efforts by Medicare to improve quality improvement processes included the following components: a workgroup identifies key indicators, there is mandatory reporting by providers, performance data is distributed, education/interventions by facilities occurs under the supervision of ESRD networks. Initial QI focused on dialysis dose, anemia and albumin. Dialysis dose and anemia improved with quality improvement interventions.

TEP comments: A member stated that measurement and reporting do not equal quality improvement. Another added that facility size will need to be taken into account in the measures. A comment was made that the rate of discards for
Deceased donor kidneys is too high. Some patients over 60 years old are told that they are too old for transplant, yet there is no consensus in the transplant community regarding upper age limits.

**Conditions for Coverage:**
Current CMS Conditions for Coverage related to transplantation include:
- An interdisciplinary medical team evaluates treatment options at least annually
- Team includes transplant surgeon or designee
- Patient is involved in care planning
- Results recorded on long-term program form

Teresa Casey, a CMS observer knowledgeable about the revised Conditions for Coverage, added that the patient must be fully informed of suitability for transplant. One TEP member commented that this does not routinely occur. There was general agreement that there is a lack of definition regarding who are designees. They are not named in facilities, and there are no job descriptions. There is a disconnect in the system. Mr. Yu commented that adequate transplantation information was not available in dialysis facilities. Kaiser Permanente has established positions for transplant coordinators within the dialysis unit; the number of transplants has increased as a result.

**Clinical Performance Measures (CPMs):**

**Desirable characteristics:**
CPMs are indicators that assess processes and outcomes of health care for quality improvement activities. Examples include: adequacy of dialysis (prescribed treatment time, Kt/V) and anemia management (erythropoietin dose, hemoglobin). A panelist pointed out that these are intermediate outcomes. True outcome measures include quality of life, rehabilitation, morbidity and mortality. Practice guidelines are systematically developed statements to assist providers in developing treatment plans for specific conditions such as the K/DOQI guidelines. Ideally, practice guidelines are developed first, however, there are none for referral to transplantation. In the Core Indicators Project, precursor to the current CMS ESRD CPM Project, indicators were developed without practice guidelines.

Desirable characteristics of CPMs include: important condition, evidence based, variable or substandard quality, process can be influenced by the provider, there is a cost-effective intervention available, an acceptable data collection burden, adequate severity of illness adjustment, and reliable, valid and interpretable. Panelists added the characteristics of timely, feasible and auditable to avoid gaming the system. A TEP member said indicators should be made within the context of the facility. Another suggested that current practices within the dialysis facility could be examined to identify “best practices.”
Discussion resumed with Ms. Ashby explaining the Dialysis Facility Report, produced by the University of Michigan Kidney Epidemiology and Cost Center with funding from CMS. This is an 18-page facility-specific report provided to the Networks, dialysis facilities and state survey agencies. Page 11 of the report compares a facility with state, network and national data. The Dialysis Facility Reports are produced by KECC using data obtained from CMS under a CMS Data Use Agreement. These data include CMS ESRD data, CMS claims data, and transplant data originating with the Organ Procurement and Transplantation Network (OPTN). UNOS is the contractor for the OPTN contract from HRSA. KECC also is a subcontractor to University Renal Research and Education Association (URREA) for the Scientific Registry of Transplant Recipients (SRTR), a HRSA contract. The SRTR database also is based on the OPTN data.

Challenges
Challenges to developing CPMs for tracking kidney transplant referral, include the fact that dialysis staff is already overburdened and the need to check reliability and validity of submitted information, possibly through chart abstraction and patient interviews. Mr. Augustine stated that 5% of charts are abstracted for auditing purposes in the national CPM project. Additional challenges are that some specific steps are not under the control of dialysis providers and the need to determine what patient characteristics to adjust for.

If measures are developed and tracked over time, there may be more equitable access to the deceased donor waiting list, an increase in the size of the waiting list and an increase in living donor transplants. Dr. Sehgal posed the question: Are there resources necessary to respond to these outcomes?

TEP comments:
- The current waitlist is not carefully maintained. Many patients listed will never get a transplant. The panelist guessed that as many as one-third “are not really there,” because they have received a transplant at another center, decided against transplant or developed medical contraindications to transplant, or have died. Another panelist stated the high number of wait listed patients could discourage a person from choosing to go on the list.
- Concern was expressed that there may be less equitable access with CPMs unless specific efforts are made to address minority/gender issues. Dr. Sehgal replied that with successful measures, disparities are reduced or the system becomes more advantageous to patients who already know how to access the system. Dr. Sugarman suggested looking at ratios (women to men, blacks/Hispanics to whites, etc.). A panelist stated that better informed patients will make better choices.
- This is a system problem and is better approached through another mechanism.
V. Implicit Guidelines.

Dr. Sehgal presented implicit guidelines to help guide the discussion of CPMs. He asked for feedback on these, even though it was somewhat outside the scope of work for the meeting. Discussion for each implicit guideline focused on the broad concepts.

Implicit Guideline A:
Dialysis Team should inform patients of benefits and risks of transplantation at ESRD onset and at least annually thereafter.

This is supported by opinions of experts, consistent with Conditions for Coverage and there may be some evidence published to support this.

TEP comments:
- Members of the group want definitions for the following: benefit vs. risk, what informing means and who on the dialysis team is responsible
- Concern was expressed that the dialysis team is not knowledgeable enough to explain the risks and benefits of transplantation to patients.
- It was noted that education should occur prior to start of dialysis, however that is beyond the scope of this project which focuses on measures at the dialysis facility level. The Fistula First project is an example where dialysis facilities are rated based on the access outcomes of its patients, but the project requires involvement of surgeons and others beyond the dialysis facility.
- Patients come to dialysis with preconceptions about transplant.
- A suggestion was made to change “ESRD onset” to “entrance to dialysis facility.”

Implicit Guideline B:
Dialysis team should evaluate patient interest in transplant at ESRD onset and at least annually thereafter.

This is supported by opinions of experts, consistent with Conditions for Coverage and there is evidence to show that patients change their minds about interest in transplantation, so it is important to reevaluate interest.

TEP comments:
- Need to define the terms “dialysis team” and “evaluate.” Questions should be developed to evaluate patient interest.
- Concerned that some patients are never educated, so how can interest be evaluated?
- “Annually thereafter” implies in perpetuity. Consider how often the evaluation should actually occur.
These guidelines are fine. Guidelines are supposed to be big and vague; they tell you what you should do, but don’t tell you how to do it.

Implicit Guideline C:
Unless a patient is uninterested or there is an absolute medical contraindication, the dialysis team should refer patient to transplant center for evaluation.

This is supported by opinions of experts and possibly consistent with Conditions for Coverage that state a transplant surgeon or designee should do the evaluation.

TEP comments:
- There is no clear accountability for the referral process. No consistent coordination or communication exists between dialysis facilities and transplant centers. Several members voiced a need for a clear delineation of who is responsible for what.
- Transplant centers will NOT be able to evaluate all those who don’t fall in the “medical contraindications” category or the “uninterested” category.
- There is a need to clarify the term “refers.” Is the onus on the patient? The team? The nephrologist? The PCP? Are facilities to give patients a list of phone numbers? Facilitating patients getting to the transplant center? There is wide variation in what “refer” means. There are areas with multiple transplant centers. Which center should patient be referred to?
- Discussions regarding lack of interest – is it a social issue? Some patients are satisfied with dialysis as their treatment or they may be too overwhelmed early in the start of dialysis treatment to consider alternatives such as transplantation.
- There is no list of “absolute medical contraindications” that is agreed upon by all transplant centers. Different centers have different criteria.
- Lack of preexisting guidelines was discussed. Concern was expressed that unless some of these issues (what is a contraindication, what is a rule?) are thought through and defined, implicit guidelines will be created by performance measures and as a result this project will create guidelines as well as measures. The recommendation was made to use tools from NCQA and Joint Commission to assist with the process of developing measures. It was noted that those tools start with pre-determined guidelines and NCQA would not create CPMs without preexisting guidelines.
- Ms. Frederick stated that this is a huge challenge for the contractor and the TEP. This group is not charged with the task of defining clear criteria, such as what patients should be referred for workup, but to determine what measures can be supported, feasible to collect, and important for a patient to know about a facility.
• There is currently no way to gather data on transplant centers. It will be necessary to determine how/what transplant centers are doing inside the referral process. There is a lot of variation in facilities in a given area. No one knows what facilities are receiving these referrals. Something is happening on the transplant center side that prevents patients from getting a transplant. For example a patient could be on hold because of insurance issues.

• Ms. Frederick said this is the type of information needs to be put on the table. In the end, the only measure may be to assure that the patient was educated regarding his treatment options and has or has not expressed interest. These issues need to be considered to determine if we can create a measure.

• Ms. Stark stated that there are many similarities to the “Fistula First” project where some aspects, such as surgeons’ preferences, are outside the scope of the dialysis facility. CMS needs to help the TEP understand where these CPMs can go.

Implicit Guideline D:
The pre-transplant work-up should be performed expeditiously.

Research shows that some patients get stuck at the pre-transplant work-up step, sometimes for years.

TEP comments:
• This is a test to help decide who gets the scarce resource.
• Individuals may be denied referral to transplant because of their unwillingness or inability to comply with the referral process; they may do poorly post-transplant.

Implicit Guideline E:
Vigorous efforts should be made to identify potential living donors.

The living donation option is currently underutilized, although this option has better outcomes than deceased donor transplants. Living donation also could relieve some of the pressure on the waiting list.

TEP comments:
• A member asked if this is a guideline for a dialysis facility. Dr. Sehgal replied that this is a guideline related to the process of care a dialysis patient goes through to get a transplant, but it is not entirely under the control of the dialysis center.
• A TEP member stated that the fact that living donor transplants have better outcomes should be part of the education process. Concern was expressed that technicians and limited practice nurses aren’t qualified to discuss this and that large numbers of registered nurses are not capable
of carrying out this conversation with patients. This is not a dialysis facility staff function. It should be, but staff is limited. There are already coordinators for access, adequacy, anemia, etc. This is going to stretch staff resources.

• Patients should be educated about the length of time on the waiting list and that living donations drastically shorten the wait time.

VI. Clinical Performance Measures

Dr. Sehgal facilitated three discussions on developing Clinical Performance Measures. The goal was to finalize the indicators, develop numerators and denominators and identify the data sources. The first pass focused on conceptual issues. The second pass focused on details such as wording, response options, numerators, denominators and possible data sources. The third pass reviewed the revised measures and assigned areas of responsibility. The discussion summarized below is organized by topic and analogous to the transplant process.

Information:
Original draft: Has patient been informed of the benefits and risks of kidney transplantation? --Yes, No

Revision following discussion: CPM #1 - Have benefits and risks of kidney transplantation and/or reasons for exclusion been discussed with patient by physician?

Choices: Yes, No
Numerator: Yes
Denominator: All patients
Data Source: 2728 (incident) and long-term care program (LTCP)

Added: CPM #2 - Patient acknowledges that his/her physician has discussed the benefits and risks of transplantation and/or reasons for exclusion.

Choices: Yes, my questions have been answered; Yes, but I have more questions; No
Numerator: Ordinal
Denominator: All patients
Data Source: 2728 (incident) and long-term care program (LTCP)

TEP discussion:
• This is consistent with Conditions for Coverage requirement that treatment options be reviewed with patients at least annually and within one month of starting dialysis.
• There was lengthy discussion regarding the need to define “benefits and risks.” Do benefits and risks include the outcomes of individual transplant
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programs? Nurses won’t know this. Will patients be informed of the need to be responsible for medications and appointments? There is a need to assess the commitment level of the patient.

- The term “informed” should be defined. It could mean the patient has received a piece of paper in an intake packet. The CPM document should include bullet points of what physicians should cover in this discussion. Information may be available from UNOS.

- Add text recommending that patients be questioned to determine if they do have an understanding of transplantation.

- Need to add separate question for incident (within 30 days) and prevalent patients.

- Dr. Goebel offered to assist with wording so question is applicable to minors. Will need text statements to clarify issue for children and patients aged 18-20.

- Suggestion made to add dates, timelines (annually, within 30 days).

- Suggestion made to change wording to patient and/or family member.

- TEP members discussed need to make physician responsible for this discussion. Other staff, such as social workers, should engage in this discussion also.

- There was concern that these questions are redundant and already part of the long-term care plan (LTCP). One organization’s LTCP was reviewed. Possibly the transplant portion of LTCPs can be standardized to collect this information to meet the needs of the CPM and avoid redundancy.

- Data sources were discussed. The CMS 2728 Medical Evidence Report form could be a data source for incident patients. The use of the CAHP survey was discussed.

- The decision was made to create two separate indicators in order to capture both the patient and provider perspective. The patient choices will indicate satisfaction with care. Concern expressed that patients may not answer truthfully if the dialysis facility asks the question.

- These will be labeled as CPMs.

Medical Contraindication:
Original draft: Is there an absolute medical contraindication to transplantation? –Yes, No

Revision following discussion: Is there an absolute medical contraindication to referring patient for transplant evaluation?

Choices: Yes (specify), No
Data Source: LTCP
TEP comments:
• There was agreement that this data is necessary to calculate the denominator for some CPMs.
• There was agreement that “absolute contraindication” must be defined, however this is not easily accomplished since transplant centers vary in what they consider to be contraindications. Dialysis facilities need a list of absolute contraindications to define which patients are not appropriate for referral, otherwise all patients will end up being referred. One transplant surgeon noted that the contraindications change with research. Ms. Frederick suggested it may be possible to get a list of contraindications from each transplant center and compile the commonalities. It was determined that this will be a very limited list.
• There was discussion of facilities compiling a list of comorbid conditions for possible patient and sending that list to transplant center for evaluation – "virtual workup”.
• This is not a CPM; it is a descriptor.

Interest:
Original draft: Is patient interested in kidney transplantation?
   –Yes, No, Unsure

Revision following discussion: Descriptor- Does the patient want to be evaluated for kidney transplantation?

Choices: Yes, Undecided, No
Data Source: 2728 (incident), LTCP

TEP comments:
• Define “interest”.
• Consider rewording to say: Is patient willing to commit to perform the activities necessary for kidney transplantation? Shows an act of commitment and understanding by the patient.
• Commitment is important but could worsen disparities; patients may not be able to work the system and be left out.
• Could reword: Has the patient refused to further consider kidney transplantation? If not, there is some level of interest.
• Need to define the dialysis facility responsibility in order to counter the impression that dialysis facilities are “hoarding” patients and obstructing access to transplant. It's easy for a doctor to get a patient to “refuse” transplantation.
• Suggestion to find out why a patient answers no or undecided
• Need to assess interest annually. Need to consider two questions with different timelines to address incident and prevalent patients. It was suggested that this information be kept serially to note change in interest over time.
• This will be called a descriptor.
Referral to Transplant Center:
Original draft: Has patient been referred to a transplant center for an evaluation?  
- Yes, No  
Revision following discussion: CPM #3 - Has the decision been made to refer the patient to a transplant center?  
Choices: Yes (specify how referred), No (specify reason for not referring)  
Numerator: Yes  
Denominator: Interested and no absolute medical contraindication  
Data Source: LTCP, progress notes, correspondence from transplant center (fax, letter)  

TEP comments:  
- The term “refer” should be defined. Does this include physician referral (or referral by other) or self-referrals? Consider using the term “consulted” instead of referred. Common themes emerged after extensive discussion. Documentation needs to occur at both the dialysis facility and transplant center. Dialysis centers need to document contact with the transplant center. The transplant center needs to document if the referral was accepted, rejected, or on hold, etc. Either the patient or dialysis facility calls the transplant center. An appointment date must be obtained. Information needs to be updated.  
- The panel discussed this as a continuity of care issue. A facility may not know if a patient was indeed referred for transplant evaluation. Who is responsible for placing the referral? Need to discuss in text that patients may not go to the center after they are referred. It was suggested that the referral process be in writing so there is a paper trail.  
- It is possible to split this into two questions: 1.) Has patient been referred to transplant center? 2.) Has transplant center accepted/agreed to evaluate patient?  
- Who is responsible for following up with the transplant center to see if they saw the patient?  
- It would be useful to include the name of the center to which the patient was referred.  
- A date needs to be associated with this question.  
- It was suggested to add a letter template to the summary.  
- Need to focus on delivering the patient through the continuum of care.  
- This CPM needs reworked prior to the next meeting.  

Pre-Transplant Workup:  
Original draft: Has pre-transplant workup been performed?  
- Yes, In progress, No  
Revision following discussion: Has pre-transplant workup been completed?
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Choices: Yes, passed (specify date), Yes, failed (specify date), No (specify reason)
Numerator: Yes
Denominator: Patients who were referred to transplant center
Data Source: Transplant center

TEP comments:
- Need to define who is responsible for what. Categories could be dialysis facility, doctor, patient or transplant center. This is a process of care at transplant centers not at dialysis centers.
- It was agreed that this is important data to capture, but CMS will need to determine how this data can be obtained. The Organ Procurement and Transplantation Network (OPTN) and The Health Resources and Services Administrations (HRSA) will need to be involved with the process. A transplant surgeon noted that UNOS requires transplant centers to notify the patient and nephrologist of workup results. The problem is that nephrologists do not always share this information with the dialysis facility. Perhaps transplant centers can require notification be sent to the dialysis facility as well.
- There was lengthy discussion about the fact that some patients who are referred don’t get into the system and that some referred patients start the workup, but don’t complete the process. Initially the question was divided into two separate questions to capture those who initiate the workup and those who complete the workup. After additional debate, the decision was made to eliminate the initial workup question because it overlaps the referral question.
- It was suggested to make recommendations regarding how long the workup process should reasonably take from date of referral to completion. Both three-month and six-month timelines were discussed. Consider adding these questions: Was workup completed within six months? If not, why not?
- The economics of increased referral was discussed. The transplant center can bill for this and put it in the organ acquisition cost center.

Waiting List:
Original draft: Is patient on deceased donor kidney transplant waiting list?
- Yes, No

Revision following discussion: Is patient on deceased donor kidney transplant waiting list?

Choices: Yes, on wait list; No, awaiting living donor kidney; No, other reason (specify reason)
Numerator: Yes
Denominator: Passed pre-transplant workup
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Data Source: Transplant center, SRTR

TEP comments:

- Discussion regarding who is responsible. This isn't a performance measure for dialysis facilities since they have no control over it.
- This information may help with quality improvement efforts in dialysis facilities, even if they aren't responsible. Knowledge of this information would allow a nephrologist to advocate for patient if the process gets held up.
- Ms. Stark stated that a clarification is needed from HRSA since this is not at the dialysis facility level. Ms. Frederick stated this may be available at the next TEP meeting, but that this will take some time.
- Consider determining if patient is on active wait list or is on hold (e.g. pending weight loss).
- There was discussion to combine deceased donor and living donor wait questions. It was decided to keep this as two questions.
- There is no current data compiled on this question per KECC representative.

Living Donor:
Is patient awaiting a kidney transplant from a living donor?
-Yes, No

Revision following discussion: Is patient awaiting a living donor transplant?

Choices: Yes, awaiting living donor kidney; No, on deceased donor waiting list; No, other reason (specify reason)
Numerator: Yes
Denominator: Passed pre-transplant workup
Data Source: Transplant center

TEP comments:

- Dialysis units may not know this information. Several members voiced the importance of dialysis facilities obtaining this information.
- Ms. Frederick noted that CMS could explore with UMKECC the possibility of adding some transplant center information in the Dialysis Facility Reports that would provide the number of ESRD patients on the wait list at transplant centers in the state where the dialysis facility is located or some variation that would help dialysis facilities understand how many of their patients get waitlisted. CMS is working with quality improvement organizations on physician education.
- Mr. Augustine stated that the summary statement can recommend other avenues to take to improve the process at transplant centers.
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- Suggest combining the waiting list and living donor questions and differentiate donor type in the answer.

Transplant Received:
Has patient received a transplant?
- Yes, No

Revision following discussion: Has patient received a transplant?

Choices: Yes, living donor (dates); Yes, deceased donor (dates); No

Numerator: Yes
Denominator: Patients on wait list or awaiting living donor transplant

Data Source: Transplant center, SRTR

TEP comments:
- Although this dangles between an indicator and a fact, it is important to know this information and it could be used for other measures. For example, some centers are “super-selective” and turn down organs that would be used at other centers.

Prior Transplant:
Has patient had a prior kidney transplant?
- Yes, No

Revision following discussion: Item deleted.

This information was collected by Network 9/10 for a while. Even so, the data didn’t always show if the patient had a prior transplant; this question was added to clarify.

TEP comments:
- This is clearly not a performance measure.
- CMS has this data already.

VII. Next Steps:

Ms. Stark reviewed the next steps in this project. The contractor is required to document and distribute the findings of this meeting for comment. Each measure will be summarized and formalized into numerators, denominators and descriptors. This summary document will be distributed to TEP members, individuals who expressed interest in serving on the TEP but were not selected, and other stakeholders. Additionally, a portion of the Networks 9/10 Web site
(www.therenalnetwork.org) will be devoted to this project. Feedback will be collected until a determined deadline, then collated and disseminated at the second TEP meeting.

The second meeting of the TEP will be held on February 9 and 10, 2005 at the Hyatt Regency Inner Harbor Hotel in Baltimore. The TEP will assist the contractor in preparing a draft set of measures and supporting information for presentation and discussion at the Stakeholders meeting.

VIII. Technical Expert Panel, Consultants, Staff & Observers:
Teri Arthur, MSW, LSW, University of Chicago
Francis Delmonico, MD, Harvard University (absent)
Jens Goebel, MD, Cincinnati Children’s Hospital Medical Center
Richard Goldman, MD, RPA & the Forum of ESRD Networks (absent)
Bonita Balkcom Guilford, Transplant Recipient, ESRD Network 6
Lawrence G. Hunsicker, MD, University of Iowa Health Care
Anil Kumar, MD, Drexel University College of Medicine
J. Michael Lazarus, MD, Fresenius Medical Care-North America
Keith Mentz, Chief Executive Officer, Nephrology, Inc. (absent)
Kim E. Phillips, MSN, RN, CCTC, U. of Utah Solid Organ Transplant Services
Kris Robinson, American Association of Kidney Patients
Marlon Yu, RN, Kaiser Permanente.

Project Consultants:
Alan Leichtman, MD, University Renal Research & Education Association
Jonathan Sugarman, MD, MPH, Qualis Health

CMS Representatives:
Brady Augustine, MS
James Bowman, MD
Pamela Frederick, MSB
Kathy Hudson
Deborah Read, Project Officer
Barry Straube, MD (absent)

eSource/CSC Representatives:
Andy Hanks, MBBS, Computer Sciences Corporation
Shannon Wright, BSW, PMP, Computer Sciences Corporation

Contractor Network 9/10:
Ashwini Sehgal, MD, MetroHealth Medical Center, Clinical Coordinator
Janeen Leon, MS, RD, LD, MetroHealth Medical Center, Project Coordinator
Melissa Aulisio, MNO, Project Assistant
Jay W. Wish, MD, President (absent)
George Aronoff, MD, MRB Chair (absent)
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Susan A. Stark, Executive Director
Bridget Carson, Assistant Director
Raynel Kinney, RN, CNN, CPHQ, Quality Improvement Director

**CMS Observers:**
Teresa Casey, RD, LD
Diane L. Frankenfield, DrPH
Heather Grimsley
Judith Kari
Condict Martak
Eileen Zerhusen

**URREA Observer:**
Valarie Ashby, Kidney Epidemiology and Cost Center, University of Michigan
Appendix C

Collated CPM Feedback
Kidney Transplant Referral Measures
February 2, 2005

CPM 4.1 Nephrologist-Patient Discussion:

Have benefits and risks of kidney transplantation and/or reasons for exclusion been discussed with patient by nephrologist within 90 days after initiation of dialysis and at least every 12 months thereafter?

a. Yes
b. No

Numerator: Yes response

Denominator: All patients of dialysis facility

Applicable Exclusions: None

Potential Data Sources: Long term care plan, other parts of the dialysis facility medical record

Applicable Setting: Dialysis facility

(B) Patients listed already for transplant, and those with whom this was discussed or are already in process i.e. have seen transplantation folks will and should not have to do this again.

(E) There may be reasonable reasons not to discuss the transplant option with patients on a yearly basis, specifically if the reason the patient is NOT a transplant candidate is something that will not change over time (age, another terminal illness, progressive dementia). In those cases it might be harmful/discouraging to regularly reinforce that they are not a candidate.

The discussion of tx candidacy may need to take place initially with someone other than the patient if, for example, the patient is demented, severely developmentally disabled, etc - some reason the pt would not understand the process. In that case, discussion with family/caregivers needs to take place instead, and documented why it was not discussed with the patient.

(G) You're asking if "the nephrologist" is having these discussions. It's usually the nurses, SW's, and RD's that have these discussions and do a lot of the educating with the pts. How would one answer this question if it's the Team, not the nephrologist, per se, having the discussions. Also, if it is documented that the person is NOT a candidate, why bring it up annually? The patient may interpret it as badgering.

(I) well thought out
"Unsuitable due to age" This has not been an acceptable reason to decline transplantation in the past. Several dialysis units were cited by surveyors stating that this is "ageism" and not an acceptable reason to decline transplantation.

If a physician refuses to provide evidence that he/she has discussed [or in fact refuses to provide the discussion] the benefits and risks of a transplant, the dialysis provider has no way to resolve such a dilemma. There must be some record provided by the physician to the facility (to accompany the long term care plan) if the facility is to be responsible for monitoring and reporting such activity. Dialysis nurses and clerks should not perform this activity independently. I believe there should be some type of form which must be completed and signed by the physician indicating this responsibility has been accomplished. Failure to do so must be managed by some organization with authority over physicians. I suggest this should be a major part of the physician MCP.

I believe that the nephrologist should be responsible for providing the information discussed in the above paragraph (see comment V in entirety-jbl), but it is clear that the only site at which this information can be gathered is the dialysis unit. The practice patterns recorded should generally be used to track the physician behavior and not the unit unless physician and unit are a single practice. However, if physician behavior clearly varies between units, i.e. if physician A and B actively refer for transplantation in Units A and B but neither of these physicians nor any other refers patients from unit C, it might be inferred that unit C might have policies and practices that discouraged referral.

Possible problem. a. Maybe it should be after admitted to a chronic program-patient may have extended stay in hospital after ESRD, patient may of been educated informally by a nephrologist in hospital about transplant, but patient was later was referred to another for care in facility.

There is a percentage of the dialysis population that have a permanent reason that are not and will never be transplant candidates. The cpm 4.2 seems to contemplate that these people will also need to be reeducated/informed of their failure to qualify for an evaluation on an annual basis.

The workflow as described in 4.1 and 4.2 does not seem practical in that a permanent comorbidity which makes a person a non candidate should circumvent future reassessment. This will avoid the inefficiency of making the same determination annually and reduce the emotional stress of rediscussing the issue with the patient which for my patients is frequently a rather sad conversation that once made doesn't need to be repeated unless they want to rediscuss the issues.

We do not understand why nephrologists should discuss transplantation with all patients annually. The requirement that a long term care plan should be made annually, that this should include transplant planning, and that the patient should review the long term care plan with a member or members of the health care team does not mean that the nephrologist must personally review transplantation with every patient annually. We suggest a different approach to the problem of transplant referral and evaluation. We suggest, first, that items 4.1-4.4 (with reservations as set forth above) should be part of the long-term care plan. Rather than creating new forms and attempting to keep them consistent with the long term care plan, we suggest that long-term care plans be given priority for incorporation into VISION. This would mean complete standardization of long-term care plans, but that would not be a bad thing. It would help the facilities by automating their long-term care plan bookkeeping. LDOs could program the long-term care plans into their computer systems.

We suggest that the CPM be amended so that the discussion could be conducted by a nephrologist or a designated educator. Moreover, a standardized information packet should be developed and utilized as part of the discussion, in order to assure a complete, up-to-date, and
balanced presentation of the transplant option. The discussion should cover the transplant process, as well as the process for evaluation for transplantation, the cost of immunosuppressive drugs, and other economic considerations. A standardized form, with a checklist, could be developed to document the discussion. This would be signed and dated by the nephrologist or designated educator. Patients should be made aware of educational resources that are available to them from organizations like the National Kidney Foundation. NKF recommends that a family member be present during the discussion to represent the interests of the patient and to assist in follow up.

(FF) Good idea, documentation is tricky—realistically should be part of long-term care plan at present; additional documentation noted re: contraindications, etc. The biggest concern here is the question of accountability. An MD can refuse to provide documentation and the facility has little recourse. Such discussions logically should not be entered into by nurses, clerical staff, technical staff, etc.

It might be important to consider a standardized form (across all facilities?) signed by the MD that such a discussion ensued. If possible, incentivizing this would be helpful.

It is unlikely that facilities will have entire authority over their MDs. Logically, those facilities with more than one practice group would not want to alienate MDs either. At present, most reasonable way to incentivize might be to make this part of the MCP.

Given the transplant-related benefits with less time on dialysis, it may be important to work towards documenting this discussion as early as possible for individuals who start dialysis in a facility (at the least, within 90 days).

Repeat documentation probably should ensue but every 12 months may be too infrequent—even 3-6 months may be better.

(HH) Clinical performance measure 1 asks whether the risks and benefits of renal transplantation have been discussed with a patient within 90 days of initiation of dialysis and or at least every 12 months afterward. Recording this event is already required in the ESRD regulations. We acknowledge that absence of this conversation can be a barrier to transplant referral but the content of this discussion can also be a barrier. All too frequently, a patient is told "you are too old", or "you won't do well" or "you have to wait too long" during this conversation with no data provided and well prior to any evaluation by a transplant team. Thus, not only is the occurrence of this conversation important, but the content of the discussion can be equally important in determining referral for transplant.

The study period chosen will affect the results of this CPM. A study period of one year at least will be required so that the there is enough time elapsing to assess the "conversation within at least every 12 months" endpoint. A longer study period will accrue more occurrences.

(JJ) Applicable Exclusions **"I don’t understand the validity of discussing transplant with patients who have absolute contraindications such as: age>85/severe dementia/cancer: I believe this population could be excluded from the denominator."

(KK) In general, it appears that performance measures one through three, with applicable settings in a dialysis facility, are, at least in large measure, already underway or fairly easy to implement and report.

(LL) There are several aspects included in this numerator, so if the answer is no, it will be difficult to know if the no answer is because:
- both benefits and risks were not discussed
- reasons for exclusion were not discussed
- the discussion did not happened between the patient and the nephrologists
- the discussion did not happen in 90 days
- the discussion did not happen every 12 months

If the answer is yes, it will be difficult to distinguish patients who were informed about risks and benefits from those that were told of reasons for exclusions. Now that the Conditions include required sign off from the health care team, is there a reason to specify only the nephrologists in the CPM? Could this CPM be revised to address that the patient or patient’s representative was informed of the transplant option (Y or N) as evidenced by signing the patient care assessment/care plan? The care plan with signatures could be automated, and then this data could be available electronically.

**CPM 4.2 Patient Acknowledgement of Discussion:**

Patient acknowledges that nephrologist has discussed the benefits and risks of transplantation and/or reasons for exclusion within 90 days after initiation of dialysis and at least every 12 months thereafter.

a. **Yes, and all my questions have been answered.**
b. **Yes, and I have more questions.**
c. **No**

**Numerator:** Any yes response

**Denominator:** All patients

**Applicable Exclusions:** None

**Potential Data Sources:** Long term care plan, other parts of the dialysis facility medical record

**Applicable Setting:** Dialysis facility

(E) If the patient is cognitively unable to understand discussion or engage in conversation (dementia, severe developmental disability, etc) it needs to be acknowledged that tx was discussed with family or caregivers and not with pt, and why not with pt, and that pt is unable to acknowledge discussion.

(I) well thought out

(K) It seems like the indicator regarding patient acknowledgment of transplant as an option should include some modifier including discussion of living donor options.

(T) If the patient indicates that he/she has more questions, or indicates that the physician has not discussed the benefits and risks of transplantation, what is the dialysis facility staff to do? What if the physician refuses to carry out this task, or simply ignores the staffs’ request or says that it has been done and that the patient simply does not remember (not uncommon occurrences). Again the dialysis facility has no authority to enforce physician behavior. Specific instructions must be issued to noncompliant physicians with MCP payment consequences. More importantly, who is to enforce physician non-activity? Is there a role for the Networks here?
I am a bit uncomfortable with Yes, and I have more questions. This would seem to require additional documentation or else it would stay on the record for 12 months!

There is a percentage of the dialysis population that have a permanent reason that are not and will never be transplant candidates. The cpm 4.2 seems to contemplate that these people will also need to be reeducated/informed of their failure to qualify for an evaluation on an annual basis.

The workflow as described in 4.1 and 4.2 does not seem practical in that a permanent comorbidity which makes a person a non candidate should circumvent future reassessment. This will avoid the inefficiency of making the same determination annually and reduce the emotional stress of rediscussing the issue with the patient which for my patients is frequently a rather sad conversation that once made doesn't need to be repeated unless they want to rediscuss the issues.

On what record will the patient rely as a basis for attesting that the nephrologist discussed transplantation with him within 90 days of ESRD and at least annually thereafter? We think that it is very unlikely that this measure will yield data that will lead to improvement in care.

We suggest a different approach to the problem of transplant referral and evaluation. We suggest, first, that items 4.1-4.4 (with reservations as set forth above) should be part of the long-term care plan. Rather than creating new forms and attempting to keep them consistent with the long term care plan, we suggest that long-term care plans be given priority for incorporation into VISION. This would mean complete standardization of long-term care plans, but that would not be a bad thing. It would help the facilities by automating their long-term care plan bookkeeping. LDOs could program the long-term care plans into their computer systems.

This is a good way to ensure that the information provided meets the patient's needs. If a patient indicates that he or she has additional questions, what kind of follow up will be expected and in what time frame? Should there be an addition CPM that would monitor/record subsequent conversations? Can a surrogate, e.g. family member, sign on behalf of the patient?

Again good idea; should already be there for those that sign long-term care plans. Also, once the conversation has ensued, it would be difficult by definition to decline information, only to decline further information.

The role of the facility is again tricky. If a patient indicates that he or she has additional questions in the absence of documented follow-up or the MD says it has been completed, what actions should the facility take to enforce? Who is responsible for physicians in this potentially sequential and repetitive process? Is there actually any incentive for MDs to engage in repeat conversations with patients? Some perfunctory issues also need to be addressed here. Who signs for illiterate patients or patients not able to give consent or understand the dialogue?

It is even at this stage that transplant center involvement may help and visits from transplant center representatives to facilities might help in the education process and could theoretically serve to buttress this measure though not replacing the primary interaction between MD and patient.

Clinical performance indicator 2 asks if the patient has acknowledged to discussion and whether he or she had any additional questions. Again the content of the initial discussion will have a large influence on the response to this question. Many patients will not question assertions noted above, though the available data may suggest that they should. More than just "yes/no" response data may not be routinely collected by dialysis centers and direct patient responses may be different than those reported secondarily by the dialysis center personnel. Similarly, the response to the "Interest Descriptor" may be biased by the role of the interviewer. Will the data be collected by direct interview with the patient? If so, by whom? Or,
will the answer to this question be inferred by data entry personnel, and if so by whom? This is an area for significant bias that may have impact on the results. The methodology here will also significantly influence resource requirements.

(JJ) Age/ co morbidities excluded patients should be removed from denominator.

(LL) We question the feasibility of patient interview for CPMs especially if CMS intends to expand CPMs to a 100% sample. Alternatively, if the patient signed the care plan and if the above 4.1 alternative was accepted, this CPM would be duplicative.

CPM 4.3 Contraindication Descriptor:

*Are there any absolute medical contraindications to referring patient for transplant evaluation?*

a. Yes (specify contraindications)

b. No

**Numerator:** Not applicable

**Denominator:** Not applicable

**Applicable Exclusions:** None

**Potential Data Sources:** Long term care plan, other parts of the dialysis facility medical record

**Applicable Setting:** Dialysis facility

(I) well thought out

(N) Medically unfit, Unsuitable due to age, Psychologically unfit, these are potentially subjective unless the exact reason for unsuitability is specified. I'd favor asking for that. Are there uniform criteria for age, psychological- or for that matter physical- requirements for transplantation? Should there be?

(T) This very obviously should be a physician's decision. Dialysis facility staff might provide information and offer opinions to physicians, but this is not a decision that the staff can make. If dialysis facility staff disagree with a physician's decision on "absolute" medical contraindication, what is the process for resolution of such disagreements? Beyond that, what is to happen in marginal cases where the dialysis staff might believe there would be differences in the opinion of the nephrologist and the transplant team regarding "absolute" medical contraindication. Dialysis facility staff must have some manner of reflecting their concern that will not interfere with the physician patient relationship. There needs to be a mechanism leading to a discussion between the patient's physician and the Transplant team. In the process, it should be the physician and not the dialysis facility staff who lists the absolute medical contraindications. Again, if this responsibility is not carried out by the physician, what authority does the dialysis provider have?

(W) This one is sticky. I suggest that they use the designated person or surgeon rule. I would also request they include notice that documented contraindicated in all local programs.
This is of real interest, but controlled vocabulary response items should be provided; although a free text "other" can be allowed, the descriptor should not rely on free text responses, which will be much harder to analyze.

We suggest a different approach to the problem of transplant referral and evaluation. We suggest, first, that items 4.1-4.4 (with reservations as set forth above) should be part of the long-term care plan. Rather than creating new forms and attempting to keep them consistent with the long term care plan, we suggest that long-term care plans be given priority for incorporation into VISION. This would mean complete standardization of long-term care plans, but that would not be a bad thing. It would help the facilities by automating their long-term care plan bookkeeping. LDOs could program the long-term care plans into their computer systems.

We suggest a pilot study to elicit the appropriate response options for the contraindication and interest descriptors. Our Network would be interested in participating in such a study.

Clinical conditions change over time. Therefore, it could be argued that there should be no absolute contraindications. It should be the responsibility of each transplant center to clearly delineate and communicate to referring dialysis centers its list of contraindications. These criteria must be openly available and consistently applied. Transparency is key. CMS should facilitate the development of basic, uniform criteria that are acceptable across all transplant programs in order to assure a level playing field.

This is an MD decision but based on what grounds? One might have to consider how familiar the MD is with contemporary transplant practices? There should also be substantive concerns as to when the facility staff and the MD disagree as to a patient's candidacy.

This is the first piece in which the transplant center has responsibility. It has to have open communication with the facility and provide criteria for the MD to aid in his or her decision, including formal contraindications to transplantation. These criteria have to be open and declared for facility-associated MDs to feel comfortable making a decision. Indeed, in this way, the transplant center has key role in this descriptor. How are differing criteria to be resolved and does this mandate some base uniform criteria that are acceptable across all programs? In the absence of these, there are theoretical possibilities advantaging or disadvantaging certain transplant programs.

Additional issues might arise as clinical conditions change over time and the necessity for follow-up documentation.

It will be necessary for the referring MD to explicitly state the reason or reasons for contraindication to transplantation and there should be some consideration for compliance or adherence to regimen as a criterion here.

Should there be stronger surveillance methodology to assure that a dispassionate assessment is provided to the patient and that the physician at the transplant center will make the final determination in instances where it is determined by the Dialysis facility that there is a contraindication to transplantation.

An alternative could be to ask if Contraindications to transplantation were explained to the patient or patient's representative (Y or N) as evidenced by documentation in the care plan. If the answer is no, it is actionable. If yes, this numerator would give useful information for CPM 4.5.

Other questions about this descriptor include:

1. Is it feasible to list contraindications if CPMs are gathered on a 100% patient census?
If contraindications vary by transplant center, would this compromise comparative data and complicate data interpretation and analyses? Would contraindications be limited to a national list as referenced in the rationale of this CPM section?

CPM 4.4 Interest Descriptor:

Does patient want to be evaluated for kidney transplantation?
   a. Yes
   b. Undecided (specify why)
   c. No (specify why)

Numerator: Not applicable

Denominator: Not applicable

Applicable Exclusions: None

Potential Data Sources: Long term care plan, other parts of the dialysis facility medical record

Applicable Setting: Dialysis facility

(B) Patients listed already for transplant, and those with whom this was discussed or are already in process i.e. have seen transplantation folks should not have to do this again.

(C) Distance from transplant center and lack of medication coverage would be good options to include as to why people are not interested in a transplant. These are the 2 barriers patients report the most to me.

(F) The patient needs to be informed of Medicare and Medicaid coverage after the transplant. This can impact on the drug costs after 3 years.

(I) well thought out

(P) Might rephrase "Is the patient willing to be referred to a transplant center?" I think it makes sense to be proactive in this. Also since you are asking the patient whether Tx has been discussed (4.2) you might put this question here instead, and additionally ask whether the patient whether they say they are willing to be referred.

(T) No issues here.

(W) Needed question and like the inclusion of why if they are not interested

(AA) Again, this is interesting and potentially important, but there is no reason to rely on free text. We suggest a pilot study to elicit the appropriate response options for the contraindication and interest descriptors. Our Network would be interested in participating in such a study.

We suggest a different approach to the problem of transplant referral and evaluation. We suggest, first, that items 4.1-4.4 (with reservations as set forth above) should be part of the long-term care plan. Rather than creating new forms and attempting to keep them consistent with the long term care plan, we suggest that long-term care plans be given priority for incorporation into...
VISION. This would mean complete standardization of long-term care plans, but that would not
be a bad thing. It would help the facilities by automating their long-term care plan bookkeeping.
LDOs could program the long-term care plans into their computer systems.

(EE) This is a reasonable approach, provided that an attestation, signed by the patient, or a
patient representative, is required. We know from Epstein’s work that patients want to be referred
for transplantation, and that nephrologists’ perceptions to the contrary are not a valid
generalization. We suggest that there be a fourth option. A patient should be able to
request that he/she be asked annually about evaluation for transplantation.

(FF) We know from Epstein’s work that patients do want to be referred and that nephrologist
perceptions to the contrary are not on the mark. This is reasonable.

(LL) This information should be captured in 4.1 or 4.3 (patient refusal). Accordingly, this
question may not be necessary.

**CPM 4.5 Referral to Transplant Center:**

Has patient been referred to a transplant center for an evaluation?
- a. Yes (specify how referred and date)
- b. No (specify reasons for not referring)

**Numerator:** Yes response

**Denominator:** All patients without absolute medical contraindications who want
to be evaluated (see Contraindication and Interest Descriptors in sections 4.3
and 4.4)

**Applicable Exclusions:** Patients with absolute medical contraindications to
transplant or who do not want to be evaluated (see Contraindication and Interest
Descriptors in sections 4.3 and 4.4).

**Potential Data Sources:** Long term care plan, other parts of the dialysis facility
medical record

**Applicable Setting:** Dialysis facility

(B) Patients listed already for transplant, and those with whom this was discussed or are
already in process i.e. have seen transplantation folks will and should not have to do this again.

(E) Many patients are not referred for tx not because of absolute contraindications but more
because of relative contraindications, including:
--active substance abuse - no referral until treatment is completed;
--non-compliance with treatment - no referral until compliance improves;
--no insurance - no referral until finances are straightened out;

These patients may end up being referred in the future but it is appropriate not to refer them due
to temporary or relative contraindications.

(I) well thought out
(S) I can only speak for my transplant center, but regular updates go out from the our Transplant Center to be placed in the dialysis or clinic chart.

(T) If answered "Yes" it would be appropriate for the dialysis facility staff to provide the manner of referral and date for those patients who have been referred. It is stated in the Rationale that "Referrals may be initiated by patients, nephrologists, or other dialysis facility personnel". I disagrees with this statement, depending on interpretation of the word "initiated". A facility staff member may initiate the referral on a physicians order, but I do not believe should do so independently. If the answer is "No", who is to provide the reasons for not referring? The discussion of absolute medical contraindication arises again. Moreover, determination of whether the patient does or does not want to be evaluated is more difficult. What if the staff believe that the patient wants to be evaluated, but the physician determines that the patient does not want to be evaluated? Dialysis facility staff do not have authority to refer patients without a physician's order. What is the mechanism for resolution of such differences? Without a process, this remains a physician decision and thus should be recorded by the physician in (or attached to) the long term care plan. Again, failure to do so must be managed by some organization with authority.

As a side issue, it is stated in the Rationale that "Dialysis facilities and transplant centers should jointly develop a process to document referral and progression of transplant evaluation." This sounds good, but I find that transplant centers commonly fail to work with our facility staffs to do this. Many transplant centers appear to be unwilling to work with small dialysis facilities in achieving this goal. I shared with the Expert Panel the forms which we have developed, but find few transplant centers acknowledge them or respond to our requests for information on patient transplant status.

(V) I agree that most of the responsibility for referral lies upon the attending physician. However, a single dialysis physician cannot be allowed to totally block the access of a patient to consideration by a transplant center. I believe that it is valid for a social worker to forward a patient initiated request for transplant review to the transplant center the patient chooses if the patient wishes to be considered. Even if a patient is turned down by the local transplant center, the patient has a right to seek reconsideration elsewhere. The dialysis unit social worker would be the obvious choice to aid the patient in doing this.

The units I work at require that I verify patient transplant status on long term care plans. These already require I give reason for long term choices, that I state whether or not the patient has been referred, and, if not, why that decision was made (patient refuses, patient medically unacceptable and why, patient psychologically unacceptable and why) and if the patient is on the waiting list or in process of work up (which should be known to the attending nephrologists who is filling out the form).

I believe that the nephrologist should be responsible for providing the information discussed in the above paragraph, but it is clear that the only site at which this information can be gathered is the dialysis unit. The practice patterns recorded should generally be used to track the physician behavior and not the unit unless physician and unit are a single practice. However, if physician behavior clearly varies between units, i.e. if physician A and B actively refer for transplantation in Units A and B but neither of these physicians nor any other refers patients from unit C, it might be inferred that unit C might have policies and practices that discouraged referral.

(W) Objective and easy to answer

(AA) We respectfully suggest that CMS should obtain dates of transplant referral and of transplant listing directly from UNOS. The date of listing is certainly known. If the date of referral is not collected, it could be added to data collected from transplant centers. We think that the date on which the transplant center first received a request for evaluation, or the date of the first
appointment, provided by the transplant center, would be a more reliable marker of referral than a
date provided by the dialysis facility.

Referral and evaluation are important steps in transplantation, and we support attempts to
improve them. However, it is critical to distinguish process information from clinical performance
measures, and to implement data collection as efficiently as possible.

(EE)  [a] should be documented, as with any order, including type of referral, date, and time of
referral. Ideally, a standardized referral form could be developed that would be utilized for all
transplant candidates.  [b] Who is responsible for a decision against referral? Is it the
nephrologist’s discretion or is it based upon the transplant center’s criteria? We suggest addition
of an item [c]: “Patient has requested assistance in making contact with the transplant center.”

(FF) This needs to be documented as with any order including type of referral, date and time
of referral. Additional documentation may be appropriate as well and thus, embedded in this
measure is the ideal development of a standardized referral form that could be universally applied
across all transplant candidates.

Who is responsible for the “No” referral? Is the MD or actually the transplant center responsible
for such, given that the transplant center has published its criteria for contraindication to
transplantation?

Again, how does the facility staff resolve a potential difference between themselves and an MD
and how is this documented. Of note, the facility staff cannot refer without an MD order.

Finally, it will be necessary to consider standardized information transfer, e.g. demographics,
basic clinical parameters, etc. and this may require an attempt at uniform documentation across
centers.

(HH) Clinical Performance indicator 3 asks "has the patient been referred to a transplant center
for evaluation"? This is an important endpoint that will require more definition. There are likely
many ESRD patients who have been referred to a transplant center by one dialysis facility but
who have moved their dialysis care since referral, sometimes several times. While the patient’s
current dialysis facility may have this information, they may not have documentation of same.

(LL) If 4.3 were revised as suggested above (see LL comment in entirety-jlb), the question has
been referred to a transplant center could apply to all patients except those patients that have
contraindications identified in 4.3.

**CPM 4.6 Transplant Center Acceptance**
**CPM 4.7 Work up Complete**
**CPM 4.8 Awaiting transplant**

The pilot will be useful to determine if this information is available in the dialysis
medical record. For 4.8, was UNOS UNet data considered as a data
source/proxy for this as evidenced by completed kidney donor candidacy forms
completed for either living or deceased donors?

**CPM 4.6 Transplant Center Acceptance of Patient for Evaluation:**

Has transplant center agreed to evaluate patient?
  a. Yes (specify date)
  b. No (specify reasons for not agreeing to evaluate)
**Numerator:** Yes response

**Denominator:** All patients referred to transplant center (see section 4.5 Clinical Performance Measure #3 - Referral to Transplant Center)

**Applicable Exclusions:** Patients with “No” response to Clinical Performance Measure #3 - Referral to Transplant Center (see section 4.5)

**Potential Data Sources:** Correspondence from transplant center to dialysis facility or nephrologist, transplant center medical record

**Applicable Setting:** Transplant center

(B) How do you plan to account for patients entering dialysis already in process or on the list?

(I) well thought out

(O) At the larger transplant center that we refer to it may take at least 6 months or longer for an appointment to be made for admission for work up. Is 6 months going to be a problem for the majority of transplant centers??

(R) I am not sure where this would go, but how about a questions in identification of appropriate living donors for patients...once a pt has been accepted at a transplant center, I usually ask if there are any living donors that need to be worked up simultaneously

(T) This is primarily a Transplant center responsibility. If dialysis facilities are to be a potential data source or are expected to monitor this CPM, then the acceptance letter must be addressed to the appropriate person at the dialysis facility. Facilities often are not informed of this information in a reliable manner (if the letter is sent to the nephrologist or the patient). We often learn of this with requests from transplant centers for blood samples for antibody screening.

(U) Getting reports back from transplant centers is difficult. There needs to be something written into their certification process that mandates timely reporting.

(W) Objective and easy to answer if documents are provided back to facility

(AA) who is to report this? What constitutes acceptance of the patient for evaluation? Does making an initial appointment constitute acceptance of the patient for evaluation? We doubt that many patients who are referred are refused evaluation.

Referral and evaluation are important steps in transplantation, and we support attempts to improve them. However, it is critical to distinguish process information from clinical performance measures, and to implement data collection as efficiently as possible.

(EE) The transplant center should provide documentation to both the referring nephrologist as well as to the dialysis clinic. The documentation should be included in the patient’s file.

(FF) Seemingly simple, this measure is fraught with potential error. Such information has to go back to the center as well as the MD as the center is responsible—this requires adequate information re: center contacts as well as the MD contacts.
Issues related to timing of this documentation arise. Does this occur when the transplant center receives formal referral? Decides to schedule? Receives approval from payer?

(HH) Clinical Performance Indicator 4 seeks to determine if a transplant center has accepted a patient for evaluation. This variable is not generally captured by transplant centers because, in almost every case, some medical and insurance information is always screened before referral. Would this be considered an acceptance for evaluation or an actual evaluation? Either way, these data will be very difficult to extract. In addition, in our experience, since the number of patients formally evaluated by a center is almost identical to the number of patients accepted for evaluation this measure is not likely to be illuminating.

(KK) Clinical performance measure number four seeks to determine if a transplant center has accepted a patient for evaluation. Based upon opinion, the stated purpose is improvement in public reporting from a transplant center. It notes that dialysis facilities and transplant centers should jointly develop a process to document referral and progression of transplant evaluation. It also suggests that this measure would provide useful information about a key step in access to kidney transplantation.

This measure would, in my opinion, add to the reporting tasks of the transplant center, encumber its personnel who are already overworked, and add a mandate which is unfunded. Further, I believe that this measure is not workable on several levels. First, even medium sized centers, such as the one I direct, may receive referrals from as many as thirty to fifty nephrologists in a given year. Each of the nephrologists may work at more than one dialysis unit. It occurs to me that an additional process of agreement between and among such entities may be overly ambitious and cause an enormous administrative burden on the transplant unit. Further, I believe this measure has little value. Documentation of a referral can occur during the course of evaluation in clinical performance measure number three. Should such a referral not be accepted or should the patient decide not to go to a specific transplant center that can simply be noted as an outcome in performance measure three. Finally, I believe the good intentions of this clinical performance measure would suggest that transplant centers actually track acceptance of patients for evaluation. Ours does not.

(LL) The pilot will be useful to determine if this information is available in the dialysis medical record.

**CPM 4.7 Work-Up Completion:**

Was pre-transplant workup completed within six months after transplant center agreed to evaluate patient?

a. Yes, and patient is a transplant candidate (specify date)
b. Yes, and patient is not a transplant candidate (specify date and reasons)
c. No (specify reasons)

**Numerator:** Yes response

**Denominator:** All patients who transplant center has agreed to evaluate

**Applicable Exclusions:** Patients with “No” response to Clinical Performance Measure #4 - Transplant Center Acceptance of Patient for Evaluation (see section 4.6)
Potential Data Sources: Correspondence from transplant center to dialysis facility or nephrologist, transplant center medical record

Applicable Setting: Transplant center

(B) How do you plan to account for patients entering dialysis already on the list?

(D) The topic of the transplant work-up process can be much more complex than this performance measure indicates. For example, required weight loss, drug treatment and 6 months of abstinence, or required (and very expensive) dental care can all be barriers to getting on a transplant waiting list that take a long time to resolve.

(I) well thought out

(Q) 6 months from initial referral to listing. It is not realistic. Our waiting time to get seen in evaluation clinic is now 3 months. A reasonable modification would be 6 months from the time a patient is seen in the transplant evaluation clinic, although, as you know, it if often much longer.

(T) This is primarily a Transplant center responsibility. If dialysis facilities are to be a potential data source or are expected to monitor this CPM, then the acceptance letter must be addressed to the appropriate person at the dialysis facility. Facilities often are not informed of this information in a reliable manner (if the letter is sent to the nephrologist or the patient).

(U) Getting reports back from transplant centers is difficult. There needs to be something written into their certification process that mandates timely reporting.

(V) As far as follow up data concerning the speed at which transplant work up is completed, and data concerning the reasons for rejection of a candidate are concerned, I believe that these data should be obtained from the transplant centers

(W) Objective and easy to answer if documents are provided back to facility

(AA) Referral and evaluation are important steps in transplantation, and we support attempts to improve them. However, it is critical to distinguish process information from clinical performance measures, and to implement data collection as efficiently as possible.

(EE) Although the pre-transplant workup need not be completed at the transplant center, the onus is on the transplant center to communicate readily, frequently and completely about the pre-transplant process. Workups can extend over lengthy periods of time. Thus, intermediate follow-up correspondence is a necessity. The transplant center must be very explicit as to why an individual is not a transplant candidate. We suggest additional data collection to record whether and when patient has been notified that the pre-transplant workup has been completed.

(FF) The onus is on the transplant center to communicate readily, frequently and completely with this one; will need to be very explicit why an individual is not a candidate if denied; hence “publishing” center-specific criteria may be important (see comment on 4.6). This is also a very problematic area as work-ups can extend over lengthy periods of time for a number of reasons. Thus, some intermediate follow-up correspondence is of necessity here.

There is danger in this process that documentation will reign but the patient will be left to his or her own resources for scheduling and completing diagnostic testing. By participating on either side of the information transfer, the facility and the transplant center need to feel as if they are engaged in mutual sharing of care for the patient.
Clinical Performance Measure 5 may be the most problematic for transplant centers and surgeons in our view. This CPM asks “was pre-transplant workup completed within 6 months after transplant center agreed to evaluate patient?” As indicated above, there is no formal documentation of the date and time of “acceptance to evaluate” in most centers so there will be extreme difficulty in determining when the 6 month’s time frame is calculated. In addition, the study period will need to be at least one year to achieve this endpoint if such a 6 month calculation can be made to allow for enough accrual. The second problem with this variable is defining a completed work-up. Many times patients do not comply with scheduling and/or dialysis schedules conflict making the timing of testing (and consequently the barrier to transplantation) patient dependent, not center or ESRD facility dependent. Moreover, the more highly morbid patients are likely to require more testing and a priori will have longer work-up times and will be more likely to not complete this work up within 6 months. Should this be scored a negative or a positive quality indicator?

The definition of a complete work-up is also problematic. Many centers where waiting times are long place patients on the list immediately after receiving minimal documentation form the referring nephrologist. In that case, the formal evaluation has not begun, yet the patient is waitlisted. Sometimes these patients are made inactive soon thereafter. At a minimum all listed patients require a blood type, HLA typing and serum for cross-matching. These can be obtained by simple blood draw, but do these represent a complete “pre-transplant work up”? Furthermore, a complete workup may result in a decision not to list a patient thus the work up was completed but the patient was never listed. We would suggest that for purposes of this study, a pre-transplant work-up is completed after a transplant surgeon and/or transplant physician have seen the patient. Since these visit dates are usually available in correspondence with the dialysis facilities, and/or at the centers, these should be relatively easy data to obtain.

Clinical performance measure five suggests that a pretransplant work-up should be completed within six months after the transplant center agrees to evaluate a patient. I stand against this as well for a number of reasons. First, our own backlog of referrals (time to appointment) averages approximately three months. While we can, “fast track,” some patients, a number of factors relate to our ability to fully evaluate patients within a specific time frame. We have tracked this from time-to-time and found that many referred patients simply do not go on to complete their own commitment to pretransplant evaluation or they miss appointments. Further, there appear to be better end points for this measure, which might be placement of the patient on the cadaveric waiting list, scheduling of a living donor evaluation and/or transplant, refusal of the patient to commit to keeping appointments, or determination that the patient is not a transplant candidate.

While I agree generally that a clinical performance measure regarding completion of evaluation may be an important tool, I would urge that this particular measure eliminate the six-month time frame, and that it be refined regarding some of the comments above. Further, I would urge that this or any measure be made as “user friendly” as possible since, once again, the end point will require significant effort by staff with no additional salary support for undertaking the work.

The pilot will be useful to determine if this information is available in the dialysis medical record.

CPM 4.8 Awaiting Transplant:

Is patient awaiting a kidney transplant?
- Yes, patient is on deceased donor waiting list (specify date)
- Yes, patient is awaiting a living donor transplant
- Both a and b
d. No (specify reasons)

**Numerator:** Any yes response

**Denominator:** All patients who completed pre-transplant workup and are transplant candidates (see section 4.7 Clinical Performance Measure #5 – Work-Up Completion)

**Applicable Exclusions:** Patients with “No” response or are not transplant candidates for Clinical Performance Measure #5 – Work-Up Completion (see section 4.7)

**Potential Data Sources:** Correspondence from transplant center to dialysis facility or nephrologist, Transplant center medical record, Scientific Registry of Transplant Recipients (for deceased donor waiting list only)

**Applicable Setting:** Transplant center

(I) well thought out

(T) This is primarily a Transplant center responsibility. If dialysis facilities are to be a potential data source or are expected to monitor this CPM, then the acceptance letter must be addressed to the appropriate person at the dialysis facility. Facilities often are not informed of this information in a reliable manner (if the letter is sent to the nephrologist or the patient).

(U) Getting reports back from transplant centers is difficult. There needs to be something written into their certification process that mandates timely reporting.

Second I could not access specific deceased donor waiting lists from the Scientific Registry, this may have been my ineptitude. However, I am not sure this listing would be legal under HIPAA.

(W) Objective and easy to answer if documents are provided back to facility

(AA) We respectfully suggest that CMS should obtain dates of transplant referral and of transplant listing directly from UNOS. The date of listing is certainly known. If the date of referral is not collected, it could be added to data collected from transplant centers. We think that the date on which the transplant center first received a request for evaluation, or the date of the first appointment, provided by the transplant center, would be a more reliable marker of referral than a date provided by the dialysis facility.

(EE) We suggest additional data collection to record whether and when patient has been notified that he/she has been entered on a deceased donor waiting list. NKF often hears from patients who thought they were on the list but were in fact not listed. There should be documentation from the transplant center in the patient’s file, indicating status and effective date. Educational materials should be provided to transplant candidates to provide the information they need during the waiting period.

(FF) This is again a transplant center responsibility. Yet, the information flow will impact the dialysis facility in a number of ways. It could become very complex for individuals who are wait-listed at more than one place or for facilities with individuals spread out among wait lists at several transplant centers. Additional clarity re: type of transplant is warranted, e.g. living donor vs. deceased donor?
Clinical performance measure 6 asks, "Is patient awaiting a kidney transplant?" This is an important endpoint but some clarification is necessary. As mentioned above, many patients are evaluated and placed on the waiting list, but at some point develop a relative, temporary contraindication for which they are made "temporarily inactive". Will these patients be counted as "yes", or "no" for this CPM? It will be important to define how these responses are to be made. In either case, these data, along with the "Transplant Descriptor" data should be readily available through the OPTN data collection mechanism and should not require direct contact with transplant centers.

Clinical performance measure number six is, in my view, the most valuable of the three measures upon which I am commenting. This measure, which is, "doable," with appropriate effort by the transplant center staff, really measures the outcome of the very first transplant issue, i.e. referral. Should the Renal Network, Inc. have data regarding referral from the dialysis unit, information regarding clinical performance measure number six would be relatively easy to collect, sound in its demographic and statistical basis, and important for further measures such as outcomes (ongoing renal function, rejection, graft loss, transplant recipient death, etc.) when transplantation finally occurs.

The pilot will be useful to determine if this information is available in the dialysis medical record. For 4.8, was UNOS UNet data considered as a data source/proxy for this as evidenced by completed kidney donor candidacy forms completed for either living or deceased donors?

**CPM 4.9 Transplant Descriptor:**

Has patient received a kidney transplant?
- a. Yes, deceased donor (specify date)
- b. Yes, living donor (specify date)
- c. No

**Numerator:** Not applicable

**Denominator:** Not applicable

**Applicable Exclusions:** All patients not awaiting a transplant (see section 4.8 Clinical Performance Measure #6 – Awaiting Transplant)

**Potential Data Sources:** Correspondence from transplant center to dialysis facility or nephrologist, transplant center medical record, Scientific Registry of Transplant Recipients

**Applicable Setting:** Transplant center

This is primarily a Transplant center responsibility. If dialysis facilities are to be a potential data source or are expected to monitor this CPM, then the acceptance letter must be addressed to the appropriate person at the dialysis facility. Facilities often are not informed of this information in a reliable manner (if the letter is sent to the nephrologist or the patient).
I could not access specific deceased donor waiting lists from the Scientific Registry, this may have been my ineptitude. However, I am not sure this listing would be legal under HIPAA.

Objective and easy to answer if documents are provided back to facility

If the answer is “No,” how frequently should this be repeated?

Again, a transplant center responsibility that will require appropriate center-facility communication. This will determine transplant status. How often should this be repeated?

This data should be available in SIMS, therefore this CPM seems unnecessary.

5.0 Feasibility of Collecting Data

As I have indicated throughout, physicians must have accountability for making timely decisions and providing written information in order for dialysis facilities to collect data. We cannot provide this data independent of active physician participation. These CPM’s must incorporate a mechanism for ensuring such physician participation.

6.0 Use Of Measures For Quality Improvement And Public Reporting

These CPMs should be used both for quality improvement and public reporting.

CPM Guideline General Comments:

Recoding the evidence grade/level for each measure would be good.

As with any true performance measure, the data on which these are based must be scientifically rigid, not opinion and the CPM’s sufficiently trialed.

I do not believe that asking "overworked" dialysis center personnel to document discussions re: the issue of transplant is burdensome. They should be doing so as part of their care anyway. If it seems that people are too overworked to do this basic of an issue regarding patient care, I believe your next project should be to dictate some reasonable patient/SW and patient/RN vs. tech caseloads so that workers are given caseloads that allow for decent patient care.

If the measures can be implemented they will provide a lot of information to the renal community. I have 3 comments: 1. I have concerns that we will really be capturing the PHYSICIAN discussion regarding the option of transplant. I feel this is a good start but it may need to be re-evaluated. 2. I am aware of several transplant centers that are reviewing financial status of the patient due to their ability/ inability to continue to pay for medication post-Medicare. 3. Also, HMO’s have identified just 1 transplant site and the patient does not have an option which may impact on absolute medical contraindications.

these measures are excellent and will be easy to track

I read the document. It is well done and captures from what I can see all the issues that we have spoken about in our conference calls. It clearly states the process and I believe the measures are obtainable and will reflect process and associated issues. I have no further suggestions at this time that would make this document stronger than already is. I see that emphasis is placed on the importance of physician counseling paralleling my thoughts.
The format is simple - I like that. Keeping it short is nice, but, I agree in that it would be nice to have objective data to validate a decision.

I completed the form which is very easy to do; the measures are excellent and will be easy to administer and track.

Should there not be a process for evaluation of patients continued status on the waiting list at least every 12 months also. Some patients wait for years on the cadaver list and during this time develop comorbid conditions that would not make them eligible but unless a nurse steps up and suggests removal from the list a patient will usually continue on when they would likely be rejected if called. As a dialysis nurse I see this more frequently than I see patients NOT being referred at all. At the two transplant centers we work with there is no formal reevaluation process for long term patients on the waiting list.

How will you contact the patients? For assessing dialysis unit compliance, how to deal with 4.3 will be the big issue.

It would be interesting to know if the centers that use this form in the future have one nurse who "coordinates" the data (like an access coordinator) or if individual nurses do this collectively for their patients.

I would like to address several concerns which I brought forward at the Expert Technical Panel which I do not believe are reflected in the draft below. These all have to do with the determination of primary responsibility or accountability for decisions and monitoring for transplant referral. As drafted below, these all fall primarily to either the dialysis provider (i.e. nursing and clerical staff) or the transplant center. I do not believe this to be a proper approach and I feel will be ineffective. Physicians must be more directly accountable or responsible. As I pointed out, dialysis providers have little authority (leverage or enforcement power, if you will) on physician behavior with regard to their individual medical practices. We have little control of attending physicians (which may account for up to 50% of patients in some dialysis facilities) and have only contractual administrative relationships with medical directors. These physicians are not employees and we cannot direct their medical practices. Physicians move freely from one facility to the other and there is not the same degree of concern about loss of privileges in dialysis facilities as there is with hospital privileges. Moreover, removing a physician's privileges, leaves the patient in a difficult position. Patients are less likely to change dialysis providers and thus, removal of their physician's privileges creates a problem. In any case, the ability of the dialysis facility provider to enforce physician behavior is limited.

The denominator for data collection should be Medicare eligible recipients—or something equivalent. We have, as I'm sure you do, many patients who have no insurance and no funds to cover the cost of transplant. The transplant centers do not want to bother seeing these patients and I don't think the dialysis units should be held accountable for the failure of these patients to register and get a transplant.

I read over the proposal. Thought it was well thought out and grounded in reality for the dialysis facility. I would concur that the goal of the project is worthy, if we can get accurate data.

At our dialysis center, we have one RN who is the designated "transplant educator/referral" nurse. Immediately upon an admission, we identify whether that patient is interested in a transplant referral. Our nephrologist informs us as to whether the patient is medically suitable for a referral. After the patient expresses which facility they want to be referred to, the transplant nurse then sends the referral. We have found that having a designated person...
to do this, makes it easier not to let any patient who may be interested, “fall through the cracks”. Your clinical performance measures will be very helpful to us for continued improvement in this area.

(Z) This draft document is very comprehensive and is scientifically based. The authors have extensively reviewed the available literature. The goals of the projects are admiral. The agenda, however, is not new. Prior attempts have failed at least in part because of the difficulties in defining who was responsible for the extensive amount of paperwork and documentation necessary. The question will be can the increased burdens placed on both the dialysis unit and the nephrologist be in some way compensated. Various proposals might include: supplements to the dialysis composite fee, and supplements to the monthly capitation fee, based on target numbers of completed transplant status reports. This is a process that clearly can be monitored. Although, the burden looks like it should be placed primarily on the dialysis unit and the nephrologist, it is clear that the responsibility of the transplant center should at least be equal, if not greater than those of the dialysis facilities. Should representatives of the transplant centers be physically required to come periodically to the dialysis facility to become an active part of this process? Are transplant programs adequately funded to reach the goals of timely evaluation and reporting that are set up in this document. All of us interested in transplantation are keenly aware of the benefit of transplantation in those patients who are possible candidates for that procedure. The goal of the document is clearly appropriate from the idealistic prospective. The cost of transplantation is ultimately cheaper than dialysis. The question remains whether there will be adequate additional funds to achieve a goal which will ultimately be cost-effective for the federal government and more importantly beneficial to the patients.

(AA) We welcome the opportunity to comment on the draft of Facility-Specific Transplant Referral Measures prepared by The Renal Network (Network 9/10). Our Network Board of Directors and Medical Review Board agree that patient education about transplantation, patient selection for transplant referral, the process of transplant evaluation, and communication between dialysis units and transplant centers are important and worthy of study.

The current proposal attempts to address the following specific questions:

a) Do nephrologists educate their dialysis patients about transplantation effectively?
b) What conditions do nephrologists consider to be contraindications to transplantation?
c) Why are some patients not interested in transplant evaluation?
d) If the nephrologist thinks the patient should be evaluated, and the patient is willing, how long does it take to make the referral?
e) How often does the transplant center accept the referral, and how long does it take to accept the patient for evaluation?
f) How long does it take to complete the evaluation?

These are interesting questions, and it is possible that answers to them will lead to changes in the distribution of deceased donor kidney transplants over the dialysis population. (We use 'distribution' in the statistical sense, not to describe the process of organ procurement.) However, answering these questions will not increase rates of deceased donor transplantation, where the problem is a limited organ supply. We doubt that they will have an important effect on living donor transplant rates. Our clinical experience suggests that entirely different dynamics are at work for patients who have potential living donors.

The review accompanying the current proposal shows how very thin is the literature addressing these questions. It does not prove, and does not even particularly support, the implicit hypothesis that the proposed data collection will lead to greater equity in transplantation. It does not support the (also implicit) hypothesis that such data collection will lead to improvement in patient care. It does not demonstrate that answers to these questions could have validity as clinical performance measures. To use a data element as
a clinical performance measure, and to publicize the resulting ranking requires either that it should be very important (e.g. coronary surgery mortality) or that it is a valid indicator of the quality of care. We do not think that these proposed measures satisfy either criterion. Some of them are important process information, which it would be valuable to collect. They are not appropriate clinical performance measures.

(General comments continue after CPM specific comments –jbl Finally, we must remember that no amount of data collection will increase the deceased donor transplant rate, and that the effect of these efforts on living donor transplantation is speculative. One might argue that public resources would be better spent in educating the public about living donor kidney transplantation, rather than in attempting to document the pace of evaluations for patients already exploring the transplant option.

We hope you will find these comments helpful.

(BB) Just a very general comment for the background section. Access to transplantation is included in the Healthy People 2010 goals for kidney disease. You can find more information at: http://www.healthypeople.gov/data/2010prog/focus04/

(CC) Thank you for the opportunity to comment. I wish I could come up with an objective way to ask patients whether they felt encouraged or discouraged (inappropriately) by any individuals, from the nephrologist to the dialysis facility to the transplant center in any way. However, that is, by nature, so subjective, I can't think of any good way to measure it. I guess those of us who work for large chains (or at least me:-)) are still smarting from the implication from the Canadian doctor in JAMA (NEJM) that implied that a patient was less likely to be referred if they were a patient at a for-profit facility. Though I know that man had his own agenda, it was still hard for me to believe that all the individuals that a patient encountered would be so unethical as to overlook this important education of the patient, but I suppose stranger things have happened.

(DD) I think this is a good draft. From a transplant center perspective, it certainly does not pose significant burden as we already document via letters to dialysis units and referring mds, the patient's status.

This initiative is a good one and should only help get patients to transplant. Thanks for sharing.

(EE) These CPMs should not be considered in a vacuum. The goals of the CPMs could be facilitated through regulatory and reimbursement changes. For example, CMS should explore the relationship of these CPMs to the pending Conditions of Coverage/Participation for dialysis providers and transplant centers.

Discussions with kidney patients about the option of transplantation should begin before the initiation of dialysis. To facilitate this, Medicare should pay for the education of beneficiaries with Stage 4 kidney disease, so that they can better understand the treatment options that will be available to them when they reach End Stage Renal Disease.

(FF) 1. It is unclear that information from evaluations conducted by the referring center are communicated to the transplant center or that there is some standard for data (prior infections, vaccinations, surgical interventions) to be transferred. 2. Should there be stronger surveillance methodology to assure that a dispassionate assessment is provided to the patient and that the physician at the transplant center will make the final determination in instances where it is determined by the Dialysis facility that there is a contraindication to transplantation. 3. The one mandate missing is methodology to increase the availability of organs for all the additional patients who presumably will be added to the waiting list.
Thank you for the opportunity to comment on this first draft. We would appreciate the opportunity to review the final draft when available.

**Summary**
This effort is reasonable as an initial effort to possibly improve referral. However, in its present form, there are many unanswered questions and potential difficulties. It is striking that there is a progression in this document from accountability at the level of the MD and facility moving towards accountability on the part of the transplant center. In general, this is a well-researched and well-written document. The significant themes noted are:

**Accountability**
The MD is accountable here for action and the facility is accountable for MD's actions. Tying the MD actions to an "incentive", i.e. the MCP, may be very necessary for this to become an achievable QI measure.

**Real targets**
What are the targets? Even though the numerators and denominators have been defined in this document, if we refer everyone for transplantation, we will have a greater disparity between wait-list and organ availability—so is the goal to feel good that a patient was referred, honor the patient's "rights" and weigh the system down further or refer in a timely and appropriate manner.

**Data collection**
There will need to be a separated, well-maintained section of the dialysis facility record re: transplant process. This process should prompt a basic universal referral form used by all facilities and all transplant centers—this form could contain many of the elements of the 2728 and UNOS/OPTN patient listing form or some amalgamation of the two but a uniform dataset will be important to track this nationally. All data obtained from this whole process should be maintained and monitored via USRDS first and cross-referenced for SRTR if possible, when someone is transplanted.

**Information flow**
There will need to be ready information flow between facilities and transplant centers. This information flow has to be bi-directional (much of this is already happening).

**The advantaged and the disadvantaged (to borrow from Bert K.)**
We know from the Meier-Kreische and Kaplan data that less time on dialysis is associated with improved transplant outcomes (though a recent publication raised some issues with this)—all efforts therefore should be made to refer early to a transplant center—those parameters should be completed by no later than 6 months after initiating dialysis. Facilities that have unique relationships with transplant centers, e.g. academic health centers, may have an advantage in this type of reporting.

**Patient understanding**
It is imperative that patients have an understanding as to this process and are kept abreast of basic information re: their health and transplantation. Health literacy becomes more than conceptual in this regard. MDs, facilities, and transplant centers will need to provide uniform information, e.g. AST patient education brochures, on a regular basis to patients to aid them in understanding the transitions and choices involved in the transplant process.

**Follow-up**
Re-evaluation, i.e. wait list management is important—mechanisms of follow up for this should build upon the initial referral process seamlessly and readily could feed back into measure 4.9.

(GG) Noncompliance needs to be included as an exclusion criteria.

Appendix C
The information should be stepwise and the form should not need to be totally completed if one of the steps precludes transplantation referral. For example if a patient is not interested then completion of the measures for that patient should stop at that step. This will reduce needless paperwork and needless data processing overhead.

Finally, if an exclusion criteria is PERMANENT (for example, the patient has stage 4 CHF or , as current criteria stand, HIV), then there should be no need to repeat this process every year for such a patient.

(HH) The draft document is quite comprehensive and detailed in its description of the indicators and descriptors that are proposed; however there is no mention of sample size and power calculations, whether the entire ESRD data reporting system will be studied or whether a sampling approach will be pursued. The study scope is critically important as the resources that will be required by CMS, dialysis facilities, and transplant centers to complete the data collection proposed will be vastly different depending on how extensive the sample size is for this effort. As the draft proposal notes, data for completion of CPM 1-3 are mostly available in the long-term care plan documentation that is already part of the ESRD reporting system. However, it is not clear if additional data extraction or new data points will be added for this project. If this is necessary, clearly the work required for completion of these will increase in proportion to the sample size. Moreover, some of the potential data sources for CPM 3-6 are cited as "transplant center medical record". It is not clear if these data will be extracted from the dialysis centers' communications with transplant centers or if transplant centers will be required to supply these directly. Furthermore, who will extract the necessary data from these records? As you are well aware, transplant centers are overwhelmed with ever increasing data requests, unfunded mandates, and documentation requirements to maintain certifications. While the simple nominal variables outlined in this proposal seem relatively straightforward on the surface, there may extreme difficulties with correct data reporting, especially for CPM 4-6 as will be discussed below.

Will participating centers be required to obtain informed consent form the subjects for this project or will this fall under the quality assessment category of HIPPA exemptions? If informed consent is required, will this be obtained by the dialysis center? If so, will transplant centers have assurances regarding this informed consent? As you are aware, many institutions require their own Investigation Review Committee approval regardless of other approvals at other institutions. IRB reviews and document preparation are also resource intensive.

The draft does not define the study period. Over what period of time will data be collected? This is important because several of the CPM and descriptors have time limits/ time frames defined. This will also impact the overall resources dialysis facilities and transplant centers will have to devote to this effort. The defined study period will also directly affect the results as indicated below. Moreover, will individual patients be studied longitudinally or will aggregates of CPM responses at a point in time be calculated? The latter approach may not adequately measure the time and scheduling factors that can pose significant barriers to ESRD patient getting transplants, most importantly the waiting time on the list. On the other hand, collecting longitudinal data will require a much longer study period, as the sequence of events from ESRD diagnosis all the way through transplantation can be quite lengthy.

The above discussion raises questions regarding the funding for this effort. If there is to be no provision for the extra resources centers will need to comply with this effort, data collection may be compromised.

(HH) This is a worthwhile initiative. The draft is well-written.

The issue is how to assist individual dialysis units in tracking the data and communicating with sometimes multiple transplant referral units. Thank you for the opportunity to review the draft.
Please note my general concerns which follow. First, transplant center staff are called upon for data by numerous agencies for seemingly good purposes. I understand this, having worked in transplant scientific database studies for nearly three decades. Data reporting has required transplant centers to add employees simply to provide information. It occurs to me that our data coordinator and our support staff simply are working at their limits. Secondly, I question the value of determining why a patient or set of patients may have been referred and not fully evaluated for renal transplantation. Should the Renal Network, Inc. believe that these data are important, a funded study by centers interested in the question might shed light on the issue in a better way than tracking every patient. In other words, a scientific, focused review may be better than a “shotgun” approach. Thirdly, I must disagree that the issue of public reporting and knowledge is as important as it is deemed in this document. I have never, for example, been asked by a patient, family member, clinical renal professional, newspaper reporter, other member of the press, or even my own administration whether or not there is sufficient public reporting of transplantation. Transplant centers already operate in a “fish bowl” regarding release of information. I do not, therefore agree that more public disclosure would, on its face, improve our outcomes. Finally, every data related task placed upon our transplant professional staff takes staff time away from the real work of kidney transplantation: evaluating and caring for patients.

I stand ready to discuss this matters with anyone at anytime. Please do not hesitate to call upon me if I can assist further with the generally good intentions regarding measures of transplantation for patients which all of us seek to serve.

Thank you for the opportunity to comment. This is a well-written document that is very thought provoking. It is interesting to review these draft CPMs in light of the newly released proposed Conditions for Coverage.

Other thoughts/questions

1. Will the unit-specific reports that include standardized transplant rates be considered?
2. If a dialysis facility has a high transplant referral rate, would they need to complete every CPM step (this comment especially applies if there is a 100% patient sample)?
Appendix D

Developing Dialysis Facility-Specific Kidney Transplant Referral Measures

Technical Expert Panel - Meeting 2 Summary
February 9 and 10, 2005

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VIII. Comments to CMS
IX. Next Steps
X. Panel Members & Observers

On February 9 and 10, 2005, a second Technical Expert Panel (TEP) was convened to assist the contractor (ESRD Network 9/10) in developing dialysis facility-specific kidney transplant referral measures. TEP members include transplant surgeons; facility representatives (including large dialysis organizations (LDOs); a transplant recipient; a transplant coordinator; representatives from a kidney patient organization, managed care organization, quality improvement organization and the Scientific Registry of Transplant Recipients; and CMS representatives. Observers included additional CMS staffers and representatives from UNOS and Computer Science Corporation. A complete listing of those in attendance is on page 18.

I. Purpose.

The goal of the meeting was to obtain input from experts on the development of dialysis facility-specific kidney transplant referral measures and supporting information for presentation and discussion at the Stakeholders meeting scheduled for April 14, 2005. These measures will assess and track steps in access to transplantation and will be used for quality improvement interventions and for public reporting at the dialysis facility level.

Public comments collated from the circulated draft Clinical Performance Measures document was reviewed, discussed, and incorporated into the TEP recommendations.
Developing Dialysis Facility Specific Kidney Transplant Referral Measures  
TEP Meeting Summary  
Meeting 2: February 9 & 10, 2005

This meeting was the second of three TEP meetings. This project will result in a formal document with recommended transplant referral measures to CMS in June 2005.

II. Overview.

Day One:
The meeting began with introductions of all TEP members and observers.

Ashwini Sehgal, MD, Clinical Coordinator gave a presentation, outlining the need for developing CPMs and what should be considered when developing these measures. Project goals and specific tasks were reviewed. Findings from the literature search were reviewed. Challenges of developing CPMs were discussed, followed by an overview of the circulated draft CPMs.

The majority of time was focused on extensive discussion relating to each draft CPM and, including the specific measure, choices (e.g., Yes/No), numerator, denominator and data source. Collated public comment relating to each CPM was incorporated into the discussion.

Day Two:
Revised measures were presented to the TEP for further discussion. TEP and Observer input was solicited in the areas of specific measure, choices, numerator, denominator, data source, feasibility of data collection and use of the measures for public reporting. Next steps in the process of fulfilling the contract were discussed. This was followed by a discussion of relevant comments for TEP members to provide to CMS related to Conditions for Coverage for End Stage Renal Disease Facilities and Conditions of Participation for Transplant Centers.

III. Meeting Highlights

Discussion focused on refinement of the draft CPM’s. In the course of discussion, the following points were raised:

- There is interest in developing a standardized referral form for use between dialysis facilities and transplant centers, with the goal of eventually making this an electronic-based referral system.

- There is interest in having transplant centers list inclusion/exclusion criteria for transplantation on an internet-based system that is readily available to both patients and dialysis providers.

- Proposed Conditions for Coverage for dialysis facilities and Conditions of participation for transplant centers support the draft CPM’s by requiring patients to be informed of the option of transplantation, requiring
transplant centers to use written selection criteria for waitlisting or declining transplantation for patients, requiring dialysis facilities and transplant centers to communicate about transplant status of patients, and requiring transplant referral tracking by dialysis facilities.

IV. Background Presentation.

Project Goals: Dr. Sehgal used the metaphor of limited lifeboats available to Titanic passengers to describe the various ways scarce kidneys could be allocated.

The goals of the project were reviewed:

1. Develop measures for quality improvement and for public reporting at the dialysis facility level
2. Should be based on evidence and conditions for coverage
3. Should be minimally burdensome to providers
4. Should be based on as much consensus as possible

These goals are important due to the shortage of deceased donor kidneys because there is an ethical obligation to distribute the scarce resource fairly and it may increase living donations. It is NOT a goal of the project to force all patients through the transplant process.

The specific tasks for fulfilling the CMS scope of work were reviewed.

1. Literature review, potential measures
2. Technical Expert Meetings (TEP)
3. Draft measures
4. Invite comments from the renal community
5. TEP meeting #2 to refine measures incorporating community input
6. ESRD stakeholders meeting, TEP meeting #3
7. Final recommended measures to CMS

Literature Review Method: Dr. Sehgal discussed the methodology and results of the literature search. The initial plan was to use a Medline search, but there were no good “key words.” For example, “kidney transplant referral measures” yielded 0 articles; “access to kidney transplantation” yielded 43 articles; and “kidney transplantation” yielded 116,000 articles. An alternative search method was used and all article titles from six major journals over last 20 years were reviewed. Journals included the American Journal of Kidney Disease; the Journal of the American Society of Nephrology; Kidney International; Nephrology, Dialysis and Transplantation; Transplantation; and Transplantation Proceedings.
Relevant articles were retrieved and abstracted. References from each retrieved article were reviewed for relevancy, articles retrieved and those references were reviewed and articles retrieved. Additionally, personal files were reviewed and expert opinions were sought to seek out additional articles. Additional resources will be added as they are identified by members of the TEP.

**Literature Results:**
Four key points were reviewed from the literature search:
5. A large and growing gap exists between need and supply of organs.
6. Several steps are involved in access to transplantation. This is more than just a waiting list problem.
7. Facility variation suggests process of care can be improved.
8. Standardized reporting of indicators has been part of successful quality improvement initiatives.
9. Facilities are already required to evaluate and record information on transplant access.

**Conditions for Coverage:**
Current CMS Conditions for Coverage related to transplantation include:
- An interdisciplinary medical team evaluates treatment options at least annually
- Team includes transplant surgeon or designee
- Patient is involved in care planning
- Results recorded on long-term program form

Limitations to current practice include:
- Thoroughness and timeliness of evaluation
- Patient understanding and involvement
- Unable to compare information in long term program forms across facilities
- No reporting to registry

On February 2, 2005, a Notice of Proposed Rulemaking was published in the Federal Register – CMS-3818-P and CMS-3835-P notifying the public of CMS' intention to establish or change requirements for Conditions for Coverage for End Stage Renal Disease Facilities and Hospital Conditions of Participation for Transplant Centers.

Teresa Casey, a CMS observer, reviewed the following proposed Conditions for Coverage for End Stage Renal Disease Facilities:
Subpart C: Patient Care
§494.70 Patient rights
§494.80 Patient assessment
§494.90 Patient plan of care
Eva Fung, also a CMS observer, reviewed the following proposed Conditions of Participation for Transplant Centers:
Part 405, Subpart U
§482.90 Patient and living donor selection
§482.94 Patient and living donor management

The public has 90 days to send comments on the dialysis facility Conditions for Coverage and 60 days to send comments regarding transplant facility Conditions of Participation. CMS is obliged to publish a final rule within 3 years.

Proposed changes most affecting this CPM project include:
- Care is being reorganized to include an assessment and a plan of care to be completed within 10 days of the assessment. This will replace the requirements for separate short and long term plans of care.
- Evaluation of suitability for a transplantation referral will be based on criteria developed by the prospective transplant center and its surgeon(s).
- If patients are a candidate for transplantation, then the dialysis team must develop plans to pursue transplantation.
- Documentation must include the plan for transplantation, patient decision regarding transplantation, and reasons for non-referral for transplantation.
- The dialysis team must track the results of transplant center referrals and monitor the status of patients on the transplant waiting list.
- Communication between the transplant center and dialysis facility must occur at least quarterly regarding patient transplant status.
- Wait list management will require patients to be removed from the waiting list if the patient receives a transplant, dies, or develops other reason for removal from the list.
- Transplant centers must use written patient selection criteria to determine a patient’s suitability for placing on the waitlist.
- Transplant centers must notify the dialysis facility of transplant status or any changes in patient transplant status on an annual basis.

Clinical Performance Measures (CPMs):
CPMs are indicators that assess processes and outcomes of health care for quality improvement activities. Examples include: adequacy of dialysis (prescribed treatment time, Kt/V) and anemia management (erythropoietin dose, hemoglobin).

Practice guidelines are systematically developed statements to assist providers in developing treatment plans for specific conditions such as the K/DOQI guidelines. Ideally, practice guidelines are developed first; however, there are none for referral to transplantation. In the Core Indicators Project, precursor to the current CMS ESRD CPM Project, indicators were developed without practice guidelines.
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Desirable characteristics of CPMs include: important condition, evidence based, variable or substandard quality, process can be influenced by the provider, there is a cost-effective intervention available, an acceptable data collection burden, adequate severity of illness adjustment, and reliable, valid and interpretable.

Challenges to developing CPMs for tracking kidney transplant referral include the fact that dialysis staff is already overburdened and the need to check reliability and validity of submitted information. Additional challenges are that some specific steps are not under the control of dialysis providers and the need to determine what patient characteristics to adjust for.

V. Public Feedback to Draft Clinical Performance Measures.

The Draft Clinical Performance Measures were posted on The Renal Network, Inc. website (www.therenalnetwork.org) on January 11, 2005 until January 28, 2005 for public comment. An email announcing the posting was distributed to renal organizations and networks, requesting review and comment. Comments received through the website were returned to the Network anonymously. Both organizations and individuals responded using this mechanism. Additional identifiable responses were received by email or mail from organizations and individuals.

TEP members were given copies of public feedback in two documents organized by responder and by CPM.

VI. Revision of Draft Clinical Performance Measures.

4.1 CPM #1 – Nephrologist-Patient Discussion
Have benefits and risks of kidney transplantation and/or reasons for exclusion been discussed with patient by nephrologist within 90 days after initiation of dialysis and at least every 12 months thereafter?

Choices: Yes, No
Numerator: Yes response
Denominator: All patients of dialysis facility
Exclusions: None
Data Sources: Long term care plan, other parts of dialysis facility medical record

Public comments:
Comments focused on the frequency and timing of the discussion, who should be held responsible and who should hold the discussion, the need to standardize the discussion, the need to standardize and possibly expand reporting options
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and miscellaneous comments lending support for the CPM and a suggestion to track practice patterns of referrals by physicians.

TEP discussion of this CPM occurred jointly with 4.2 CPM #2 – Patient Acknowledgement of Discussion.

Following discussion, this CPM was merged with 4.2 CPM #2 – Patient Acknowledgement of Discussion below, then split into incident and prevalent CPM’s A and B.

4.2 CPM #2 – Patient Acknowledgement of Discussion
Patient acknowledges that nephrologist has discussed the benefits and risks of transplantation and/or reasons for exclusion within 90 days after initiation of dialysis and at least every 12 months thereafter.

Choices: Yes, and all my questions have been answered; Yes, and I have more questions; No
Numerator: Any yes response
Denominator: All patients
Exclusions: None
Data Sources: Long term care plan, other parts of dialysis facility medical record

Following discussion, this CPM was merged with 4.1 CPM #1 – Nephrologist-Patient Discussion to form CPM’s A and B.

Public comments: Comments focused on the frequency and timing of the discussion, analysis issues, who should be held responsible and who should hold the discussion, the need to standardize the discussion, the need to standardize and possibly expand reporting options, and miscellaneous comments both supporting and not supporting this CPM.

TEP discussion of 4.1 CPM #1 – Nephrologist – Patient Discussion and 4.2 CPM #2 – Patient Acknowledgement of Discussion:
Members advised splitting these into separate measures to capture incident and prevalent patients. Definition of incident was discussed at length. Members debated the feasibility of reporting incident at start of dialysis treatments versus incident to current dialysis facility. The decision was made to report incident to current dialysis facility within 90 days, consistent with documentation requirements for long term care plans. Members stated that 90 days of admission to current facility was a reasonable period of time to have this completed for incident patients and annually for prevalent patients.

There was discussion about adding the word “burdens” to risks and benefits in the CPM’s 4.1 and 4.2. Some TEP members felt that nephrologists do not know enough about transplantation to have this conversation.
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Members discussed who should provide this information. There was concern that dialysis facilities cannot enforce that physicians hold this transplantation discussion. It was suggested that MCP payments be tied to completion of this responsibility. It was noted that current Conditions for Coverage require that there be a discussion of treatment options by the nephrologist, so the nephrologist-patient discussion about transplantation is required.

Members agreed with public comment that once prevalent patients have a permanent exclusion, that they be exempt from further transplantation discussion.

There was lengthy discussion about adding interest or lack of interest to the answer choices. Decision was made to leave interest as separate descriptor item.

It was suggested that a form be created to capture the information required by these CPM’s and then have the nephrologist and patient sign off to attest completion.

TEP members discussed the need for standardized education packet so dialysis staff can participate in educating patients about transplantation.

It was noted that patients already on the waiting list would fit the “Yes” response.

Following discussion, CPM’s A and B were developed.

CPM A – Incident Discussion
Patient and/or representative acknowledge that nephrologist or dialysis team has presented, before 90 days after initiation of dialysis at current facility, the option of transplantation.

Choices: Yes, No
Numerator: Yes response
Denominator: All incident patients of dialysis facility
Exclusions: None
Data Sources: Long term care plan, other parts of dialysis facility medical record
Public reporting: Yes

CPM B – Prevalent Discussion
Patient and/or representative acknowledge that nephrologist or dialysis team has presented, within the last 12 months, the option of transplantation.

Choices: Yes, No, Patient permanently excluded from transplantation
Numerator: Yes response
Denominator: All prevalent patients of dialysis facility

Exclusions: None
Data Sources: Long term care plan, other parts of dialysis facility medical record
Public reporting: Yes

4.3 – Contraindication Descriptor
Are there any absolute medical contraindications to referring patient for transplant evaluation?

Choices: Yes (specify contraindication), No
Numerator: Not applicable
Denominator: Not applicable
Exclusions: None
Data Sources: Long term care plan, other parts of dialysis facility medical record

Following discussion, this descriptor was deleted. Contraindication information will be gathered from CPM C – Referral to Transplant Center.

Public comments:
Comments focused on the areas of definition of contraindication, who is responsible for declaring a contraindication exists, the need to standardize or expand reporting options and concern that varying contraindications between transplant centers would compromise comparative data interpretation and analysis.

TEP discussion:
There was agreement that the word medical should be dropped since contraindications such as noncompliance may exist.

The new Conditions for Coverage will make this more clear since transplant facilities will need to specify in writing their selection criteria for transplantation.

It was decided to delete this descriptor and to instead capture this information in the referral CPM.

4.4 – Interest Descriptor
Does patient want to be evaluated for kidney transplantation?

Choices: Yes, Undecided (specify why), No (specify why)
Numerator: Not applicable
Denominator: Not applicable
Exclusions: None
Data Sources: Long term care plan, other parts of dialysis facility medical record
Following discussion, the wording for this descriptor was retained as originally proposed.

Public comments:
Public comment for this descriptor included alternative wording suggestions, the need to standardize reporting options, the need to require attestation by patient or their representative, and the suggestion to incorporate this with CPM #1 Nephrologist-Patient Discussion.

TEP discussion:
Clarification was made that if a patient is interested, but not a candidate, they would be listed as a “Yes” response. If patient is not interested and not a candidate, that they would be listed as a “No” response.

TEP members brainstormed possible standardized responses for reasons why patients may not interested. The reasons identified include: age, fear, financial, religious/ethical, medical, told not a candidate

There was discussion regarding why it is important to collect this information. It was compared to the Fistula First project and the identification of educational opportunities for improvement. If this information is important to be collected, the long term care plan will need to be modified to capture the reasons why patients are not interested, because that won’t be in the medical record already. If this information is not gathered, we may lose an educational opportunity with the patient. For instance, a patient may think they are too old for a transplant, but not be aware that they are within the accepted age range at the local transplant center. Another member suggested that we not develop a list of national reasons because reasons for disinterest may vary by locale. For quality improvement purposes, it would be best to analyze reasons in terms of that particular facility or region. May miss a best or worst practice if the “buckets” are too long. It was suggested that we provide a blank line for reasons to be written in as an option to see what we get back because of concern regarding burden of collecting information.

It was noted that the SRTR Minority Affairs Committee is very interested in this question.

The decision was made to not resolve the issue of specifying reasons for no or undecided now. This information will be requested (per open ended response field) in the pilot testing of the CPM’s. The information returned will be assessed to determine the value of collecting the specific reasons or leaving as yes, no, undecided response choices.
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4.5 CPM #3 - Referral to Transplant Center
Has patient been referred to a transplant center for an evaluation?

Choices: Yes (specify how referred and date), No (specify reasons for not referring)
Numerator: Yes response
Denominator: All patients without absolute medical contraindications who want to be evaluated
Exclusions: Patients with absolute medical contraindications to transplant or who do not want to be evaluated
Data Sources: Long term care plan, other parts of dialysis facility medical record

Following discussion, the CPM was modified as follows:

CPM C – Referral to Transplant Center
Has patient been referred to a transplant center for an evaluation?

Choices: Yes (specify how referred (will include who: nephrologist, patient or dialysis unit team or secretary, other and how: written (letters, forms, email), phone call, or other and date), No (specify reasons for not referring will include: contraindications specified by transplant center, physician judgment or refuses to refer, patient not interested, or patient already on the waitlist.)
Numerator: Yes response
Denominator 1: All patients
Denominator 2: Exclude patients with contraindications
Denominator 3: Exclude uninterested patients
Denominator 4: Exclude patients with contraindications, uninterested patients
Exclusions: Patients with absolute medical contraindications to transplant or who do not want to be evaluated
Data Sources: Long term care plan, other parts of dialysis facility medical record
Public reporting? Yes, denominator 4

Public comment:
Comments included alternative wording suggestions, concerns about the frequency and timing of discussion, communication issues between transplant centers and dialysis facilities, the need to standardize or expand reporting options, who should be responsible, analysis issues, and miscellaneous comments supporting the CPM and pointing out the need to distinguish process information from CPM measures and implement data collection as efficiently as possible.

TEP Discussion: Methods of referral were brainstormed to develop a drop-down list of responses. Need to define elements that must be recorded such as patient name, nephrologist making referral, where referral made and date. These will need to be pilot-tested to determine appropriateness of options.
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It was decided that denominator 4 is the most actionable, so it will become the CPM and the others will be descriptors, but providers receive the information back.

There was discussion about how to handle the fact that some physicians don’t refer patients for transplantation. This option was added to the “No” response list. However, it was agreed that if a patient doesn’t have a medical contraindication, is interested in transplantation, but the staff and nephrologist do not agree on decision to refer for transplantation, that it is the dialysis facility’s responsibility to influence that physician’s judgment.

Methods of collecting this information were discussed. There was interest in creating a standardized referral form and form to document the complete transplant referral process that could be signed off by the patient, nephrologist and other dialysis team members as appropriate. This form may become part of the long term care plan. The National Kidney Disease Education Program is in the process of finalizing a web-based consult letter template. This could be used as a model. Desire for an eventual electronic form was deemed desirable, but it will be necessary to start with a paper form.

There will be both universal absolute contraindications that apply across centers and local center-specified contraindications. The contraindications might include insurance coverage, compliance, etc. specific to the local transplant center. There was discussion about how to determine which local transplant center exclusion list to include in instances of multiple local transplant centers. One member suggests having the nephrologist select a local transplant center to be used for his patients, but this could be modified on a per patient basis. If physician refuses to name a local transplant center, then the dialysis facility should be empowered to use one local transplant center’s exclusion list so they know what list to use for a patient. We would need to define how to choose a local transplant center to use. The structural CPM would also help with this issue.

4.6 CPM #4 – Transplant Center Acceptance of Patient for Evaluation
Has transplant center agreed to evaluate patient?

Choices: Yes (specify date), No (specify reasons for not agreeing to evaluate)
Numerator: Yes response
Denominator: All patients referred to transplant center
Exclusions: Patients with “No” response to CPM #3 – Referral to Transplant Center
Data Sources: Correspondence from transplant center to dialysis facility or nephrologist, transplant center medical record

Following discussion, this CPM was deleted.
Public comments: Comments focused on the areas of frequency and timing, suggestion to expand reporting options, who should be responsible, communication issues and miscellaneous comments supporting CPM and the need to distinguish process information from CPM measures and implement data collection as efficiently as possible. There was also a comment that the number of patients formally evaluated equals the number of patients accepted for evaluation, so this CPM is not necessary.

TEP comments: There was discussion that this is a transplant center CPM, not dialysis facility CPM. As extensively discussed at the first TEP meeting, communication between dialysis facilities and transplant centers is poor, so dialysis facilities will not be able to answer this CPM.

It was noted that transplant centers don’t track referrals, as a nephrologist may send a written referral letter, but the patient doesn't show up. There was lengthy discussion about the value of a web-based referral system to coordinate and track this process. Perhaps the networks could play a role as intermediary between dialysis facilities and transplant centers in terms of communication. For instance, networks could be informed when a transplant referral is made to a transplant center, when a transplant center receives a referral for a patient and when the patient has been seen. This information could then be provided to the transplant centers and dialysis facilities. The networks can typically locate where a patient dialyzes, so that helps communication and tracking. CMS would need to allow networks to function in this capacity. It was suggested that comments be submitted regarding the proposed Conditions of Participation for transplant centers, stressing the importance of tracking referrals and their completion, for the continuity of care for patients. That will inform CMS that this needs to be done. Volume of letters on an issue carries weight.

It was suggested that this CPM be replaced with a “structural” CPM that measures that procedures and policies are written.

4.7 CPM #5 – Workup Completion
Was pre-transplant workup completed within six months after transplant center agreed to evaluate patient?

Choices: Yes, and patient is a transplant candidate (specify date), Yes, and patient is not a transplant candidate (specify date and reasons), No (specify reason)
Numerator: Yes response
Denominator: All patients who transplant center agreed to evaluate
Exclusions: Patients with “No” response to CPM #4 – Transplant Center Acceptance of Patient for Evaluation
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Data Sources: Correspondence from transplant center to dialysis facility or nephrologist, transplant center medical record

Following discussion, this CPM was deleted.

Public comments: Timing issues, communication issues, who should be responsible, the fact that this is often patient driven, and miscellaneous comments regarding need for a pilot study and that patients with more comorbid conditions require more testing and a longer workup period were the main areas of comment.

TEP discussion: There was discussion that the timeline needs to change from after the transplant center agreed to evaluate patient to after the referral was made.

There was agreement that this is a very important issue, a place where patients often “fall through the cracks”. There is a role for dialysis facilities, as dialysis staff may be able to help patients overcome barriers to getting appointments, getting to appointments, etc. for workup.

4.8 CPM #6 – Awaiting Transplant
Is patient awaiting a kidney transplant?

Choices: Yes, patient is on deceased donor waiting list (specify date); Yes, patient is awaiting a living donor transplant; Both a and b; No, (specify reasons)
Numerator: Any yes response
Denominator: All patients who completed pre-transplant workup and are transplant candidates
Exclusions: patients with “No” response and are not transplant candidates for CPM #5 – Work-Up Completion
Data Sources: Correspondence from transplant center to dialysis facility or nephrologist, transplant center medical record, Scientific Registry of Transplant Recipients (deceased donor waiting list only)

Following discussion, this CPM was modified to:
Descriptor: Waiting List/ Living Donor Transplant

Was patient placed on deceased donor waiting list or did patient receive living donor transplant within twelve months after referral to transplant center?

Choices: Yes, placed on waiting list (specify date); Yes, received living donor transplant; No, (specify reasons)
Numerator: Any yes response
Denominator 1: All patients referred to transplant center
Denominator 2: Exclude patients who are not transplant candidates after workup.
Data Sources: UNOS, Scientific Registry of Transplant Recipients
Public Reporting? Yes

Public comments:
Comments focused on areas of communication issues, who should be responsible, need to possibly expand reporting options, data source and miscellaneous comments supporting the CPM.

TEP discussion:
It was decided to change the CPM as above because TEP members felt that completion of workup is synonymous with getting on the list or getting a living donor transplant. Little time elapses between completion of workup and waitlisting or living donor transplantation.

There was discussion that some transplant centers place patient on waitlist on hold-status (Status 7) before they've completed their workup. There was agreement that a Yes response is generated only when patient is listed as Status 1 (active status) and ready for transplantation.

Two denominators were created. Denominator 1 could be instituted right away. Denominator 2 could be incorporated if the Conditions for Coverage are implemented as proposed, as they require transplant centers to routinely inform dialysis facilities of patient waitlisting and transplant status.

4.9 Transplant Descriptor
Has patient received a kidney transplant?

Choices: Yes, deceased donor (specify date); Yes, living donor kidney (specify date); No
Numerator: Not applicable
Denominator: Not applicable
Exclusions: All patients not awaiting a transplant – CPM #6 – Awaiting Transplant
Data Sources: Correspondence from transplant center to dialysis facility or nephrologist, transplant center medical record, Scientific Registry of Transplant Recipients

Following discussion, this descriptor was changed as follows:

Deceased Donor Transplant Descriptor
Has patient received a deceased donor kidney transplant?
Choices: Yes (specify date); No
Numerator: Not applicable
Denominator: Not applicable
Data Sources: UNOS, Scientific Registry of Transplant Recipients
Public Reporting? Yes
Public comment:
Comments focused on the areas of who should be responsible, frequency of reporting, data source and miscellaneous support for the descriptor.

TEP comments:
None.

VII. Proposed Structural Performance Measurement

TEP members discussed developing a performance measurement to measure dialysis facilities and transplant centers in terms of their policies and procedures related to referral to transplantation.

Members discussed that the goal of this performance measure is to determine if the dialysis facility has received, from the transplant center(s) where it refers patients, policy and procedure information outlining inclusion/exclusion criteria for transplantation. Transplant center-affiliated TEP members thought it reasonable that each center should have a list of inclusions/exclusions as this information must already be provided to insurance companies. Potential authority to enforce this comes from the proposed conditions for Coverage for dialysis facilities. The rationale section for §494.90 Patient Plan of Care states: “We are proposing that the dialysis facility must have inclusion/exclusion criteria, defined by the transplant surgeon based at the transplant center that would receive the transplantation referral, to use in the evaluation of patients for transplant referral.” If these proposals become rules, than this step will be important to monitor.

There was concern that since the Contraindications Descriptor was deleted and contraindications incorporated into CPM C: Referral to Transplant Center, contraindications were now left to the judgment of the person filling out the CPM form. Physicians could claim that none of their patients are appropriate for referral to transplantation because they are over the age of 60. Since only denominator #4 (exclude patients with contraindications and uninterested patients) will be publicly reported, this could be a large loophole. As a result, it is important to require and monitor the process of dialysis facilities obtaining inclusion/exclusion criteria from transplant centers to reduce the likelihood of gaming elsewhere.

It was suggested that it be recommended to CMS to include language in the Conditions of Participation for transplant centers that require inclusion/exclusion criteria be provided to dialysis facilities, mirroring the language of the Conditions for Coverage for dialysis facilities.

It was strongly suggested that transplant center inclusion/exclusion criteria be posted to an internet-available central database, perhaps through UNOS or the
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ESRD networks so that the information be readily available to dialysis facilities and patients.

It was decided to remove the words risks, burdens and benefits from this CPM, but it was suggested that it measure how risks, burdens and benefits will be communicated to patients. For example, a) will refer to nephrologist for discussion of risks, burdens, benefits of transplantation, b) will give educational booklet regarding transplantation, etc.

It was suggested that this CPM include wording that the education process for transplant by dialysis facilities be developed in conjunction with transplant center staff.

Although not completely finalized, the TEP developed the following structural CPM:

Does the referring dialysis facility have a copy of the transplant center’s written policies and procedures relating to exclusion criteria; referral process; communication intervals; and educational process?

The contractor will continue to refine this CPM and present the revision at the next TEP meeting.

VIII. Comments to CMS regarding Conditions for Coverage.

TEP members discussed comments that can be made by TEP members to CMS regarding Conditions for Coverage for dialysis facilities and Conditions of Participation for transplant centers that align with the draft transplant referral CPM’s. A bulleted list was developed as follows:

- Transplant centers make available exclusion criteria
- Listing on transplant list should not be standard for dialysis facility; it should be referral to transplant center.
- Transplant centers should make public their referral process requirements
- Transplant centers should report back to dialysis facilities about acceptance for evaluation, completion of work-up, placement on waitlist, status on waitlist
- 20 days for initial assessment is too short; change to 90 days
- Patient education should include specific topics developed in conjunction with transplant centers
- Networks should have a role in transplant centers (support current language)
- Dialysis facilities are to communicate quarterly with transplant centers, but transplant centers only need to communicate annually with dialysis
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- Include date patient is listed as status 1 in care plan and other items needed for transplant CPM project
- Create a standardized referral form to be used nationally

IX. Next Steps.

The contractor is required to document and distribute the findings of this meeting for comment. Each measure will be summarized and formalized into numerators, denominators and descriptors. This summary document will be distributed to TEP members, individuals who expressed interest in serving on the TEP but were not selected, and other stakeholders. Additionally, a portion of the Networks 9/10 Web site (www.therenalnetwork.org) will be devoted to this project. Feedback will be collected until a determined deadline, then collated and disseminated at the third TEP meeting. The draft CPM’s will be presented and discussed at a Stakeholders meeting on April 14, 2005.

The third meeting of the TEP will be held on April 15, 2005 in Baltimore. The TEP will assist the contractor in finalizing the draft set of measures and supporting information for the Final Project Report to CMS, due June 30, 2005.

X. Technical Expert Panel, Consultants, Staff & Observers.

Teri Arthur, MSW, LSW, University of Chicago
Francis Delmonico, MD, Harvard University
Erick B. Edwards, Ph.D., United Network of Organ Sharing
Jens Goebel, MD, Cincinnati Children’s Hospital Medical Center
Richard Goldman, MD, RPA & the Forum of ESRD Networks
Bonita Balkcom Guilford, Transplant Recipient, ESRD Network 6
Lawrence G. Hunsicker, MD, University of Iowa Health Care
Mysore S. Anil Kumar, MD, Drexel University College of Medicine
J. Michael Lazarus, MD, Fresenius Medical Care-North America
Keith Mentz, Chief Executive Officer, Nephrology, Inc.
Kim E. Phillips, MSN, RN, CCTC, U. of Utah Solid Organ Transplant Services
Kris Robinson, American Association of Kidney Patients
Marlon Yu, RN, Kaiser Permanente.

Project Consultants:
Alan Leichtman, MD, University Renal Research & Education Association
Jonathan Sugarman, MD, MPH, Qualis Health

CMS Representatives:
Brady Augustine (absent)

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James Bowman, MD
Pamela Frederick, MSB
Jayne Hammen
Kathy Hudson
Deborah Read, Project Officer (absent)
Barry Straube, MD (absent)

eSource/CSC Representatives:
Andy Hanks, MBBS, Computer Sciences Corporation (absent)
Shannon Wright, BSW, PMP, Computer Sciences Corporation

Contractor Network 9/10:
Ashwini Sehgal, MD, MetroHealth Medical Center, Clinical Coordinator
Janeen Leon, MS, RD, LD, MetroHealth Medical Center, Project Coordinator
Melissa Aulisio, MNO, Project Assistant
Jay W. Wish, MD, President
George Aronoff, MD, MRB Chair (absent)
Susan A. Stark, Executive Director
Bridget Carson, Assistant Director
Raynel Kinney, RN, CNN, CPHQ, Quality Improvement Director

CMS Observers:
Teresa Casey, RD, LD
Gina Clemons
Diane L. Frankenfield, DrPH
Eva Fung
Heather Grimsley
Judith Kari
Mathew Leipold
Condict Martak
Siddhartha Mazumdar
Marcia Newton
Eileen Zerhusen

URREA Observer:
Valarie Ashby, Kidney Epidemiology and Cost Center, University of Michigan
Appendix E

Developing Dialysis Facility-Specific Kidney Transplant Referral Measures

Stakeholders Meeting – April 14, 2005

Below are the questions/comments raised by key stakeholders regarding the proposed Clinical Performance Measures for Kidney Transplant Referral. Written comments are at the end of the document.

1. Commenter Unknown:
The CPM related to the “discussion” is a weak measure. Someone could provide a sheet of paper and say this was discussion. Really need to test patient knowledge. Need to validate patient knowledge and quality of discussion.

RESPONSE: Ash Sehgal--We will be pilot testing the CPMs and plan to validate the discussion item regarding the nature and quality of the discussion.

2. Raymond Hakim, Renal Care Group:
46% of dialysis patients are wait-listed and the percent who receive a transplant is even less. CPMs should be focused on this point. CMS should address what % of the 46% are not getting transplant. The solution should fix the bottlenecking issues related to legislation, informed consent etc. rather than focusing on number of people getting into the transplant center.

RESPONSE: Ash Sehgal--46% is not all patients in dialysis centers that are waitlisted. Only about 7% of patients make it through the process. Also, there is huge variation across facilities over who get to the waitlist; lots of things are happening before people even get waitlisted at the nephrologist and dialysis provider levels.

3. Raymond Hakim, Renal Care Group:
What happens if a nurse has a differing opinion from the nephrologist? The issue of referral has to come from the nephrologist NOT from dialysis centers. This should be incorporated into the long-term care plan and have two parts: one part for the dialysis centers and one part for the nephrologist. Should have two domains of responsibility. CMS makes rules for dialysis facilities, so it will hit here.
RESPONSE: Pamela Frederick--This is where project is right now; part of today's meeting is to get feedback and then go back and work out the issues.

4. Sheila Weiner, National Kidney Foundation:
   Of the 50% of patients who express interest, only 54% are medically suitable. What is happening to other 43%? Why are they not getting a work-up even though they are suitable and interested?

RESPONSE: Ash Sehgal—Many people are stuck at the work-up stage for 1-2 years or more. We need to improve the efficiency of the pre-transplant work-up process.

RESPONSE: Pamela Frederick—This will help us find out why people are falling through the cracks.

5. William Haley, Mayo Clinic, Jacksonville, FL made three points:
   - I don't think it is a good idea to have dialysis center staff serving up the transplant option on their own. This could generate angst on the part of the patient.
   - On the slide showing increasing gap: It should be pointed out that in the 70s and early 80s, patients were more rigorously selected for dialysis and that contributed to the gap.
   - The descriptor on contraindications is not clear. If you leave this open-ended then it becomes matter of medical judgment. Is the intent to define contraindications?

RESPONSE: Ash Sehgal—We are going to recommend that facilities look at all absolute contraindications and also determine what their local transplant center’s contraindications are.

Commenter interjected: What if there is a conflict between these two lists? For example, a patient’s life expectancy could be less than 2 years. This is an absolute contraindication for some centers and not for others. Some guidance needs to be given here; this should be assigned to medical review boards.

6. Raymond Hakim, Renal Care Group:
   We tracked this (contraindications) in Boston. Four local centers had four different lists. The nurse had to sort it out. For example, one transplant center says BMI should be lower, but best medical outcome for dialysis patient is a higher BMI. The solution needs to come from outside the dialysis unit.

7. Mysore Kumar, Drexel University (TEP member) made two points:
Should not be the sole responsibility of the nephrologist; this effort should show teamwork by the dialysis staff. For example, the social worker should be involved. This is what happens at the transplant center now.

- Contraindications change over time. From a transplant surgeon perspective, most patients should be seen at the transplant center to discuss transplantation.

8. Lawrence Hunsicker, University of Iowa College of Medicine (TEP member): The TEP approached this project by what can be done today. This is what we can do now. Two main points came up in this process:
   - Dialysis units do not have responsibility over the actions of the nephrologist.
   - There is a huge gap in cooperation/communication between transplant centers and dialysis centers. No system is in place to track what is happening between the two, and patients get lost. We can’t fix everything, but the renal community can. We need to account for when patients go from here to there. We are proposing what can be done today.

9. Chris Lovell, Dialysis Clinic, Inc.: Thank you! You tried not to burden the dialysis staff. I propose you add a line between “discussion” and “interested” on a cascading graph –this should be a patient focused question. If there is a trust issue, I worry about clinics that aren’t talking to patients. Providers should be savvy in reminding their patients to recall this conversation when asked. If you really just want to know who gets referred, then should just make this a YES/NO question with a DATE. This could be overwhelming to the transplant center regardless of contraindications. Then transplant centers can report on what happens. Work this out at the transplant level to ding the transplant centers.

RESPONSE: Ash Sehgal—We have two CPMs at the Dialysis Center Level and 2 CPMS and 2 descriptors at the transplant center level.

Commenter: This discussion should be at Transplant center level also

RESPONSE: Ash Sehgal—There are two responses to this: 1) To pilot test this; and 2) Then we can see the % of this discussion and the quality of this discussion.

Commenter: “Reasons” could become unruly.

RESPONSE: Ash Sehgal—Yes, from the pilot data we will establish the most common reasons for contraindications, then develop a fixed response category and then a “write in” category of “other”.

Appendix E

May 2, 2005
10. **Unknown Commenter:**
The goal is to refer those who are ready and able to be transplanted. Don’t want this to be paperwork burden; could just use the 2728 form, so by the time patient starts dialysis, we can find out if they’ve been approached for transplant. We need to make education tools so patients can be educated early in CKD levels 3 and 4.

11. **Lisa Taylor, ESRD Network 12:**
I second the last comments. The renal and health community as a whole has not done a good job of designing patient-centered education tools. They are written at too high an education level, disregard patient educational needs in terms of variety, priority, etc. Thanks to the committee, I hope this leads to better education tools. She will forward some suggested materials to Ash Sehgal/Renal Network.

12. **Francis Delmonico, UNOS, Massachusetts General Hospital (TEP member).** Commenter made two points:
- UNOS wants to expand educational information and their website regarding live donations. In the CPM discussion there can be a point regarding where someone can access information about live donation.
- There should be a standardization of what the “discussion” should include.

13. **Sheila Weiner, National Kidney Foundation:**
Spoke of a packet of patient information regarding transplantation that has been assembled according stages of CKD progression. NKF has this packet and commenter will forward to Ash Sehgal/Network.

14. **Lisa Taylor, Network 12:**
Spoke of Live Donor Education Project being done by Amy Waterman at University of Washington, St. Louis, involving data collection on barriers individuals experience when approaching friends/family to be live donors. She plans to develop an educational tool.

**RESPONSE:** Ash Sehgal—I will be meeting with her in a few months.

15. **Barbara Fivush, American Society of Pediatric Nephrology, Johns Hopkins Hospital.** Commenter had two points:
- In certain populations the level of education varies. There is a need to address the cultural competency issue in the education tools. For example, Hispanics have been found to have a lower ability to understand medical education material. Tools provided must target the population both educationally and culturally.
This is a huge problem in getting people to transplantation; it is just the tip of the iceberg. This will get people started talking about these issues and current practices.

16. Juan Bosch, Gambro Healthcare. Commenter had two points:
   - All CPMs above the line should be able to get data easily.
   - All CPMs below the line are driving at the transplant workup and should be at the transplant center level to find out why it takes so long for patients to get worked up. Also, patients may be interested but not have the means to get a transplant workup. These data will help to identify these barriers.

17. Unknown Commenter:
CMS is trying to come up with measurement strategies in continuity of care.

18. Sally Burrows-Hudson, Bone Care International:
ANNA guidelines will be released next week that focus on standardized patient assessment, intervention, and education. Guidelines are provided to develop a standardized approach to education. Commenter will send this information to Ash Sehgal/Renal Network.

19. Kim Phillips, University of Utah Hospital (TEP member):
After 3 years, Medicare eligibility ends so patients stretch out, then discontinue their medications. What percent of transplanted patients return to dialysis? Patients are circling back around. CMS helps people get transplants, but is not supporting their long-term care or success.

   RESPONSE: Pamela Frederick—This will get put in the recommendations.

   RESPONSE: Susie Stark – There are good data on percent returning to dialysis, but not good data on the reasons why.

20. Unknown Commenter:
Could separate this into cadaveric vs. living donors – see this as an education issue.
Written comments collected at end of the meeting follow.

1. Concern about subjective reporting of data from boxes 1 & 2 (interest + discussion). Would recommend just broaden outcome measure @ box 3 - % of referral from each unit.
2. Outcome measure for timing of pre tx w/n = look @ billing for services – is data of service greater than 1 yr between 1st and last study
3. Focus really needs to address access to living donation – not just adding to the wait list! – Celia Clarke, Kaiser Permanente

Relative to the increase # of referrals that this CPM may generate, we need to create a better system of promotion of live donation to patients within the dialysis units – work with the community, organizations like NKF to create a PR campaign to highlight the topic of live donation, so that we can meet the need of a growing volume of patients who need transplant. i.e. NKF has an ad campaign “Save a life – Donate a car” that raises funds for them – we need to create a public ad campaign that highlights the importance and opportunity of donating a kidney – anonymously to someone on the wait list. We’ve had 15 of these transplants/donations anonymously in our state without any advertising – I think we have a large potential to reduce the wait list issue if we were to present this issue as a community problem – not a transplant only problem.

Key point to include – transplant is better for patient than is dialysis. Proposed CPM says (infers) tx work-up within 12 months is “ok”. I recommend 6 months is a better starting point – 3 months should be the goal. Patient appears to get lost when everyone is saying “not my responsibility”.

Transplant education is the responsibility of the transplant experts, not the dialysis team. Accountability for transplant referrals/outcome processes have never been consistently reviewed (i.e. most transplant centers don’t consistently F-U on patients >5 years out or those seen by nephrologists, subsequently they are LTFU and removed from outcomes measures)

A list of project members would have been helpful.

I’m a member of the TEP, so shouldn’t comment on this.

As RE: comment from Dr. Hakim that discussion is responsibility for nephrologist not dialysis team: all ESRD patients should be educated about transplant as a treatment option. This can be done by the nephrologist and/or a qualified member of the dialysis team (nurse, social worker). When education is provided by a non-physician, the patient should be made aware that a discussion with the nephrologist is appropriate for advice.
The patient should also know that he/she has the absolute right to a transplant evaluation regardless of the nephrologist’s opinion.

The idea that withholding information from a patient because it might cause “angst” (as suggested by another questioner) is not “patient-centered” – it is the kind of paternalism that I hoped had disappeared from healthcare!

This is a progressive project that intends to improve the quality of life for patients and cost-effective. This should be rushed forward.

Very informative. The members of the Technical Expert Panel should be listed on materials distributed.
Appendix F

Developing Dialysis Facility-Specific Kidney Transplant Referral Measures

Technical Expert Panel - Meeting 3 Summary
April 15, 2005

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III. Proposed Measures Review
IV. Proposed Data Collection Forms
V. Proposed Pilot Project
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VII. Panel Members & Observers

On April 15, 2005, a third meeting of the Technical Expert Panel (TEP) was convened to assist the contractor (ESRD Network 9/10) in developing dialysis facility-specific kidney transplant referral measures. This meeting followed an ESRD Stakeholders meeting held by CMS on April 14, 2005. TEP members include transplant surgeons; facility representatives including large dialysis organizations (LDOs); a transplant recipient; a transplant coordinator; representatives from a kidney patient organization, managed care organization, quality improvement organization and the Scientific Registry of Transplant Recipients; and CMS representatives. Observers included additional CMS staffers and representatives from UNOS and Computer Science Corporation. A complete listing of those in attendance at the end of the document.

I. Purpose

The goal of the meeting was to obtain input from experts on the development of dialysis facility-specific kidney transplant referral measures, to discuss public comments received at the Stakeholders meeting on April 14, 2005, and to formulate a plan for pilot testing the proposed measures. These measures will assess and track steps in access to transplantation and will be used for quality improvement interventions and for public reporting at the dialysis facility level.

This meeting was the third of three TEP meetings. This project will result in a formal document with recommended transplant referral measures to CMS in June 2005.
II. Overview

Ashwini Sehgal, MD, Clinical Coordinator, gave a presentation, outlining the draft proposed measures and descriptors, a description of a proposed pilot project, and issues relating to the proposed pilot project. Following that discussion, draft data collection forms were reviewed and discussed by Susan Stark, Executive Director of The Renal Network, Inc. Comments were solicited from TEP members and observers and final steps in fulfilling the contract were discussed.

III. Proposed Measures Review

Dr. Sehgal reviewed the following schematic diagram below to outline the steps in the transplant process. He stressed that events do not always occur in this order, as a patient may move ahead a step or go back a step, depending on individual circumstances. The horizontal line divides the process: steps above the line are under the influence of dialysis facilities and steps below the line are under the influence of transplant centers. Discussion, referral and waitlisting/living donor transplant are CPMs and interest, contraindications and deceased donor transplant are descriptors.

Each proposed measure and descriptor was reviewed with the TEP panel and additional comments were collected.
Clinical Performance Measure: Incident Patient Discussion

Data Collection Question: Patient and/or representative acknowledge that nephrologist or dialysis team has discussed, within 90 days of initiation of dialysis at the current facility, the option of transplantation.

a. Yes
b. No

Measure: Percent of patients and/or patient representatives who acknowledge that nephrologist or dialysis team has discussed, within 90 days of initiation of dialysis at the current facility, the option of transplantation

Numerator: Yes response

Denominator: All incident patients of dialysis facility (i.e. <90 days at current facility)

Potential Data Sources: Long term care plan, other parts of the dialysis facility medical record

Applicable Setting: Dialysis facility

Clinical Performance Measure: Prevalent Patient Discussion

Data Collection Question: Patient and/or representative acknowledge that nephrologist or dialysis team has discussed, within the last 12 months, the option of transplantation.

a. Yes
b. No

Measure: Percent of patients and/or patient representatives who acknowledge that nephrologist or dialysis team has discussed, within the last 12 months, the option of transplantation

Numerator: Yes response

Denominator: All prevalent patients of dialysis facility (i.e. >90 days at current facility)

Applicable Exclusions: Patients with permanent exclusions to transplantation
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Potential Data Sources: Long term care plan, other parts of the dialysis facility medical record

Applicable Setting: Dialysis facility

TEP Comments:
Definition/content of discussion:
- Need to provide definition of discussion. If physician tells a patient that they are not a candidate for transplant, should that count as the discussion and do we check off yes? Need to address does a patient that clearly is not a transplant candidate, need to have full education provided?
- Stakeholders made the point that discussion criteria need to be defined.
- Might be better to provide bulleted list of what that discussion might include vs. did you have the discussion?
- We could define elements to include discussion and have a check off box for each, such as contraindications. List of elements could include: outcomes of transplants (benefits/risks), types of transplants (living/deceased donor), what is involved in referral and evaluation process, financial considerations, what is the next step, and, if discussed by someone other than nephrologist, what needs to be discussed with their nephrologist.

Educational issues:
- Stakeholders made the point that we need well developed educational materials and consistency of that material; education needs to be consistent to ensure that all necessary information is presented.
- Standardized packet development is a good idea, but it is not part of this project.

Contraindications:
- Contraindications should be first step. No need to hold detailed discussion otherwise.
- TEP members felt the transplant community has a responsibility to clearly define contraindications to transplant. AST/ASTS need to get together and provide a list and guidance in this regard. Some members are willing to write a letter urging this action, as it will be necessary to comply if proposed Conditions of Participation for transplant centers are implemented as proposed. It was suggested that Dr. Sehgal take the lead in this effort to write a letter stating that the CPM necessitates discussion with patients and it is a practical important manner to define who is appropriate for this discussion. Therefore we need guidance from the transplant community as to who to rule out immediately as not appropriate for the discussion. Otherwise, everyone needs to have the discussion and here is the content of the discussion.
Measurement issues:
- Could determine what constitutes substantive discussion and define the measurement population. Will need to make clear this doesn’t define the clinical population.
- Could have two denominators. First to include all patients, used for internal quality improvement and the second to exclude those with contraindications, used for public reporting. There was some concern about this since contraindications are not well defined. There is some distrust in the system and concern that some patients will be denied transplant option by hiding behind exclusions.

Physician directed discussion:
- Need to have a physician order to nursing staff to discuss transplant with patients if physician is going to delegate this responsibility.
- Not just any staff should discuss this with patient. A patient could believe misinformation from a dialysis technician more than information from the physician.
- First responsibility lies with physician, but performance measures lie with unit and they are responsible to see that this gets done. If not done, then unit must do it. Community must accept that it is the physician responsibility and if not done, that he is breaking the rules. Suggests discussing this with RPA, AMA, etc.
- If staff/physician disagree, it is not professional for the staff to contraindicate the physician to the patient directly. Staff could go to physician’s supervisor with concern, but should not tell this to patient.
- If patient/physician disagree, patient can always get a second opinion.
- Would like CMS to allow physician-specific data to be collected so this can be tracked and feedback to physicians.

Current regulations:
- Team is currently held responsible for holding this discussion in current conditions for coverage.

Calculation Descriptor: Interest

Data Collection Question: Does patient want to be evaluated for kidney transplantation?

a. Yes
b. Undecided (specify why)
c. No (specify why)

Descriptor: Number of patients who want to be evaluated for kidney transplantation
Numerator: Not applicable

Denominator: Not applicable

Applicable Exclusions: Patients with permanent exclusions to transplantation

Potential Data Sources: Long term care plan, other parts of the dialysis facility medical record

Applicable Setting: Dialysis facility

Purpose of Measure: To calculate denominator for subsequent CPM

TEP Comments:

- Consider using term “existing” instead of, or in addition to, the word “permanent” or consider separate denominator.

Calculation Descriptor: Contraindication

Data Collection Question: Are there any contraindications to referring patient for transplant evaluation?

  a. Yes (specify contraindication)
  b. No

Descriptor: Number of patients with contraindications to referral for transplant evaluation

Numerator: Not applicable

Denominator: Not applicable

Applicable Exclusions: None

Potential Data Sources: Long term care plan, other parts of the dialysis facility medical record

Applicable Setting: Dialysis facility

Purpose of Measure: To calculate denominator for subsequent CPM
TEP Comments:

- Comment at Stakeholders meeting to have networks collate information on transplant center contraindications and distribute that to dialysis facilities within the network area.
- This would be fine, but physician needs to determine whose exclusions to follow.

**Clinical Performance Measure: Referral to Transplant Center**

Data Collection Question: Has patient been referred to a transplant center for an evaluation?
- c. Yes (specify who referred, how referred, name of transplant center, and date)
- d. No (specify reasons for not referring)

Measure: Percent of patients referred to a transplant center for evaluation

**Numerator:** Yes response

**Denominator 1:** All patients  
**Denominator 2:** Exclude patients with contraindications  
**Denominator 3:** Exclude uninterested patients  
**Denominator 4:** Exclude patients with contraindications, uninterested patients

**Applicable Exclusions:** Varies based on denominator

**Potential Data Sources:** Long term care plan, other parts of the dialysis facility medical record

**Applicable Setting:** Dialysis facility

TEP Comments:

**Data collection issues:**
- Burden on dialysis facilities to prove referral is made. Difficult to document phone calls. Suggest requiring this be a written document, and requiring a written document back from the transplant center.
- The process needs to be improved, however what is written here is what can be done now. Phone calls are a common way that referrals are made. Last TEP meeting we discussed benefit of a coordinated referral system.
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- Concerned that an acknowledgement from the transplant center be received so it is clear that the responsibility has been passed to the transplant center.
- Consider another denominator to differentiate temporary contraindications from permanent contraindications.

Clinical Performance Measure: Waiting List/Living Donor Transplant

Data Collection Question: Was patient placed on deceased donor waiting list or did patient receive living donor transplant within twelve months after referral to transplant center?

a. Yes, placed on waiting list (specify date)
b. Yes, received living donor transplant (specify date)
c. No (specify reasons)

Measure: Percent of referred patients who were placed on deceased donor waiting list or received a living donor transplant within twelve months after referral to transplant center

Numerator: Any yes response

Denominator 1: All patients referred to a transplant center
Denominator 2: Exclude patients who are not transplant candidates after pre-transplant workup

Applicable Exclusions: Denominator 1: Patients not referred to transplant center; Denominator 2: Patients not referred to transplant center and patients not transplant candidates after pre-transplant workup

Potential Data Sources: UNOS, Scientific Registry of Transplant Recipients

Applicable Setting: Transplant Center

TEP Comments:

Denominator 1 Issues:
- Need to determine what perspective this should be collected: all dialysis facility patients referred to any transplant center vs. all dialysis facility patients referred to X transplant center, Y transplant center, etc. vs. all patients referred to X transplant center from any dialysis facility.
- Need to specify that a patient is listed on “active” transplant waiting list for X number of days to exclude patients who are placed on transplant list,
but have not yet had workup. This practice is increasingly common in urban transplant centers.

Unlisting Issues:
- If someone is on the list, but then comes off the list, how do we answer this CPM? It was determined that once a patient is on active list for X number of days, that the workup has been completed.
- There is currently no process in place for dialysis facilities to communicate patient medical changes that impact suitability for transplant. Transplant centers can remove a patient from the active wait list if they know of a newly identified contraindication (permanent or temporary), however the UNOS data does not specify why someone has been taken off active status. This should be discussed as an issue in the final report, but doesn’t affect this project today.
- Although it is beyond the scope of this particular project, a communication structure between dialysis facilities and transplant centers must be established. Communication regarding patient from transplant centers should be sent to the dialysis facility in addition to being sent to the nephrologist.

Calculation Descriptor: Deceased Donor Transplant

Data Collection Question: Has patient received a deceased donor kidney transplant?
   1. Yes (specify date)
   2. No

Descriptor: Number of patients who have received a deceased donor kidney transplant

Numerator: Not applicable

Denominator: Not applicable

Applicable Exclusions: Patients not on deceased donor waiting list

Potential Data Sources: UNOS, Scientific Registry of Transplant Recipients

Applicable Setting: Transplant center

Purpose of Measure: Quality improvement and public reporting
TEP Comments:

- Many wait-listed patients will get a living donor transplant. Consider changing to say has patient received a kidney transplant rather than specifying deceased donor here.

- Change UNOS to SRTR/OPTN or “SRTR or OPTN”. Order of OPTN and SRTR is not important.

IV. Proposed Data Collection Forms for Pilot Project

A form was drafted as a possible addendum to the long term care plan. The form was reviewed with TEP members and substantial changes were suggested.

- Date of discussion would be the acknowledgement date on this form. Suggestion was made to change this to a check-off box.

- Patient signature will be required so this form would stand alone to answer the CPMs.

- Suggestion made to create check-off boxes for nephrologist, staff, or both to denote who held discussion. Need to also collect nephrologist name on the form. Consider including name of person who did the patient education. Consider having the direct statement “I informed patient of his treatment modalities, including transplant” with a date and signature as part of the form.

- Would like form to modify behavior rather than just collect data if possible.

- Would like form to complete picture of transplant status for patient, even if information is not necessary to answer a CPM. Adding dates may be a burden.

- URREA already links patient dialysis unit to patient records

- Transplant Candidacy Status section – check off boxes for:
  - Is a candidate for transplant
    - Patient referred to transplant center for evaluation (date, where, who referred, how referred)
    - Living donor transplant is scheduled
    - Patient is on deceased donor waiting list
    - None of the above (why not)
  - Is not a candidate for transplant
    - Contraindicated due to advanced age and significant co-morbidity (possible drop-down list – severe cardiac disease, severe peripheral occlusive vascular disease, nonskin cancer, advance liver disease, infection, dementia, psychosis, other (specify))
    - Contraindicated due to general condition
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- Contraindicated due to medical complication (specify; use pull-down menu)
- Contraindicated due to psychological/mental complication
  
  o Patient declines transplant option (why)
  
  o None of the above
    
    ▪ Physician judgment or refuses to refer
    ▪ Patient undecided concerning transplant option (provide reason(s) why)
    ▪ Financial reasons (free text or pull down menu to determine if this is impacting referral, waitlisting)
    ▪ Noncompliance (specify, (ex. overweight, drug abuse, skips treatments))
    ▪ Other (specify)

V. Proposed Pilot Project

- Needs to be done prospectively, but then hard to fit into one year pilot project if piggy-backed onto annual CPM data collection.
- Need to first educate facilities about pilot project and data collection requirements.
- Either have many facilities with a few patients included per facility or few facilities with all patients included per facility.
- Consider 10-20 volunteer facilities in 2 or 3 renal networks, as long-term care plan due to be updated, use new supplement and submit form to us.
- Proposed timeline reviewed
  
  o Month 1 – recruit facilities
  o Months 2 & 3 – educate facilities on project and data collection tool
  o Months 4-9 – collect data using tool in concert with completing patient long-term care plan. Submit data form for patients completed monthly. Network staff monitor submissions and assist as needed
  o Months 8-9 – Network staff validate subset of completed data collection forms by patient interview and chart abstraction
  o Month 10 – analyze data
  o Month 11 – convene TEP meeting to review pilot process and results
  o Month 12 – final report and modified data collection tool to CMS

- Benefits of proposed pilot include prospective data collection, network staff can assist facilities and closely monitor data collection, and it could be completed within one fiscal year.
TEP Comments:

- Need equal focus on transplant centers and dialysis facilities.
- Consider piloting in an area with limited transplant centers to determine feasibility. Example 3 clumps – 2 where limited transplant centers and 1 where many transplant centers.
- Suggest a large sample to obtain sufficient free text options.
- Suggest geographically diverse areas, some where patients located near transplant center and others where patients are located far from transplant center.
- Pilot seems ambitious. Consider a shorter pilot first to be sure data form and questions are obvious and answered as intended.
- Avoid homogeneous facilities.
- Need to clearly define objective of the pilot.
- Look at current waitlist rates and sample from those with lower, medium and higher rates to get a representative sample. URREA has the data.
- Consider first on incident patients.
- Ms. Stark: At this point there is no funding for the pilot. We will describe the “ideal” pilot, but may need to scale back. CMS will need to tell us when and if there is funding available to do it. This project shouldn’t go on without a pilot, but we need to describe something reasonable within the terms of the budget. Struggling with how to collect this data. Traditionally this data is collected at one point in the year, but long-term care plans are filled out at various times throughout the year. Can we look at data whenever it is completed, or will we need to force facilities to complete this data at a particular point in time?
- Ms. Frederick: These issues need to go into final report. Need to address national implementation, particularly how to educate all facilities nationally. How will data collection form be disseminated? There are issues related to national implementation in addition to issues related to the pilot project. Try to address those issues, or put them together so we at CMS can understand the scope of the issue. We may ask other agencies within CMS that collect similar data to see how they do it.
- Ms. Stark: We requests that data be taken from long-term care plan instead of forcing facilities to collect data at one point in time.
- This data is not that different to collect from determining if a vaccine was given over the course of a year.
- At least send out 10-12 data forms to determine if questions are appropriate to collect information that we are looking for, even if funds are limited. A feasibility test is easier than a real pilot test. This is looking at burden of collection, reliability of data, etc.
• Ms. Stark: Our original intent was to add a form to the CPM data collection, but we think this type of data form tagged to the long-term care plan will give us more information to help facilities monitor this process without excess burden. We have also considered using Chicago, Indianapolis, Cleveland, etc. as pilot study areas so our staff can do validation testing.

• Getting coherent contraindication and qualification lists from transplant centers may be a limiting factor in pilot testing.

• Consider reordering data collection form by putting contraindication descriptor item first.

• Include a data elements list in the final report.

VI. Next Steps.

The contractor will modify the draft clinical performance measures based on stakeholder and TEP member comments. A list of final proposed measures is due to CMS on June 1, 2005. This document will be distributed to TEP members for additional comment before sending to CMS. The Final Project Report will summarize the work completed for each task of this project and include the final proposed measures, data collection questions, numerators, denominators, and descriptors. Modified data collection tools and a proposed pilot testing plan and budget will also be included in the report. The Final Project Report is due to CMS June 30, 2005.

VIII. Technical Expert Panel, Consultants, Staff & Observers.

Teri Arthur, MSW, LSW, University of Chicago
Francis Delmonico, MD, Harvard University
Erick B. Edwards, Ph.D., United Network of Organ Sharing (UNOS)
Jens Goebel, MD, Cincinnati Children’s Hospital Medical Center
Richard Goldman, MD, RPA & the Forum of ESRD Networks (absent)
Bonita Balkcom Guilford, Transplant Recipient, ESRD Network 6
Lawrence G. Hunsicker, MD, University of Iowa Health Care
Mysore S. Anil Kumar, MD, Drexel University College of Medicine
J. Michael Lazarus, MD, Fresenius Medical Care-North America
Keith Mentz, Chief Executive Officer, Nephrology, Inc. (absent)
Kim E. Phillips, MSN, RN, CCTC, U. of Utah Solid Organ Transplant Services
Kris Robinson, American Association of Kidney Patients
Marlon Yu, RN, Kaiser Permanente.

Project Consultants:
Alan Leichtman, MD, University Renal Research & Education Association
Jonathan Sugarman, MD, MPH, Qualis Health
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CMS Representatives:
Brady Augustine (absent)
James Bowman, MD
Pamela Frederick, MSB
Jayne Hammen
Kathy Hudson
Deborah Read, Project Officer (absent)
Barry Straube, MD (absent)

eSource/CSC Representatives:
Andy Hanks, MBBS, Computer Sciences Corporation (absent)
Shannon Wright, BSW, PMP, Computer Sciences Corporation

Contractor Network 9/10:
Ashwini Sehgal, MD, MetroHealth Medical Center, Clinical Coordinator
Janeen Leon, MS, RD, LD, MetroHealth Medical Center, Project Coordinator
Melissa Aulisio, MNO, Project Assistant
Jay W. Wish, MD, President
George Aronoff, MD, MRB Chair (absent)
Susan A. Stark, Executive Director
Bridget Carson, Assistant Director
Raynel Kinney, RN, CNN, CPHQ, Quality Improvement Director

CMS Observers:
Teresa Casey, RD, LD
Gina Clemons
Diane L. Frankenfield, DrPH
Eva Fung
Heather Grimsley
Judith Kari
Mathew Leipold
Condict Martak
Siddhartha Mazumdar
Marcia Newton
Eileen Zerhusen

URREA Observer:
Valarie Ashby, Kidney Epidemiology and Cost Center, University of Michigan
## Appendix G
Data Elements for Dialysis Facility-Specific Kidney Transplant Referral Clinical Performance Measures

<table>
<thead>
<tr>
<th>CPM/Descriptor</th>
<th>Element</th>
<th>Definition/Acceptable Values</th>
<th>Data Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPM A Incident Patient Discussion</td>
<td>Date of first dialysis at current facility.</td>
<td>mm/dd/yyyy</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>CPM A Incident Patient Discussion</td>
<td>Did treatment start within last 12 months?</td>
<td>1 Yes 2 No 3 Unknown</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>CPM A Incident Patient Discussion</td>
<td>Patient acknowledgement that discussion of kidney transplantation option occurred within 90 days of first dialysis at current facility.</td>
<td>1 Yes 2 No 3 Unknown</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>CPM A Incident Patient Discussion</td>
<td>Number of incident patients in dialysis facility (i.e. &lt; 90 days at current facility).</td>
<td>X Digit Number</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>CPM B Prevalent Patient Discussion</td>
<td>Patient acknowledgement that discussion of kidney transplantation option occurred within last 12 months.</td>
<td>1 Yes 2 No 3 Unknown</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>CPM B Prevalent Patient Discussion</td>
<td>Number of prevalent patients in dialysis facility (i.e. ≥ 90 days at current facility).</td>
<td>X Digit Number</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>CPM B Prevalent Patient Discussion</td>
<td>Number of prevalent patients with permanent contraindications to kidney transplantation</td>
<td>X Digit Number</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>Interest Descriptor</td>
<td>Patient interest in transplantation</td>
<td>1 Yes 2 Undecided 3 No 4 Unknown</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>Interest Descriptor</td>
<td>Reason undecided (if applicable)</td>
<td>Free text</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>Interest Descriptor</td>
<td>Reason uninterested (if applicable)</td>
<td>1 Financial burden 2 Medical complication 3 Age 4 Satisfied w/dialysis 5 Other</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>Interest Descriptor</td>
<td>Uninterested reason other</td>
<td>Free text</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>Contraindication Descriptor</td>
<td>Presence of contraindication</td>
<td>1 No 2 Unknown 3 Yes</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>Contraindication Descriptor</td>
<td>Contraindication identifier cutting point</td>
<td>Who determined contraindication present? 1 Transplant Center 2 Dialysis Facility</td>
<td>Dialysis Facility</td>
</tr>
</tbody>
</table>
### Appendix G
Data Elements for Dialysis Facility-Specific Kidney Transplant
Referral Clinical Performance Measures

<table>
<thead>
<tr>
<th>CPM/Descriptor</th>
<th>Element</th>
<th>Definition/Acceptable Values</th>
<th>Data Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contraindication Descriptor</td>
<td>Contraindication reason (if applicable)</td>
<td>1 Severe cardiovascular disease 2 Severe peripheral occlusive vascular disease 3 Active non-skin cancer 4 Dementia 5 Psychosis 6 Noncompliance 7 Severe obesity 8 Other</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>Contraindication Descriptor</td>
<td>Contraindication reason other (if applicable)</td>
<td>Free text</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>CPM C Referral to Transplant Center</td>
<td>Patient referred to transplant center</td>
<td>1 Yes 2 No 3 Unknown</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>CPM C Referral to Transplant Center</td>
<td>Date referred to transplant center (if applicable)</td>
<td>mm/dd/yyyy</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>CPM C Referral to Transplant Center</td>
<td>Who referred patient (if applicable)</td>
<td>1 Nephrologist 2 Patient 3 Nurse 4 Social Worker 5 Secretary 6 Other</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>CPM C Referral to Transplant Center</td>
<td>Who referred patient other (if applicable)</td>
<td>Free text</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>CPM C Referral to Transplant Center</td>
<td>How patient referred (if applicable)</td>
<td>1 Written communication 2 Phone call 3 Other</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>CPM C Referral to Transplant Center</td>
<td>How patient referred other (if applicable)</td>
<td>Free text</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>CPM C Referral to Transplant Center</td>
<td>Nonreferral reason (if applicable)</td>
<td>1 Contraindication 2 Physician judgment 3 Patient uninterested/undecided 4 Pt already on waitlist 5 Other</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>CPM C Referral to Transplant Center</td>
<td>Nonreferral reasons other (if applicable)</td>
<td>Free text</td>
<td>Dialysis Facility</td>
</tr>
<tr>
<td>CPM C Referral to Transplant Center</td>
<td>Total number of patients in dialysis facility</td>
<td>X Digit Number</td>
<td>Dialysis Facility</td>
</tr>
</tbody>
</table>
## Appendix G
### Data Elements for Dialysis Facility-Specific Kidney Transplant Referral Clinical Performance Measures

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</tr>
</thead>
<tbody>
<tr>
<td>CPM C Referral to Transplant Center</td>
<td>Number of patients with contraindication to transplant</td>
<td>X Digit Number</td>
<td>Contraindication descriptor</td>
</tr>
<tr>
<td>CPM C Referral to Transplant Center</td>
<td>Number of patients uninterested in transplant</td>
<td>X Digit Number</td>
<td>Interest descriptor</td>
</tr>
<tr>
<td>CPM C Referral to Transplant Center</td>
<td>Number of patients undecided about kidney transplantation</td>
<td>X Digit Number</td>
<td>Interest descriptor</td>
</tr>
</tbody>
</table>

## Data Elements for Proposed Transplant Center-Specific Measures

<table>
<thead>
<tr>
<th>CPM/Descriptor</th>
<th>Element</th>
<th>Definition/Acceptable Values</th>
<th>Data Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPM D Waiting List/Living Donor Transplant</td>
<td>Date patient placed Active Status (Status 1)</td>
<td>mm/dd/yyyy</td>
<td>SRTR/OPTN</td>
</tr>
<tr>
<td>CPM D Waiting List/Living Donor Transplant</td>
<td>Date received living donor transplant</td>
<td>mm/dd/yyyy</td>
<td>SRTR/OPTN</td>
</tr>
<tr>
<td>CPM D Waiting List/Living Donor Transplant</td>
<td>Reason not Active Status (status 1) or not did not receive living related donor transplant within 12 months of referral to transplant center</td>
<td>Free text</td>
<td>Transplant Center</td>
</tr>
<tr>
<td>CPM D Waiting List/Living Donor Transplant</td>
<td>Number of patients not referred to transplant center</td>
<td>X Digit Number</td>
<td>CPM C Referral to Transplant Center</td>
</tr>
<tr>
<td>CPM D Waiting List/Living Donor Transplant</td>
<td>Number of patients not transplant candidates after pre-transplant workup</td>
<td>X Digit Number</td>
<td>Transplant Center</td>
</tr>
<tr>
<td>Deceased Donor Transplant Descriptor</td>
<td>Date received deceased donor transplant</td>
<td>mm/dd/yyyy</td>
<td>SRTR/OPTN</td>
</tr>
</tbody>
</table>
APPENDIX H
TRANSPLANT REFERRAL MEASURES
PILOT DATA COLLECTION FORM

Patient Name: __________________   Patient ID #: _____________ Date:_______________

Dialysis Facility: ______________________________________________________________

Nephrologist: ________________________________________________________________

Individual Completing Form: ____________________________________________________

Phone: __________________ Fax: _______________________ E-Mail: _________________

Date of First Dialysis at this Facility: ___/___/___

Answer the questions below using the patient’s dialysis facility medical record. Be sure
to check the most appropriate reasons for response when asked to do so. Do not leave
any questions blank. Answer “Unknown” if the information cannot be located.

Answer questions 1 and 2 if the patient is new to your dialysis facility:

1. Did this patient initiate dialysis AT YOUR FACILITY within the last 12 months?  
   □ Yes (go to question 2)  
   □ No (go to question 3)  
   □ Unknown

2. Did the patient and/or representative acknowledge that the nephrologist or dialysis team
discussed, within 90 days of initiation of dialysis at your facility, the option of
transplantation?  
   □ Yes (go to question 4)  
   □ No (go to question 4)  
   □ Unknown (go to question 4)

Answer question 3 if the patient has been dialyzing at your facility for more than 12
months:

3. Did the patient and/or representative acknowledge that the nephrologist or dialysis team
discussed, within the last 12 months, the option of transplantation?  
   □ Yes  
   □ No  
   □ Unknown

4. Does the patient want to be evaluated for a kidney transplant?  
   □ Yes  
   □ No (specify why)  
      □ Financial barrier  
      □ Medical complication  
      □ Age  
      □ Satisfied with dialysis  
      □ Other ___________________________________________________________
   □ Undecided (specify why) _______________________________________________
   □ Unknown
5. Are there any contraindications to referring patient for transplant evaluation?
   □ No (go to 6)
   □ Unknown (go to 6)
   □ Yes, contraindication determined by: □ Transplant Center □ Dialysis Facility (go to 5a)

5a. Specify contraindication(s):
   □ Severe cardiovascular disease
   □ Severe peripheral occlusive vascular disease
   □ Active non-skin cancer
   □ Advanced liver disease
   □ Active infection
   □ Dementia
   □ Psychosis
   □ Noncompliance
   □ Severe obesity
   □ Other (specify) ________________________________

6. Has the patient been referred to a transplant center for an evaluation?
   □ Yes, specify date ____/____/_____ (go to 6a)

6a. Specify who referred patient: (go to 6b)
   □ Nephrologist
   □ Patient
   □ Nurse
   □ Social worker
   □ Secretary
   □ Other______________________________

6b. Specify how patient was referred:
   □ Written communication (letters, standard form, email)
   □ Phone call
   □ Other______________________________

 □ No (go to 6c)

6c. Specify reasons for not referring:
   □ Contraindication(s)
   □ Physician judgment or refuses to refer
   □ Patient not interested/undecided
   □ Patient already on the waitlist
   □ Other (specify) ________________________________

 □ Unknown
Instructions For Completing Questions 1 Through 6: Review the patient’s clinic or facility medical record. Be sure to check the most appropriate reasons for response when asked to do so. Do not leave any questions blank. Answer “Unknown” if the information cannot be located.

1. Check the appropriate space to indicate if the patient initiated dialysis AT YOUR FACILITY within the last 12 months. If “Yes”, go to question 2. If “No” or “Unknown” go to question 3.

2. Specify whether a nephrologist or dialysis team member discussed, within 90 days of initiating dialysis AT YOUR FACILITY, the option of transplantation. Then go to question 4.

3. Specify whether a nephrologist or dialysis team member discussed, within the last 12 months, the option of transplantation for those patients who have been dialyzing at your facility for longer than 12 months. Then go to question 4.

4. Check the appropriate space to indicate if the patient is interested in being evaluated for a kidney transplant. If “No” is the choice selected, check all the appropriate reasons for the patient not wanting to be evaluated for a kidney transplant. If “Undecided” is the choice selected, specify the reason why.

5. Check the appropriate space to indicate if there is any contraindications to referring the patient for transplant evaluation. If “No” or “Unknown” go to question 6. If there are contraindications, check who determined the contraindication (Transplant Center or Dialysis Facility) and then choose all the contraindications that would apply from the list in question 5a.

6. Check the appropriate space to indicate if the patient has been referred to a transplant center for an evaluation. If “Yes”, provide the date the referral was made. Then go to 6a and specify who referred the patient. Specify by choosing from the reasons in 6b how the patient was referred. If “No”, check the appropriate space to indicate all the reasons that the patient was not referred for kidney transplant.
APPENDIX I

TRANSPLANT REFERRAL MEASURES
PILOT CARE PLANNING SUPPLEMENT

Patient Name: ________________________________   Patient ID #: __________________

Dialysis Facility: _____________________________________________________________

Nephrologist: ___________________    Date of First Dialysis at this Facility: ___/___/___

Date transplant option discussed:  ___/___/___

Discussed by: __________________________

A.  Candidate for transplant  (Check all that apply)
   □ Patient referred to Transplant Center
      Referral date: ___/___/___   Transplant Center: _______________________
      Who made referral:
         □ Nephrologist □ Patient □ Secretary □ Nurse
         □ Social Worker □ Other:
      Referral Method:
         □ Letter □ Standard Form □ Email
         □ Phone □ Other:
   □ Living donor transplant scheduled
   □ Patient active status on deceased donor waiting list
   □ None of the above. Why not?: __________________________________________

B.  Not a candidate for transplant determined by  □ Transplant Center  □ Dialysis Facility
   Contraindicated due to: (Check all that apply)
   □ Medical complication. Specify: _______________________________________
   □ Psychological/mental complication. Specify: ____________________________
   □ Financial barrier. Specify: ___________________________________________
   □ Other. Specify: _____________________________________________________

C.  Patient declines transplant option  (Check all that apply)
   □ Financial barrier. Specify: ___________________________________________
   □ Undecided concerning transplant option. Specify: _______________________
   □ Other. Specify: _____________________________________________________

D.  None of the above  (Check all that apply)
   □ Other. Specify: _____________________________________________________

Patient Signature: ___________________________________________  Date: ___/___/___

Nephrologist Signature: _______________________________________  Date: ___/___/___