

The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

Task 1a: Vascular Access Quality Improvement Project	
Project Title: Prevalent Fistula Rate Improvement	
Project Description	<p>CMS, through the Fistula First Breakthrough Initiative, sets prevalent fistula goals for all Networks.</p> <ul style="list-style-type: none"> • Network 9 is expected to improve the prevalent fistula rate by 3.64 percentage points to 51.4% in March 2010. • Network 10 is expected to improve the prevalent fistula rate by 3.34 percentage points to 52.6% in March 2010. <p>This project includes three interventions, Changing Patient Culture, Decreasing Catheters and Community Partnerships, designed to increase prevalent fistula rates Network-wide to meet CMS goals.</p>
Background/ Justification	<p>The 2008-2009 Network 9/10 Prevalent Fistula Rate Improvement QIP included four interventions targeting specific facilities with specific barriers to improvement. The interventions utilized a seven-step project design focused on working with small populations, identifying barriers and implementing process changes to improve prevalent fistula rates in Network 9 and in Network 10. A fifth intervention was designed to provide data feedback in the form of quarterly reports to all facilities in Networks 9 and 10.</p> <p>The 2008-2009 QIP achieved goal in all four of the facility specific interventions in Network 10 and three of the four facility specific interventions in Network 9. It demonstrated that face-to-face learning sessions were associated with a significant improvement in prevalent fistula rates for facilities where representatives were in attendance. However, facilities that were provided with quarterly data feedback only (non-intervention) fell short of goal; this kept both Networks 9 and 10 from reaching the CMS target goal for prevalent fistula rate improvement by the March 31, 2009 deadline.</p> <p>Project momentum continued past the March deadline. In May, Network 10 surpassed the CMS goal by 0.2 percentage points. By the end of June, the Network 9 prevalent fistula rate was still improving but was still short of the CMS goal by 0.3 percentage points. The Medical Review Board concluded that the seven-step project design is a successful intervention strategy for improving prevalent fistula rates and that larger numbers of facilities should be included to better effect Network-wide improvement. Additionally, a more aggressive approach to data feedback in the non-intervention facilities is needed to improve fistula rates in large populations.</p>
Root Cause Analysis (RCA)	<p>Staff and MRB members conducted a root cause analysis in May 2009 to determine why Networks 9 and 10 failed to achieve a 4 percentage point and 3.9 percentage point increase in prevalent fistula rates during the project period, respectively. The RCA included the analysis of:</p> <ul style="list-style-type: none"> • Fistula First dashboard data • A vascular access coordinator (VAC) questionnaire • Phone interviews with facility staff. <p>Fistula First dashboard data analysis revealed:</p>

The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

- Non-intervention facilities fistula rate increases were only 1.54 and 1.89 percentage points for Network 9 and 10 respectively. The expected rate was 4 percentage points based on an actual average of a 4.52 percentage point increase per year seen in this group from March 2005 to March 2008. Our expectations were that this group would continue to increase and that this increase in fistulae for the 2008-2009 project would be at least 4.0 percentage points. Providing a quarterly report to key facility staff with no other focused intervention was insufficient for the non-intervention facilities to be able to sustain the historical (yearly) 4.52 percentage point increase this year.
- The prevalent catheter rate decreased but remains high at 30.3% in Network 9 and 30.5% in Network 10.
- The intervention facilities experienced an increase in fistula rate between 2.79 and 6.30 percentage points in Network 9 and between 3.21 and 9.06 percentage points in Network 10.
- All of the intervention groups except for the Network 9 VA Coordinator project achieved a minimum 4 percentage point increase in fistula rate.

Network staff contacted the Network 9 facility vascular access coordinators that did not meet goal to learn why the facilities had not improved. An analysis of the facility systems revealed several common factors including:

- Patient refusal
- Communication barriers between facilities and surgeons and hospitals
- Patients starting dialysis with a catheter only

The results of a questionnaire (sent to 535 facility VACs) designed to evaluate the project interventions revealed that vascular access coordinators lack:

- Tools regarding patient education
- Continuous feedback to be used in vascular access management QAPI
- Learning session opportunities that provide networking opportunities
- Information on best practice models (spread)
- Information on developing patient care processes with outside facility caregivers that effect fistula placement (surgeon offices, vascular access centers, hospital discharge planners)

The RCA concluded:

1. Future interventions will need to take into account the decreasing return that can be expected as AVF rates increase.
2. The rate of rise in the non-intervention group was over estimated.
3. The reliance of this QIP on continued increases in the non-intervention facilities resulted in the negative variance observed. The vascular access quarterly report alone did not give the non-intervention facilities enough incentive to sustain the fistula improvements from the past four years.
4. The number of facilities in the intervention group was too small.

The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

	<p>Improvements in fistula rates will require more intensive interventions in larger populations of hemodialysis patients.</p> <p>5. The rate of rise in Network 9 for the VAC intervention was too small. Analysis of the specific intervention shows a lack of facility involvement in the process with only 50% providing information to the Network regarding their VAC plan. This percentage fell to under 30% when participating facilities were asked to participate in a WebEx or learning session. Increasing facility involvement will be a goal for future activities.</p> <p>6. Future interventions need to include 38% of Network facilities to increase the Network prevalent fistula rate to the CMS goal.</p>
<p>Barriers Identified from RCA</p>	<p>The root cause analysis identified three primary barriers in facility systems to the improvement of prevalent fistula rates.</p> <ol style="list-style-type: none"> 1. High catheter rates due to <ul style="list-style-type: none"> o Incident catheter only o Large catheter only >90 day population o Poor fistula utilization 2. Patient refusal due to <ul style="list-style-type: none"> o Poor staff/patient communication skills o Patient lack of knowledge o Facility culture 3. Lack of communication between facilities and surgeons and hospitals
<p>Goal for Change</p>	<p>Goal - The percentage of patients dialyzing with an AVF on March 31, 2010: Network 9 = 51.4% Network 10 = 52.6%</p> <p>In March 2009, Network 9 had 24,639 hemodialysis patients with 11,815 fistulae equaling 47.8%. Therefore, Network 9 will need at least 986 new fistulae to achieve a 4 percentage point increase in the prevalent patient population to achieve goal.</p> <p>In March 2009, Network 10 had 14,666 patients with 7240 fistulae for 49.3%. Therefore, Network 10 will need at least 587 new fistulae to achieve a 4 percentage point increase in the prevalent patient population to achieve goal.</p>
<p>Numerator/ Denominator</p>	$\frac{\text{Number of hemodialysis patients in Network 9 dialyzing with an AVF}}{\text{Total number of hemodialysis patients in Network 9}}$ $\frac{\text{Number of hemodialysis patients in Network 10 dialyzing with an AVF}}{\text{Total number of hemodialysis patients in Network 10}}$
<p>Measurement & Frequency</p>	<p>Prevalent fistula rates for each participating facility will be reviewed monthly.</p> <p>Each facility that is participating in one of the three interventions will be expected to improve by at least 0.33 percentage points each month with an increase of 1</p>

The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

	percentage point each quarter.
Threshold for action	<ol style="list-style-type: none"> 1. Facilities that are not participating in the monthly activities and/or are not meeting monthly goals will be contacted by Network staff to discuss barriers to the original project plan and assist with changes to processes and actions. 2. Medical Directors of facilities that do not meet quarterly targets will be contacted by physician members of the MRB to discuss their commitment to the project, barriers for attaining goals and process changes that are necessary for improvement. 3. Facilities that refuse to participate in the project will be reported to CMS and the state survey agency.
Population Inclusion/ Exclusion Criteria	<p>Based on prior year results we are making the following assumptions:</p> <ul style="list-style-type: none"> • The non-intervention rate of increase in fistulae will be 1.5 percentage points and the average intervention effect will be 8 percentage points. • The average dialysis facility size is 75 patients. • Algebraically, we determined the percentage of the population in which we need to intervene to have the desired Network increase of 4 percentage points using these assumptions is 38%. <p>In order to assure that we have sufficient facilities to participate and that those facilities have the greatest opportunity for success, we will evaluate those facilities with fistula rates at or below 50.5% (poor performing facilities). This value will allow us to select a sufficient number of underperforming facilities to provide the Network work staff some leeway in selection.</p> <p>Poor performing facilities will be divided randomly into two groups:</p> <ul style="list-style-type: none"> • The first group (facility targeted intervention) - half of the poor performing facilities in Network 9 (n=68) and half in Network 10 (n=40) will be placed in one of three intervention groups based on a facility-specific root cause analysis of their barriers for improving prevalent fistula rates. • The second group (Network-wide-intervention) will receive a letter describing their poor performance, the need for improvement and possible consequences when future reimbursement rates are dependent on facility outcomes, monthly data feedback and bimonthly newsletters.
Project Design/ Methodology	<p>This project will incorporate a seven-step project model in three separate interventions; Changing Patient Culture, Decreasing Catheters and Community Partnerships. The seven steps include:</p> <ol style="list-style-type: none"> 1. Statistical analysis to identify facilities in need of intervention; facilities with outcomes that were at or below 50% prevalent fistulae. 2. Conducting root cause analysis with targeted facilities to discover barriers to improvement at the facility level. 3. Requiring action plans that align with facility QAPI projects addressing barriers from each facility targeted for intervention. 4. Providing monthly conference calls for QIP participants and learning sessions for targeted facilities on topics identified through the RCA.

The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

	<p>5. Collecting facility specific data through the fistula first dashboard and providing participating facilities with data feedback reports monthly.</p> <p>6. Identifying benchmark facilities (defined as those facilities with either a fistula rate at goal or increasing by at least one percentage point per quarter) and sharing tools and resources with participating facilities.</p> <p>7. Analysis of facility specific data monthly to determine which facilities are successfully achieving QIP goals and which facilities are in need of additional intervention.</p> <p>These interventions combined with an aggressive approach to data feedback in the non-intervention facilities will be used as the project design this QIP.</p>				
Interventions	<p>I. Facility-Specific Targeted Interventions:</p> <p>Facilities selected for targeted intervention will participate in one of three intervention projects outlined below.</p> <ul style="list-style-type: none"> • Facility medical directors, nurse managers, and VACs will receive an introductory letter outlining their poor performance and an overview of the project. • Facility staff will be asked to attend a “kickoff” WebEx describing the three intervention projects • Facility staff will be asked to complete a RCA to identify barriers to improving fistula rates in their facility. • The results of the RCA will be used to place facilities in one of the following interventions. <p>Three intervention projects have been developed to address the Network 9/10 barriers to facility systems improving prevalent fistula rates. Facilities will participate in the project that best meets their needs based on the completion of a facility-specific RCA.</p> <table border="1" data-bbox="418 1402 1430 1864"> <thead> <tr> <th data-bbox="423 1409 776 1444">Barrier</th> <th data-bbox="781 1409 1425 1444">Intervention</th> </tr> </thead> <tbody> <tr> <td data-bbox="423 1451 776 1858"> <p>High catheter rates due to:</p> <ul style="list-style-type: none"> • Incident catheter only • Large catheter only >90 day population • Poor fistula utilization </td> <td data-bbox="781 1451 1425 1858"> <p>Decreasing Catheters</p> <p>Facilities will complete a root cause analysis identifying the reasons for a high catheter rate:</p> <ol style="list-style-type: none"> a. High percentage of new patients starting with catheter only b. High percentage of catheter only >90 days c. High percentage of catheters with maturing AVF (AVF utilization/maintenance) d. Or other reason that is identified <p>The facilities will be advised to initiate a process change that will address the barriers to decreased</p> </td> </tr> </tbody> </table>	Barrier	Intervention	<p>High catheter rates due to:</p> <ul style="list-style-type: none"> • Incident catheter only • Large catheter only >90 day population • Poor fistula utilization 	<p>Decreasing Catheters</p> <p>Facilities will complete a root cause analysis identifying the reasons for a high catheter rate:</p> <ol style="list-style-type: none"> a. High percentage of new patients starting with catheter only b. High percentage of catheter only >90 days c. High percentage of catheters with maturing AVF (AVF utilization/maintenance) d. Or other reason that is identified <p>The facilities will be advised to initiate a process change that will address the barriers to decreased</p>
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The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

		catheters/increased fistula in their facility. Network staff will provide specific tools and resources to assist in process change and plan development.
	<p>Patient refusal due to:</p> <ul style="list-style-type: none"> • Poor staff/patient communication skills • Patient lack of knowledge • Facility culture 	<p>Changing Patient Culture</p> <p>The Network has developed and will be providing two products for use by the participating facilities:</p> <ol style="list-style-type: none"> a. "Helping Patients Make Healthy Fistula Choices" is a program designed to educate staff on techniques to help identify a patient's readiness to have a fistula placed or used and techniques in listening and empathy. Utilizing this teaching module will assist staff in discussing best care options with the patients. It will also identify patient fears and patient barriers to fistula placement and usage in order to assist staff in addressing those issues. b. The Fistula Coaching Program is designed to promote the best vascular access choice among patients through peer-to-peer education, communication, planning and problem solving. The program is provided through a trained, facility-based, patient volunteer program. Utilizing this teaching module will identify a patient champion that will be able to have a dialogue with the patient opposed to a fistula to help that patient make a best care decision.
	<p>Lack of communication between facilities and surgeons and hospitals</p>	<p>Community Partnerships</p> <p>Facilities will complete a root cause analysis identifying the external ESRD stakeholder(s) who are hindering fistula rate improvements which could include:</p> <ol style="list-style-type: none"> a. Vascular surgeon(s) b. Nephrology office staff c. Primary care physician d. Hospital discharge planner e. Acute dialysis staff f. Other identified stakeholder <p>The facility will develop a plan to build a mutually rewarding relationship with their identified stakeholder. Network staff will suggest techniques to begin the partnering process and provide specific tools and resources to assist in the project.</p>

The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

	<p>Each project will be conducted over a seven month period with monthly activities that include:</p> <ul style="list-style-type: none"> • Intervention-specific conference calls for participant networking and technical assistance from Network staff • Evaluation of facilities' monthly prevalent fistula rate increase (goal 0.33 percentage point) and reports to facilities • Evaluation of project progress through the assessment of the facility vascular access management QAPI minutes <p>Additionally, each intervention will include the following educational activities:</p> <ul style="list-style-type: none"> • Month 2 -Facilities attend QAPI and Vascular Access Management I WebEx • Month 3 - Facilities attend "Networking for Solutions" Learning Session • Month 5 - Facilities attend QAPI and Vascular Access Management II WebEx <p>II. Network Wide Intervention:</p> <p>Each facility medical director and vascular access coordinator in Networks 9 and 10 will receive:</p> <ol style="list-style-type: none"> 1. A monthly outcomes feedback report including: <ul style="list-style-type: none"> • Outcome expectation • Actual outcome • Poor outcome message calling for vascular access team review or a congratulatory positive outcome message 2. Bi-monthly electronic newsletter including: <ul style="list-style-type: none"> • Information on tools for changing facility processes • Important aspects of a successful QAPI program 3. Notification/invitation to educational programs: <ul style="list-style-type: none"> • Two QAPI WebEx conferences presenting best practice QAPI programs • One Fistula First Learning Session providing tools and resources on <ul style="list-style-type: none"> • Changing patient culture • Decreasing catheters • Partnering outside of the facility • Networking with peers
<p>Effectiveness & Sustainability</p>	<p>The project will be assessed using the March 31, 2010 fistula first data to determine whether the CMS goals for Network 9 and Network 10 were met.</p> <p>The effectiveness and sustainability of the project will be evaluated using the following assessments:</p> <ol style="list-style-type: none"> 1. Did the Network demonstrate that its interventions improved facility performance toward goal? 2. Did the facilities in the QIP meet the stated goals of the QIP? If so, to what degree can that be attributed to Network interventions (outcome measures)?

The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

	<p>3. Did the facilities participating in the QIP complete all intervention activities?</p> <p>For each intervention activity we will determine what proportion of the facilities completed the following tasks:</p> <ol style="list-style-type: none"> 1. Attend “kickoff” informational WebEx 2. Complete a root cause analysis and identify the barrier that will be targeted for improvement as discussed in QAPI minutes 3. Submit project questionnaire to the Network providing their project plan information 4. Attend QAPI and Vascular Access Management I & II WebEx 5. Attend “Networking for Solutions” Learning Session 6. Attend four scheduled QIP conference calls 7. Submit vascular access management QAPI minutes quarterly to include project progress <p>A statistical analysis of each intervention will be performed looking at the change in the fistula rate as the dependent variable and the facility specific parameters, including the completion of each of the specific intervention items to determine what was best associated with the response. Comparisons will be made to facilities not included in the intervention.</p> <p>Sustainability of improved outcomes will be assessed monthly as data are reported to the Network. Network staff will be looking for incremental improvement month to month during the life of the project to assess whether interventions are achieving set targets. Participating facilities will continue to be followed for a period of six months following the completion of the outlined interventions to determine sustainability of facility level prevalent fistula rate outcome improvements.</p>
Contacts	<p>Raynel Kinney, RN, Director of Quality Improvement Cindy Miller, RN, Quality Improvement Coordinator</p>
References	<ol style="list-style-type: none"> 1. Fistula First Breakthrough Initiative Change Concepts 2. Fistula First Dashboard 3. Network 16 - QIP “Back to the Basics: Increasing the Use of Arterial Venous Fistulas in Hemodialysis Patients” 4. Swerissen H, Crisp BR. The sustainability of health promotion interventions for different levels of social organizations. Health Promotion Int. 19: 123-130, 2004. 5. 2008-2009 Task 1.a Vascular Access Quality Improvement Project (QIP) Root Cause Analysis (RCA), 6. 2008-2009 QIWP Final Report Analysis, Task 1.a-Vascular Access Improvement Project, Project Title: Network 9/10- Prevalent Fistula Rate Improvement.

The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

Task 1b: CPM Plan	
Project Title: Anemia Management: Increasing the Percentage of Patients in the Hemoglobin Target Zone (10-12gm/dL)	
Project Description	<p>The clinical performance measures (CPM) plan will address the problem of a continuing low percentage of patients within the hemoglobin target range of 10-12 gm/dL as defined in the erythropoietin product literature, KDOQI guidelines, and recommendations by CMS. The project will address the lack of understanding within facilities of the differences between individual hemoglobin variability and population variability. The project will address the statistical considerations that should be taken into account when facilities look at their anemia data and how the nature of the hemoglobin distribution will always result in some percentage of patients outside the target range.</p>
Background/Justification	<p>Due to several FDA advisories released in 2007 as well as new <u>KDOQI</u> and <u>CMS guidelines</u> to avoid targeting hemoglobin over 12 gm/dL the anemia management practices of facilities within Network 9 and 10 were evaluated in 2008. Previously, facilities were judged on the percentage of patients within a facility that had a hemoglobin measurement above 11.0 gm/dL (89.1% in Network 9/10 in 2005). This metric was in place for a number of years and perhaps an unintended consequence of this policy was that the mean hemoglobin for ESRD patients reported by the USRDS had risen as high as 12.2 gm/dL when measured six months after initiation (USRDS 2007). New reporting standards for anemia now present the percentage of patients within 10.0 to 12.0 gm/dL, the percentage below 10.0 gm/dL, and the percentage above 12.0 gm/dL. Implicit in this new reporting standard is that the facility mean should be near 11.0 gm/dL. What is not known is what a dialysis provider should expect these percentages to be.</p> <p>In 2008 Network 9 and 10 undertook a quality improvement project for anemia management that addressed barriers to achieving the maximum percentage of patients in a facility in the range of 10.0 and 12.0 gm/dL. The following activities took place during this project:</p> <p>Dialysis facilities received four resources:</p> <ol style="list-style-type: none"> 1. FDA Statement on ESAs along with revised Network 9/10 goal for Anemia Management 2. Facility specific anemia data report based on 2007 Elab data with regional comparatives 3. The Table of Expected Hemoglobin Rates and instructions for use 4. MRB Recommendations to Medical Directors on achieving hemoglobin targets <p>With the help of the information that the Network provided to providers and other educational activities, the percentage of patients within the newly identified target range increased from 48.5% in 35,542 patients in 2007 to 56.8% in 36,210 patients in 2008. The percentage of patients below 10.0 gm/dL remained low (8.8% in 2008).</p>

The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

	<p>In order to achieve the maximum percentage of patients within the newly identified target range of 10-12 gm/dL facilities need to achieve mean hemoglobin of 11.0 gm/dL. In order to maximize the percentage of patients within the target, facilities need to avoid a situation where they will over correct for hemoglobin values outside the target range by too frequently altering the ESA dose in the mistaken belief that they can eliminate all patients either above 12.0 or below 10.0 gm/dL. Network 9 and 10 determined the 95% confidence interval (CI) around the percentage of patients within the target range so that facilities can judge how well they are performing in comparison to the Network adjusting for facility size. Based on our analysis of greater than 22,000 individual hemoglobin measurements in December 2003, for the average dialysis facility we can expect 55.9% of patients within the target range in any one month period. This value is based on facilities achieving mean hemoglobin of 11.0 gm/dL.</p>
<p>Root Cause Analysis (RCA)</p>	<p>In May 2009 staff and MRB members conducted a root cause analysis that included the following:</p> <ol style="list-style-type: none"> 1. An analysis of 4th Quarter 2008 Lab and CPM data showing: <ul style="list-style-type: none"> • Network 9 hemoglobin rates: <ul style="list-style-type: none"> - 57.5% of patients between 10-12 gm/dL - 7.5% of patients <10gm/dL - 34.9% of patients >12 gm/dL • Network 10 hemoglobin rates: <ul style="list-style-type: none"> - 55.9% of patients between 10-12 gm/dL - 8.0% of patients <10gm/dL - 36.1% of patients >12 gm/dL • There are 157 facilities in Network 9 and 73 facilities in Network 10 with significantly fewer (< 49%) patients within the 10.0 to 12.0 gm/dL range than expected. • There are 36 facilities in Network 9 and 20 facilities in Network 10 that have significantly greater (> 67%) patients within the 10.0 to 12.0 gm/dL range than expected. These facilities were identified as potential best practice facilities. 2. A review of the revised KDOQI and FDA guidelines for ESA and iron use to assess anemia management as the combination of use of both of these agents. 3. The results of a questionnaire that was sent to 688 dialysis facility medical directors and nurse managers in Network 9/10 to determine to what extent the 2008 Anemia Management QIP intervention educational material and the Table of Expected Hemoglobin Rates were used and what processes/protocols were put in place to sustain change. 4. A reanalysis of Network data using the new variability measures demonstrated in the 4th quarter of 2008. <p>The RCA concluded that:</p> <ol style="list-style-type: none"> 1. Providing educational information led to an adjustment in ESA dosing protocols to maximize the percentage of patients within 10-12 gm/dL and minimize the percentage of patients above 12.0 gm/dL and below 10.0 gm/dL.

The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

	<ol style="list-style-type: none"> 2. The low percentage of patients within the target range of 10.0 to 12.0 gm/dL is primarily due to inadequate targeting of appropriate hemoglobin within this range. Movement of facility mean hemoglobin to within the target range appears to have had a beneficial effect on hemoglobin variability. 3. Possible variations in facilities meeting the hemoglobin target range of 10-12 gm/dL were identified as the impact of stops and holds of ESA doses vs. dosage reductions and the contribution of hospitalizations resulting in an increased proportion of patients outside the target range.
Barriers Identified from RCA	<p>Based on information provided in the RCA and the expertise of MRB members, five barriers were identified to reaching goal:</p> <ol style="list-style-type: none"> 1. Lack of awareness and understanding of the new FDA hemoglobin target range of 10-12 gm/dL 2. Failure to adapt ESA and iron dosing algorithms to new hemoglobin target range 3. Lack of awareness that based on the underlying distribution of the hemoglobin concentration in the population (all patients in the Network), one can reasonably expect to see specific percentages outside the target range and that this is dependent on facility size. 4. Impact of stops and holds of ESA doses vs. dosage reductions on variability within facilities 5. Contribution of hospitalizations to increased variability resulting in an increased proportion of patients outside the target range
Goal for Change	<p>Goal – To increase the percentage of patients in targeted facilities with hemoglobin 10-12 gm/dL to at least the Network 9/10 mean by March 31, 2010.</p> <p>Network 9 - at least 5 out of the 9 intervention facilities will increase the percentage of patients with hemoglobin 10-12 gm/dL to at least 57.5% by March 31, 2010.</p> <p>Network 10 - at least 5 out of the 9 intervention facilities will increase the percentage of patients with hemoglobin 10-12 gm/dL to at least 55.9% by March 31, 2010.</p>
Numerator /Denominator	$\frac{\text{Number of patients with hemoglobin 10-12 gm/dL}}{\text{Total number of patients}}$
Measurement & Frequency	<p>Facilities targeted for intervention will provide monthly hemoglobin data. Quarterly interim measures will be determined for each facility by subtracting the facility baseline measure from the project goal and dividing by four. Data submitted by the intervention facilities will be reviewed by Network staff each quarter to assure that facilities are meeting quarterly targets.</p>
Threshold for Action	<ol style="list-style-type: none"> 1. Facilities that are not participating in the monthly activities and/or are not meeting quarterly targets will be contacted by Network staff to discuss barriers to original project plan and assist with changes to processes and actions. 2. Medical Directors of facilities that do not meet quarterly targets will be contacted by physician members of the MRB to discuss commitment to the project, barriers

The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

	<p>for attaining goals and process changes that are necessary for improvement.</p> <p>3. Facilities that refuse to participate in the project will be reported to CMS and the state survey agency.</p>																
<p>Population Inclusion/ Exclusion Criteria</p>	<p>The Network will evaluate anemia management for all facilities in the Network 9/10 area based on the facility's most recently recorded hemoglobin (Hb) data (4th Quarter 2008). Based on a model previously developed to determine the expected distribution of Hb levels in a dialysis facility according to the number of patients treated, the Network will calculate number of patients in each facility that would be expected to fall into the three ranges noted below. The model assumes the mean Hb level in that facility is 11.0 g/dL and that the standard deviation varies indirectly with the size of the facility.</p> <p>1. Facilities will be assigned points based on</p> <ol style="list-style-type: none"> a. the percentage of patients with Hb below 10.0 gm/dL, b. the percentage of patients with Hb within 10.0 to 12.0 gm/dL c. the percentage of patients with Hb above 12.0 gm/dL. <p>Using the following table, facilities will be assigned points from 0 (worst) to 6 (best) which is the sum of the points assigned for each Hb range. Those facilities with the "best" anemia management would have a number of patients less than expected below 10 (2 points), greater than expected between 10 and 12 (2 points), and less than expected above 12 (2 points), for a total of 6 points. All facilities can then be ranked according to the number of points they received and inclusion/exclusion criteria applied.</p> <table border="1" data-bbox="396 1178 1430 1314"> <thead> <tr> <th></th> <th>0 points</th> <th>1 point</th> <th>2 points</th> </tr> </thead> <tbody> <tr> <td>% pts Hb <10</td> <td>More than expected</td> <td>As expected</td> <td>Less than expected</td> </tr> <tr> <td>% pts Hb 10-12</td> <td>Less than expected</td> <td>As expected</td> <td>More than expected</td> </tr> <tr> <td>% pts Hb >12</td> <td>More than expected</td> <td>As expected</td> <td>Less than expected</td> </tr> </tbody> </table> <p>Expectations for each of the three hemoglobin ranges were determined by a bootstrap approach using actual 2007 hemoglobin data from approximately 35,000 patients. The bootstrap was performed 10,000 times for facility sizes ranging from 2 to 200. Ninety-five percent confidence intervals (CI) were then determined and facility numbers were compared to these 95% CI's. Using this analysis we will be able to identify facilities that have the best practices and also those facilities for potential intervention.</p> <p>2. Using the above data, facilities will be selected for participation in this QIP meeting the following criteria:</p> <p style="padding-left: 40px;">9 Facilities from Network 9 with 3 facilities each in KY, IN, and OH 9 Facilities from IL (Network 10)</p> <p style="padding-left: 40px;">In each Network area:</p> <ul style="list-style-type: none"> • 6 out of 9 Facilities from LDOs with no more than 3 facilities in one 		0 points	1 point	2 points	% pts Hb <10	More than expected	As expected	Less than expected	% pts Hb 10-12	Less than expected	As expected	More than expected	% pts Hb >12	More than expected	As expected	Less than expected
	0 points	1 point	2 points														
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The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

	<p style="text-align: center;">specific LDO</p> <ul style="list-style-type: none"> • 3 out of 9 Facilities from an small or independent provider • 7 out of 9 Facilities from an urban area • 2 out of 9 Facilities from a rural area <p>3. Facilities selected for inclusion in this QIP will be asked to submit recent Hb data to ascertain appropriateness for participation. Final determination of participating facilities will be based on confirmation of Hb outcomes through the examination of recent facility data.</p>						
Project Design/ Methodology	<p>The project design that was used successfully in the 2008 Task 1.c QIP will be repeated in this project targeting 9 facilities in Network 9 and 9 facilities in Network 10. The project includes the following steps:</p> <ol style="list-style-type: none"> 1. Notify facilities that have been identified for inclusion in the project. 2. Provide educational materials and resources to describe the need for change in anemia management 3. Conduct a facility RCA to identify barriers to increasing the percent of patients in the hemoglobin target zone. 4. Provide tools for tracking and analyzing data 5. Share best practice models that use policies/procedures/processes of high performing facilities as benchmarks for participating facilities 6. Provide one on one technical support 						
Interventions	<p>This intervention will include all of the following.</p> <ol style="list-style-type: none"> 1. Facilities will be notified that they have been identified for inclusion in the project. 2. With the help of Network staff facility staff will conduct an RCA to identify barriers to increasing the percent of patients in the hemoglobin target zone. 3. Interventions designed to address each barrier include: <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Barrier</th> <th style="text-align: left;">Intervention</th> </tr> </thead> <tbody> <tr> <td style="vertical-align: top;">Lack of awareness and understanding of the new FDA hemoglobin target range of 10-12 gm/dL</td> <td style="vertical-align: top;">The medical director and anemia management nurse at each participating facility will receive four resources: <ul style="list-style-type: none"> - FDA Statement on ESAs along with revised Network 9/10 goal for Anemia Management - Facility specific anemia data report based on 2008 Elab data with regional comparatives - The Table of Expected Hemoglobin Rates and instructions for use MRB Recommendations to Medical Directors on achieving hemoglobin targets </td> </tr> <tr> <td style="vertical-align: top;">Failure to adapt ESA and iron dosing algorithms to new</td> <td style="vertical-align: top;">The anemia management nurse will receive an excel spreadsheet that can be used to track monthly hemoglobin, ESA dose, TSAT, ferritin, iron dose, and</td> </tr> </tbody> </table>	Barrier	Intervention	Lack of awareness and understanding of the new FDA hemoglobin target range of 10-12 gm/dL	The medical director and anemia management nurse at each participating facility will receive four resources: <ul style="list-style-type: none"> - FDA Statement on ESAs along with revised Network 9/10 goal for Anemia Management - Facility specific anemia data report based on 2008 Elab data with regional comparatives - The Table of Expected Hemoglobin Rates and instructions for use MRB Recommendations to Medical Directors on achieving hemoglobin targets	Failure to adapt ESA and iron dosing algorithms to new	The anemia management nurse will receive an excel spreadsheet that can be used to track monthly hemoglobin, ESA dose, TSAT, ferritin, iron dose, and
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The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

	<p>hemoglobin target range.</p>	<p>hospitalizations. This spreadsheet will allow the intervention facilities to calculate monthly average hemoglobin and the variability of this hemoglobin, percentage of patients within the target range as well as the percentage of patients both above 12 gm/dL and below 10 gm/dL.</p> <p>The medical director and anemia nurse will be asked to determine if the percentages that they are observing are similar to what they should expect using the Table of Expected Hemoglobin Rates.</p> <p>The anemia management nurse will be asked to provide facility anemia management protocols to the Network (ESA and iron dosing algorithms).</p> <p>The MRB will evaluate the facility ESA dosing algorithm using a tool written in Matlab. This tool tests the robustness of the ESA algorithm by dosing 80 simulated patients. Additionally, using this Matlab tool we can determine what hemoglobin the facility will target using their ESA algorithm. We will be able to compare the results of this process to ESA algorithms from facilities that are performing well.</p>
	<p>Lack of awareness that based on the underlying distribution of the hemoglobin concentration in the population (all patients in the Network), one can reasonably expect to see specific percentages outside the target range and that this is dependent on facility size.</p>	<p>The MRB will evaluate the results of Matlab simulation for each facility along with their protocols for ESA and iron dosing in order to make recommendation for improvement.</p>
	<p>Impact of stops and holds of ESA doses vs. dosage reductions on variability within facilities</p>	<p>Anemia management nurses will provide QAPI minutes to the Network quarterly for review of activities/changes related to anemia management process.</p> <p>The Network will provide one on one technical support for changes to anemia management protocol.</p>

**The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010**

	<p>Contribution of hospitalizations to increased variability resulting in an increased proportion of patients outside the target range.</p>	<p>The anemia management nurse will receive an excel spreadsheet that can be used to track monthly hemoglobin, ESA dose, TSAT, ferritin, iron dose, and hospitalizations. This spreadsheet will allow the intervention facilities to calculate monthly average hemoglobin and the variability of this hemoglobin, percentage of patients within the target range as well as the percentage of patients both above 12 gm/dL and below 10 gm/dL.</p> <p>The Network will provide one on one technical support for changes to anemia management protocol.</p>
<p>Effectiveness/ Sustainability</p>	<p>Effectiveness will be seen as an increase in the percentage of patients within the target range of 10.0 to 12.0 gm/dL and can be judged on a per facility basis using the 95% CI.</p> <p>A statistical analysis of the intervention will be performed looking at the change in the percentage of patients within the target range as the dependent variable and the facility specific parameters, including the completion of each of the specific intervention items and using the facility QAPI minutes to determine what was best associated with the response. Comparisons will be made to determine what activities resulted in the largest change in the dependent variable.</p> <p>Outcomes will be assessed monthly as data are reported to the Network. Network staff will be looking for incremental improvement month to month during the life of the project to assess whether interventions are achieving set targets. Participating facilities will continue to be followed for a period of six months following the completion of the outlined interventions to determine sustainability.</p>	
<p>Contacts</p>	<p>Mary Ann Webb, RN, Quality Improvement Coordinator Raynel, Kinney, RN, Director of Quality Improvement</p>	
<p>References</p>	<ol style="list-style-type: none"> 1. KDOQI 2. Hemoglobin Target Calculator, Brier et al Abstract 2008 ASN 3. FDA Statement on ESA 4. Revised Network 9/10 Goal for Anemia Management 5. Swerissen H, Crisp BR. The sustainability of health promotion interventions for different levels of social organizations. Health Promotion Int. 19: 123-130, 2004. 6. U.S. Renal Data System, USRDS 2007 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2007 	

The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

Task 1c: Network Specific Quality Improvement Project	
Project Title: Increasing Serum Phosphorus Percentage in the Target Zone (3.5-5.5 mg/dl)	
Project Description	<p>Phosphorus control is defined as serum phosphorus between 3.5 and 5.5 mg/dL. In the 4th quarter of 2008, only 54% of hemodialysis patients in Network 9 and 55% of hemodialysis patients in Network 10 achieved this target range.</p> <p>ESRD patients are unable to excrete phosphorous. This leads to hyperphosphatemia and is exacerbated with high phosphorus intake. High serum phosphorus levels are associated with increased morbidity and mortality. Hyperphosphatemia also is involved in causing atherosclerotic heart disease, secondary hyperparathyroidism, and bone disease in renal patients.</p> <p>We propose a quality improvement project aimed at increasing the serum phosphorus percentage in the 3.5 – 5.5 mg/dL range in dialysis patients using an educational program to reduce dietary intake of phosphate additives. The results of testing the proposed educational program were reported by Sullivan et al. in JAMA in February 2009. (<i>JAMA</i>. 2009;301(6):629-635)</p>
Background/ Justification	<p>The amount of phosphorus in the American diet has increased considerably, primarily from phosphorus-containing additives in convenience and ready to eat foods.¹ It is estimated that, depending on individual food choices, such additives add as much as 1000 mg/day of phosphorus to the diet.² Moreover, phosphorus in additives is almost entirely absorbed while only 60% of naturally occurring phosphorus is absorbed.³ Elevated phosphorus levels are common among the 350,000 Americans receiving chronic hemodialysis treatment and associated with poor outcomes among dialysis patients, including increases in both all-cause and cardiovascular mortality rates.^{4,5} Excess phosphorus combines with calcium and deposits in arteries and other soft tissues and leads to the development of atherosclerotic heart disease.⁶ Elevated serum phosphorus also stimulates parathyroid hormone and contributes to secondary hyperparathyroidism and renal bone disease.^{4,7,8} Education regarding high phosphorus foods is a key component of hyperphosphatemia management,^{8,10} but the use of “hidden” phosphorus additives may make it difficult for patients and dietitians to estimate phosphorus content of foods. It has been suggested that hyperphosphatemia is a nutritional barrier to preventing renal bone disease and cardiovascular mortality and that an intervention focusing on phosphate containing food additives has great potential.^{11,12}</p> <p>The design and methodology of this QIP is modeled after a project design reported in <i>JAMA</i> 2009;301(6):629-635. In that 3-month project, dietitians provided phosphorus additives education in-person and by telephone to patients with persistently high serum phosphorus levels (defined as <u>both</u> current month and 3-month average phosphorus exceeding 5.5 mg/dL). Patients were provided education on label reading and given lists of phosphate additives to avoid, fast foods containing additives to avoid, suggested alternative fast foods to substitute, and a pocket magnifier to aid in reading</p>

The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

	<p>small print on labels. Patients in the intervention group reduced their serum phosphorus an average of 1.0 mg/dL, while patients in the control group receiving usual care reduced their serum phosphorus by an average of only 0.4 mg/dL. The 0.6 mg/dL larger decline in average phosphorous level among intervention participants compared with control participants corresponds to a 5% to 15% reduction in relative mortality risk in observational studies.^{4,5, 13-17}</p>
<p>Root Cause Analysis (RCA)</p>	<p>In May 2009, the MRB conducted a root cause analysis that included the following information:</p> <ol style="list-style-type: none"> 1. An analysis of 2008 October, November, December facility-specific phosphorus data provided through the Elab project (4th quarter lab data collection) revealed that Network 9/10 had only a mid-range percentage of patients with a serum phosphorus between 3.5 and 5.5 mg/dL (54% of patients in Network 9 and 55% of patients in Network 10). 2. The members discussed reasons for increased phosphorus after being introduced to the information presented in the JAMA article. (<i>JAMA</i>. 2009;301(6):629-635) <p>Based on the experience and discussion of the MRB membership, reasons for increased phosphorus were identified:</p> <ul style="list-style-type: none"> • Most of the public at large as well as dialysis patients are unaware of phosphorus additives in fast and processed foods. • There is an increase in eating fast foods due to convenience and economics. • Phosphorus is unseen and tasteless so patients are unaware of its presence in foods. • Due to increased phosphorus intake patients can be prescribed many binders which can be cost prohibitive. • Dietitians have a larger number of patients to follow and educate with no specific tools or resources to assist in the education.
<p>Barriers Identified from RCA</p>	<p>The following barriers to controlled phosphorus were identified:</p> <ol style="list-style-type: none"> 1) Patients are not aware of phosphorus additives in foods 2) There is a high reliance on fast foods and convenience food items 3) Insufficient RD time to adequately educate patients with inadequate educational materials available 4) Phosphate binder non-adherence due to large doses and inability to afford binders
<p>Goal for Change</p>	<p>Increase the percentage of patients within participating facilities with serum phosphorus between 3.5 and 5.5 mg/dL. by at least 5% by March 2010</p> <p>Network 9 (Ohio) - At least eight of fifteen participating facilities will increase the percentage of patients with serum phosphorus between 3.5-5.5 mg/dL by at least 5% by March 2010.</p> <p>Network 10 (Illinois) - At least nine of seventeen participating facilities will increase the percentage of patients with serum phosphorus between 3.5-5.5 mg/dL by at least 5%</p>

The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

	by March 2010
Numerator/ Denominator	<u>The number of patients in facility with serum phosphorus 3.5-5.5 mg/dL</u> Total number of patients in facility
Measurement & Frequency	<p>This project will be conducted over a six-month period. Targeted facilities will be assigned a monthly phosphorous interim goal based on the 5% target minus their baseline rate and then divided by six.</p> <p>Data submitted by the participating facilities will be reviewed by Network staff monthly to assure that facilities are meeting monthly targets.</p>
Threshold for Action	<ol style="list-style-type: none"> 1. Facilities that are not participating in the monthly activities and/or are not meeting monthly goals will be contacted by Network staff to discuss barriers to original project plan and assist with changes to processes and actions. 2. Dietitians of facilities that do not meet quarterly targets will be contacted by dietitian members of the MRB to discuss commitment to the project, educational techniques and individual barriers to phosphorus control.
Population Inclusion/ Exclusion Criteria	Fifteen facilities from Ohio (Network 9) and seventeen facilities from Illinois (Network 10) have expressed interest in participating in the project. A WebEx informational session targeting facility administrators, medical directors, and dietitians will be held to provide an overview of the project, what is expected of participating facilities, and background information on the problem of phosphorus additives in the United States food supply. The Network will request the most recent serum phosphorus data to ensure that the participating facilities have ≤ 54% patients with serum phosphorus 3.5 – 5.5 mg/dL so that we can evaluate the impact of this educational QIP.
Project Design/ Methodology	<p>The QIP design/methodology will include all facility patients, with both controlled (as defined ranging 3.5 mg/dL to 5.5 mg/dL) and uncontrolled serum phosphorus. Therefore, instead of proposing an outcome measure of reducing mean facility phosphorus, we propose an outcome measure evaluating the percentage of patients in the facility with serum phosphorus within the acceptable range. Given that this is a quality improvement design, there is reason to believe that patients with controlled serum phosphorus levels will benefit from education about hidden phosphorus additives.^{14, 18-21}</p> <p>Renal dietitians (RD) are expected to educate patients on phosphorus control as part of the normal RD scope of practice, however education is not provided uniformly to patients or across facilities. This project translates the method of a successful research intervention as described in the literature (JAMA) into clinical practice. It also provides the dietitian with sound educational tools to assist the patient with making appropriate and healthy food choices.</p> <p>Facilities will receive the following for their own use: - A report detailing the percentage of patients with phosphorus greater than 5.5 mg/dL based on the 2008 4th quarter lab data.</p> <p>Facilities will receive the following materials for dietitians to provide to patients:</p>

The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

	<ul style="list-style-type: none"> - label reading instructions - pocket magnifier - list of phosphate additives to avoid - lists of fast foods to avoid and recommended alternative fast foods <p>In the course of two educational sessions, dietitians will instruct patients on how to read nutrition facts panels and ingredient lists to determine if foods contain phosphate additives. Dietitians will determine which fast food restaurants are used by each patient and provide lists of additive-containing and additive-free (and appropriate for renal diet) foods at the restaurant. Patients will be advised and encouraged to select phosphorus additive-free menu items at supermarket/restaurant.</p> <p>Providing these educational materials and the phosphorus additive information to the dietitians will also be helpful in educating patients during the holiday months when extra reinforcement of appropriate dietary choices is crucial for renal patients.</p>								
Interventions	<p>All participating facilities will participate in the following interventions:</p> <ol style="list-style-type: none"> 1. Dietitians will be trained in the project methodology via an in-person training session held in a central location within the Network 9/10 region. 2. Dietitians will provide the Network with a list of patient names and patient serum phosphorus levels for the current month as baseline. 3. The following interventions will take place during the six month project period: <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left; padding: 5px;">Barrier</th> <th style="text-align: left; padding: 5px;">Intervention</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;">Patients are not aware of phosphorus additives in foods</td> <td style="padding: 5px;"> Patients will receive education materials describing: <ul style="list-style-type: none"> • phosphorus additives and their effect on the phosphorus content of foods; • a listing of common phosphorus additives; • a pocket magnifier; • fast food restaurant-specific handouts listing additive-containing foods to avoid and additive-free foods that are reasonable to include in the renal diet. The educational materials and educational sessions with the dietitian will inform the patients of the hidden phosphorus additives. </td> </tr> <tr> <td style="padding: 5px;">There is a high reliance on fast foods and convenience food items</td> <td style="padding: 5px;"> Patients will be educated on how to use the tools provided to identify the hidden phosphorus additives in fast foods and grocery stores in order to make more appropriate food choices. </td> </tr> <tr> <td style="padding: 5px;"></td> <td style="padding: 5px;">Patients will be instructed to use the materials when</td> </tr> </tbody> </table>	Barrier	Intervention	Patients are not aware of phosphorus additives in foods	Patients will receive education materials describing: <ul style="list-style-type: none"> • phosphorus additives and their effect on the phosphorus content of foods; • a listing of common phosphorus additives; • a pocket magnifier; • fast food restaurant-specific handouts listing additive-containing foods to avoid and additive-free foods that are reasonable to include in the renal diet. The educational materials and educational sessions with the dietitian will inform the patients of the hidden phosphorus additives.	There is a high reliance on fast foods and convenience food items	Patients will be educated on how to use the tools provided to identify the hidden phosphorus additives in fast foods and grocery stores in order to make more appropriate food choices.		Patients will be instructed to use the materials when
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The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

	<p>shopping or eating out to avoid phosphorous additives. Using patient materials provided, dietitians will provide patients with education regarding:</p> <ul style="list-style-type: none"> • The phosphorus content of foods (naturally occurring and phosphorus-based food additives) • How to read labels to identify presence of phosphorus-based food additives • The phosphorus content and additives in fast food menu items • Advice to limit foods containing naturally occurring phosphates, avoid foods containing phosphorus-based food additives, and alter fast food purchases (if applicable)
<p>Insufficient RD time to adequately educate patients with inadequate educational materials available</p>	<p>Providing the QIP educational materials to the RD will give them the resources to efficiently educate the patient on phosphorus additives.</p> <p>Conference calls will be held with the participating facility dietitians to troubleshoot and answer questions and provide an update of new research or data on the topic of phosphorus-based additives. These calls will be used to promote ongoing motivation and enthusiasm for the project.</p>
<p>Phosphate binder non-adherence due to large doses and including inability to afford binders</p>	<p>By educating the patient on hidden phosphorus additives, and giving patients tools to identify those additives, serum phosphorus levels should decrease and in turn the large doses of phosphate binders would be decreased alleviating the affordability factor.</p>
<p>4. During months 1 and 3 participating facilities will send (to the Network) patient-specific barriers to phosphorus control (nursing home/institutional resident, unable to purchase phosphorus binders, patient refused education, patient unable to be educated); date patient educated; dietitian-assessed level of patient interest rated using Likert scale (highly interested, moderately interested, slightly interested, not at all interested) by the last day of the month.</p> <p>5. Each month all facilities will send to the Network patient identified serum phosphorus levels by the 15th of the following month. Facility dietitians will be expected to work with Network staff to review facility-level and patient-level data monthly to track progress toward goal.</p>	

The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

	<p>6. Every other month conference calls will be held with the participating facility dietitians to troubleshoot and answer questions and provide an update of new research or data on the topic of phosphorus-based additives. These calls will be used to promote ongoing motivation and enthusiasm for the project.</p> <p>Throughout the duration of the project, facility dietitians will reinforce with patients the information contained in educational materials, address shopping and eating habits, and answer questions.</p> <p>The Network staff will assist the dietitians in changing techniques and/or developing other actions to improve phosphorus control.</p>
<p>Effectiveness & Sustainability</p>	<p>The project will be assessed using each participating facility's lab data to determine whether goals were met.</p> <p>A statistical analysis will be performed looking at the change in the percentage of patients within a facility with serum phosphorus between 3.5-5.5 mg/dL at final measure compared to baseline measure, compared to non-participating facilities. The comparisons will be made to determine if the educational activities and materials provided to the patients resulted in a significant difference in outcomes.</p> <p>Note: We intend to start a Phase 2 of this project, repeating the original project from April 2010 to October 2010. Phase 2 will consist of the following components:</p> <ol style="list-style-type: none"> 1. An additional group of facilities of like composition to the facilities in Phase 1 in each Network will have their dietitians trained to: <ul style="list-style-type: none"> • use the materials described to educate patients on phosphorus management, • follow the Phase 1 QIP design. 2. Phase 2 facilities will provide retrospective September 2009 phosphorous data (Baseline Phase 1) AND March 2010 phosphorous data (Phase 1 Project Completion) in order to: <ul style="list-style-type: none"> • analyze data on an intervention versus non-intervention comparison, • provide information pointing to the success of the QIP's patient educational materials and the changed facility educational processes related to phosphorus management. 3. Phase 1 facilities will continue to provide facility and patient phosphorus levels to the Network in order to: <ul style="list-style-type: none"> • determine the effectiveness of the changed facility educational process based on sustained improved outcomes related to phosphorus management, • determine the effectiveness of the QIP after Network assistance is removed based on sustained improved outcomes related to phosphorus management. 4. The Network will compare results of both the Phase 1 and Phase 2 projects in

The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

	<p>order to provide more information regarding the success of the educational program in making changes in the patient and facility phosphorus levels, determine the portability to other facility systems of the educational materials and changes to the facility educational processes related to phosphorous management.</p> <p>Outcomes will be assessed monthly as data are reported to the Network. Network staff will be looking for incremental improvement month to month during the life of the project to assess whether interventions are achieving set targets. Participating facilities will continue to be followed for a period of six months following the completion of the outlined interventions to determine sustainability.</p>
<p>Contacts</p>	<p>Mary Ann Webb, RN, Quality Improvement Coordinator, Network staff Raynel Kinney, RN, Quality Improvement Director, Network Staff Janeen León, MS, RD, LD, Case Western Reserve, Cleveland, OH Ashwini Sehgal, MD, Case Western Reserve, Cleveland, OH</p>
<p>References</p>	<ol style="list-style-type: none"> 1. Calvo MS, Park YK. Changing phosphorus content of the U.S. diet: potential for adverse effects on bone. <i>J Nutr.</i> Apr 1996;126 (4 Suppl):1168S-1180S. 2. Bell RR, Draper HH, Tzeng DY, Shin HK, Schmidt GR. Physiological responses of human adults to foods containing phosphate additives. <i>J Nutr.</i> Jan 1977;107(1):42-50. 3. Uribarri J, Calvo MS. Hidden sources of phosphorus in the typical American diet: does it matter in nephrology? <i>Semin Dial.</i> May-Jun 2003;16(3):186-188. 4. Block GA, Hulbert-Shearon TE, Levin NW, Port FK. Association of serum phosphorus and calcium x phosphate product with mortality risk in chronic hemodialysis patients: a national study. <i>Am J Kidney Dis.</i> Apr 1998;31(4):607-617. 5. Rodriguez-Benot A, Martin-Malo A, Alvarez-Lara MA, Rodriguez M, Aljama P. Mild hyperphosphatemia and mortality in hemodialysis patients. <i>Am J Kidney Dis.</i> Jul 2005;46(1):68-77. 6. Ribeiro S, Ramos A, Brandao A, et al. Cardiac valve calcification in haemodialysis patients: role of calcium-phosphate metabolism. <i>Nephrol Dial Transplant.</i> Aug 1998;13(8):2037-2040. 7. Goodman WG. The consequences of uncontrolled secondary hyperparathyroidism and its treatment in chronic kidney disease. <i>Semin Dial.</i> May-Jun 2004;17(3):209-216. 8. Malluche HH, Mawad H, Monier-Faugere MC. The importance of bone health in end-stage renal disease: out of the frying pan, into the fire? <i>Nephrol Dial Transplant.</i> Mar 2004;19 Suppl 1:i9-13. 9. Cupisti A, D'Alessandro C, Baldi R, Barsotti G. Dietary habits and counseling focused on phosphate intake in hemodialysis patients with hyperphosphatemia. <i>J Ren Nutr.</i> Oct 2004;14(4):220-225. 10. Ford JC, Pope JF, Hunt AE, Gerald B. The effect of diet education on the laboratory values and knowledge of hemodialysis patients

The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

	<p>with hyperphosphatemia. <i>J Ren Nutr.</i> Jan 2004;14(1):36-44.</p> <p>11. Sherman RA. Dietary phosphate restriction and protein intake in Dialysis patients: a misdirected focus. <i>Semin Dial.</i> Jan-Feb 2007;20(1):16-18.</p> <p>12. Sullivan C, Sayre SS, León JB, Machekano R, Love TE, Porter D, Marbury M, Sehgal AR. Effect of food additives on hyperphosphatemia among patients with end-stage renal disease: A randomized controlled trial. <i>JAMA.</i> 2009; 301(6): 629-635.</p> <p>13. Gutierrez OM, Mannstadt M, Isakova T, et al. Fibroblast growth factor 23 and mortality among patients undergoing hemodialysis. <i>N Engl J Med.</i> 2008; 359(6):584-592.</p> <p>14. Ganesh SK, Stack AG, LevinNW, et al. Association of elevated serum PO(4), Ca^o— PO(4) product, and parathyroid hormone with cardiac mortality risk in chronic hemodialysis patients. <i>J Am Soc Nephrol</i> 2001; 12: 2131–2138.</p> <p>15. Kalantar-Zadeh K, Kuwae N, Regidor DL, et al. Survival predictability of time-varying indicators of bone disease in maintenance hemodialysis patients. <i>Kidney Int.</i> 2006;70(4):771-780.</p> <p>16. Tentori F, Blayney M, Albert J, et al. Mortality risk for dialysis patients with different levels of serum calcium, phosphorus, and PTH: the Dialysis Outcomes and Practice Patterns Study (DOPPS). <i>Am J Kidney Dis.</i> 2008;52(3):519-530.</p> <p>17. Block GA, Klassen PS, Lazarus JM, Ofsthun N, Lowrie EG, Chertow GM. Mineral metabolism, mortality, and morbidity in maintenance hemodialysis. <i>J Am Soc Nephrol.</i> 2004;15(8):2208-2218.</p> <p>18. Tonelli M, Sacks F, Pfeiffer M, et al. Relation Between Serum Phosphate Level and Cardiovascular Event Rate in People With Coronary Disease <i>Circulation.</i> 2005;112:2627-2633.</p> <p>19. Stevens LA, Djurdjev O, Cardew S et al. Calcium, phosphate, and parathyroid hormone levels in combination and as a function of dialysis duration predict mortality: evidence for the complexity of the association between mineral metabolism and outcomes. <i>J Am Soc Nephrol</i> 2004; 15: 770–779.</p> <p>20. Young EW, Akiba T, Albert JM et al. Magnitude and impact of abnormal mineral metabolism in hemodialysis patients in the Dialysis Outcomes and Practice Patterns Study (DOPPS). <i>Am J Kidney Dis</i> 2004; 44(Suppl 2): 34–38.</p> <p>21. Slinin Y, Foley RN, and Collins AJ. Calcium, Phosphorus, Parathyroid Hormone, and Cardiovascular Disease in Hemodialysis Patients: The USRDS Waves 1, 3, and 4 Study <i>JASN</i> 16 2005.</p>
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The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

Task 1d: Facility Specific Quality Assessment and Improvement Project	
Project Title: Hemodialysis Adequacy: Increasing the Percentage of Patients with Kt/V ≥ 1.2	
Project Description	Dialysis adequacy is defined as Kt/V ≥ 1.2 . In the 4 th quarter 2008, 92% of patients in Network 9/10 had a three month reported mean Kt/V ≥ 1.2 . Ten dialysis facilities in Network 9 and two dialysis facilities in Network 10 had dialysis adequacy rates below the MRB threshold of two standard deviations below the Network mean (83.6% Kt/V) raising concerns of inappropriate patient care.
Background/Justification	<p>In 2008-2009, Network 9/10 conducted a Hemodialysis Adequacy QIP using components of a previous project:</p> <ol style="list-style-type: none"> 1. Provided quality improvement tools to facilities in the QIP for tracking and analyzing data 2. Collected data from facilities monthly and reported facility specific data to facilities quarterly 3. Created best practice models that compare process measures of high performing facilities with that of QIP participants 4. Provided one on one technical support from Network staff as needed 5. Collected facility action plans 6. Conducted calls with facility staff, Network staff and MRB physicians <p>Twenty-seven dialysis facilities in Networks 9 and 10 with <74.7% of patients with adequate dialysis were included in this 2008-2009 Hemodialysis Adequacy QIP. The goal of the QIP was for 60% of the targeted facilities to meet or exceed the Network average of 88% patients with adequate dialysis by March 2009. This goal was met by the third month of the project (74% met) with 78% of the targeted facilities meeting the goal by March 2009.</p> <p>The same project design will be used in this QIP.</p>
Root Cause Analysis (RCA)	<p>In May 2009, staff and MRB members conducted a root cause analysis that included the following information:</p> <ol style="list-style-type: none"> 1. An analysis of 2008 October, November, December facility-specific Kt/V data provided through the Elab project (4th quarter lab data collection) that identified dialysis facilities with adequacy rate two standard deviations below the Network mean of 92% Kt/V. 2. Outcomes of the 2008-2009 Hemodialysis Adequacy QIP (2008-2009 QIWP Final Report Analysis, Task 1.b-CPM Plan, Project Title: Hemodialysis Adequacy: Increasing the Percentage of Patients with URR $\geq 65\%$) to determine successes and barriers. 3. Results of phone interviews with 8 of the targeted dialysis facilities to more closely examine the internal barriers affecting outcomes and to identify that the specific barriers to adequacy exist in the targeted facilities. <p>Results of the RCA concluded:</p> <ol style="list-style-type: none"> 1. The interventions in the 2008/2009 QIP successfully met goal.

The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

	<ol style="list-style-type: none"> 2. Facilities participating in the 2008/2009 QIP have sustained improved adequacy outcomes measures 3. Ten dialysis facilities in Network 9 and two dialysis facilities in Network 10 are considered poor performers with $<83.6\% \text{ Kt/V} \geq 1.2$. 4. Facilities must have a process for measuring adequacy 5. Facility protocols are effective in increasing and sustaining adequacy goals
Barriers Identified from RCA	<p>The root cause analysis identified two barriers prevalent in the 12 underperforming facilities:</p> <ol style="list-style-type: none"> 1. Lack of a quality assessment and performance improvement (QAPI) process to track facility adequacy rates in Kt/V. 2. Lack of policies and algorithms to monitor and adjust processes of care to improve the percentage of patients with $\text{Kt/V} \geq 1.2$. <p>Telephone conversations with nurse managers at targeted facilities confirmed the lack of a structured QAPI program, data collection and analysis initiatives, and structured policies, processes, and/or algorithms to improve adequacy. The facilities could not make improvements in adequacy because they did not regularly review this measure.</p>
Goal for Change	At least 60% of targeted facilities will meet or exceed the Network average of 92% patients with adequate dialysis by March 2010.
Numerator/ Denominator	<p><u>The number of targeted facilities with at least 92% of their patients with adequate dialysis</u></p> <p>Total number targeted facilities</p>
Measurement & Frequency	<p>The 4th quarter 2008 Kt/V measurement for each facility participating in this QIP will be documented as baseline.</p> <p>Targeted facilities will be assigned a quarterly adequacy goal based on the target of 92% minus their baseline rate and then divided by four.</p> <p>Monthly data will be collected to track improvement toward goal and a quarterly analysis will be completed to determine if facilities are improving dialysis adequacy.</p>
Threshold for Action	<ol style="list-style-type: none"> 1. Facilities that are not participating in the monthly activities and/or are not meeting quarterly targets will be contacted by Network staff to discuss barriers to original project plan and assist with changes to processes and actions. 2. Medical Directors of facilities that do not meet quarterly targets will be contacted by physician members of the MRB to discuss commitment to the project, barriers for attaining goals and process changes that are necessary for improvement. 3. Facilities that refuse to participate in the project will be reported to CMS and the state survey agency.
Population Inclusion/ Exclusion Criteria	<ol style="list-style-type: none"> 1. There are 10 hemodialysis facilities in Network 9 that have been identified as having Kt/V outcomes greater than two standard deviations below the Network mean and a barrier related to CQI techniques. These facilities are distributed throughout two of the three states with 1 in Indiana, 1 in Kentucky, and 8 facilities in Ohio. 2. There are 2 hemodialysis facilities in Network 10 that have been identified as

The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

	<p>having Kt/V outcomes greater than two standard deviations below the Network mean and a barrier related to CQI techniques. The participating facilities in Illinois are in a northeastern region and a middle eastern section of the state.</p> <ol style="list-style-type: none"> 3. Two out of the 27 facilities in last year's Hemodialysis Adequacy QIP are included again in the 12 targeted facilities for this year. 4. Facilities selected for inclusion in this QIP will be asked to submit recent Kt/V data to ascertain appropriateness for participation. Final determination of participating facilities will be based on confirmation of poor Kt/V outcomes through the examination of recent facility data. 				
<p>Project Design/ Methodology</p>	<p>The project design for this QIP includes:</p> <ol style="list-style-type: none"> 1. Providing quality improvement tools to facilities in the QIP for tracking and analyzing data 2. Collecting data from facilities monthly and reported facility specific data to facilities quarterly 3. Creating best practice models that compare process measures of high performing facilities with that of QIP participants 4. Providing one on one technical support from Network staff as needed 5. Collecting facility action plans 6. Conducting calls with facility medical director & staff, Network staff and MRB physicians <p>This year's project will collect and monitor Kt/V only because facilities use Kt/V as the measurement for dialysis adequacy. URR is no longer considered a preferred measure of dialysis adequacy.</p>				
<p>Interventions</p>	<p>Head nurses and medical directors of participating facilities will be expected to work with Network staff to review facility-level and patient-level data monthly to track progress toward goal. Facilities will be asked to submit adequacy QAPI plans/minutes quarterly. Specific intervention activities include:</p> <table border="1" data-bbox="396 1325 1427 1866"> <thead> <tr> <th data-bbox="396 1325 745 1367">Barrier</th> <th data-bbox="745 1325 1427 1367">Intervention</th> </tr> </thead> <tbody> <tr> <td data-bbox="396 1367 745 1866"> <p>Lack of a quality assessment and performance improvement (QAPI) process to track facility adequacy rates in Kt/V.</p> </td> <td data-bbox="745 1367 1427 1866"> <p>The medical director and head nurse will be directed to the Hemodialysis Adequacy Template on the Network's Web site.</p> <p>They will be asked to complete a Facility Barriers to Adequate Dialysis Questionnaire and submit to the Network. Network QI staff will review the results of the questionnaire to determine facility specific barriers and work with the facilities to develop action plans to address facility specific barriers.</p> <p>Medical directors and head nurses will be asked to develop an action plan using the tools provided, including facility adequacy policies/procedures to be</p> </td> </tr> </tbody> </table>	Barrier	Intervention	<p>Lack of a quality assessment and performance improvement (QAPI) process to track facility adequacy rates in Kt/V.</p>	<p>The medical director and head nurse will be directed to the Hemodialysis Adequacy Template on the Network's Web site.</p> <p>They will be asked to complete a Facility Barriers to Adequate Dialysis Questionnaire and submit to the Network. Network QI staff will review the results of the questionnaire to determine facility specific barriers and work with the facilities to develop action plans to address facility specific barriers.</p> <p>Medical directors and head nurses will be asked to develop an action plan using the tools provided, including facility adequacy policies/procedures to be</p>
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The Renal Network, Inc.
Networks 9/10
Quality Improvement Work Plan (QIWP)
2009 - 2010

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<p>Effectiveness & Sustainability</p>	<p>Medical Directors of facilities that do not meet their quarterly goal will be asked to participate on a conference call with Network staff and MRB representatives to discuss QAPI minutes, policies and algorithms.</p> <p>Note- Two out of the 27 facilities in last year's Hemodialysis Adequacy QIP are included again in the 12 targeted facilities for this year. The nurse managers of these facilities will receive weekly telephone calls from Network staff assisting in identifying barriers, developing action plans, and completing dialysis adequacy QAPI minutes. These facilities will also receive specific tools and resources based on barriers identified.</p> <p>The project will be assessed using the facility adequacy data from March 2010 to determine whether goals were met.</p> <p>The effectiveness of the project will be evaluated using the following assessments:</p> <ol style="list-style-type: none"> 1. Did the Network demonstrate that its interventions improved facility performance toward goal 2. Did the facilities in the QIP meet the stated goals of the QIP and, if so, to what degree can that be attributed to Network interventions (outcome measures) 3. Did the facilities participating in the QIP complete all intervention activities <p>For each intervention activity we will determine what proportion of the facilities completed the following tasks:</p> <ol style="list-style-type: none"> 1. Utilize the Hemodialysis Adequacy Template for QAPI activities 2. Complete a Facility Barriers to Adequate Dialysis Questionnaire and submit to the Network 3. Incorporate tools to address adequacy protocols and patient adherence issues. 4. Develop an action plan using the tools provided, including facility adequacy policies/procedures and include in dialysis adequacy QAPI minutes 5. Submit data monthly 6. Submit dialysis adequacy QAPI minutes quarterly <p>A statistical analysis of the intervention will be performed looking at the change in the</p>				

**The Renal Network, Inc.
 Networks 9/10
 Quality Improvement Work Plan (QIWP)
 2009 - 2010**

	<p>percentage of patients achieving goal as the dependent variable and the facility specific parameters, including the completion of each of the specific intervention items and using the facility QAPI minutes to determine what was best associated with the response. Comparisons will be made to determine what activities resulted in the largest change in the dependent variable.</p> <p>Outcomes will be assessed monthly as data are reported to the Network. Network staff will be looking for incremental improvement month to month during the life of the project to assess whether interventions are achieving set targets. Participating facilities will continue to be followed for a period of six months following the completion of the outlined interventions to determine sustainability.</p>
<p>Contacts</p>	<p>Mary Ann Webb, RN, Quality Improvement Coordinator Raynel, Kinney, RN, Director of Quality Improvement</p>
<p>References</p>	<ol style="list-style-type: none"> 1. CQI & QAPI Adequacy Development Tools 2. Adequacy of Dialysis Quality Improvement Template 3. Needs Assessment Tool 4. "Improving the Adequacy of Hemodialysis in In-Center Hemodialysis Facilities in Illinois, ESRD Network 10 - Final Project Report" 5. Henrich WL, Principles and Practice of Dialysis, 4th Edition 2009. 6. Swerissen H, Crisp BR. The sustainability of health promotion interventions for different levels of social organizations. Health Promotion Int. 19: 123-130, 2004. 7. 2008-2009 QIWP Final Report Analysis, Task 1.b-CPM Plan, Project Title: Hemodialysis Adequacy: Increasing the Percentage of Patients with URR \geq65%.