ESRD NETWORK 2018 ANNUAL REPORT

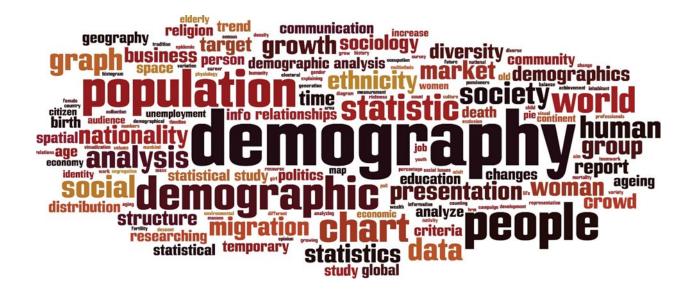
Health Services Advisory Group (HSAG): End Stage Renal Disease (ESRD) Network 7

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ESRD DEMOGRAPHIC DATA

ESRD Network 7

As part of the HSAG team, Network 7 works with patients and providers in the state of Florida to improve the quality of care and quality of life for ESRD patients. HSAG has held the Network 7 contract for 16 years.

Geography and General Population

The state of Florida covers 54,090 square miles and is bordered by Alabama, Georgia, the Gulf of Mexico, and the Atlantic Ocean. According to the U.S. Census Bureau, Florida's population was estimated at 21,299,325 in 2018¹. This represented a 4.8% increase from the 2016 population estimate. In 2018, the state of Florida ranked as third largest in population in the nation.

ESRD Population

Throughout 2018, Network 7 worked in collaboration with key stakeholders from the renal community in the Network's service area to improve the quality of life and quality of care for individuals living with ESRD. During the reporting period of December 31, 2017 to December 31, 2018, the Network's dialysis patient census increased by 620 patients (1.9%), for a total of 32,047 prevalent patients; this compares to the national total of 518,106 as of December 31, 2018. The number of incident dialysis patients in the Network service area increased by 461, for a total of 8,731 individuals newly diagnosed with ESRD in 2018. As of December 31, 2018, Network 7 comprised 6.2% of the total national dialysis patient population. (See Chart A)

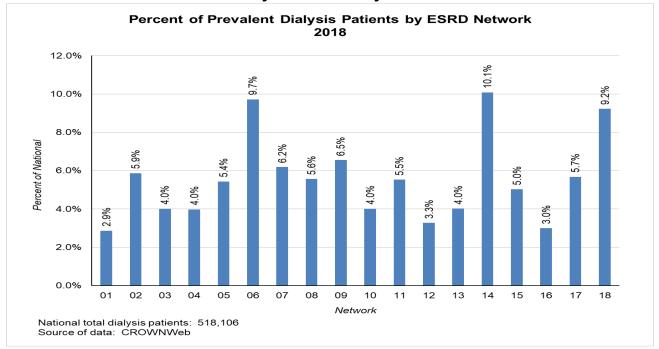


Chart A: Percent of Prevalent Dialysis Patients by ESRD Network 2018

¹ https://www.census.gov/quickfacts/fl

Race and Ethnicity²

The demographics of the ESRD population in the Network 7 service area are similar to those of the national ESRD population; 58.7% of Florida's dialysis population is characterized as White and 38.2% as African American. Asians comprise the third largest racial group in the service area, representing 1.7% of the entire ESRD population in Florida as of December 31, 2018. Per U.S. Census Bureau data, individuals who identified as Hispanic or Latino accounted for 25.6% of Florida's general population as of July 1, 2018. As of December 31, 2018, 17.7% of Florida's ESRD patients were reported as Hispanic or Latino.

Gender and Age

As of December 31, 2018, 41.0% of Florida's ESRD population was female, 59.0% was male, and 50.4% was age 65 or older, as compared to Florida's general population, in which only 20.1% of residents were estimated to be age 65 or older as of July 1, 2018.

Dialysis Treatment Options

As of December 31, 2018, 87.4% of Florida's dialysis patients were receiving in-center hemodialysis (ICHD) treatments and 12.5% were using a home dialysis modality, including continuous-cycling peritoneal dialysis (CCPD), continuous-ambulatory peritoneal dialysis (CAPD), or home hemodialysis (HHD). (See Chart B) Nationally, the Network comprised 6.1% of all CCPD, CAPD and HHD patients. (See Chart C)

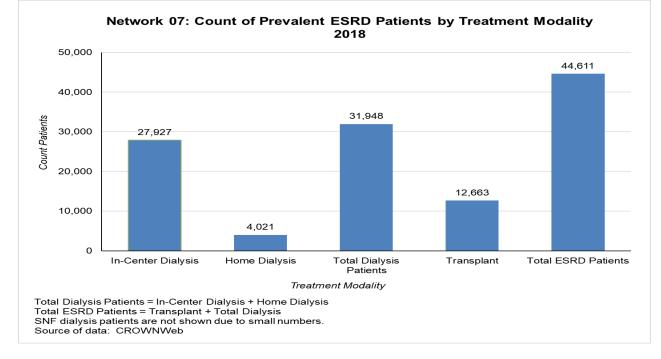


Chart B: Network 7 Count of Prevalent ESRD Patients by Treatment Modality 2018

² Data on "ethnicity" and "race" should be interpreted with caution because of the inherent instability of race/ethnicity data.

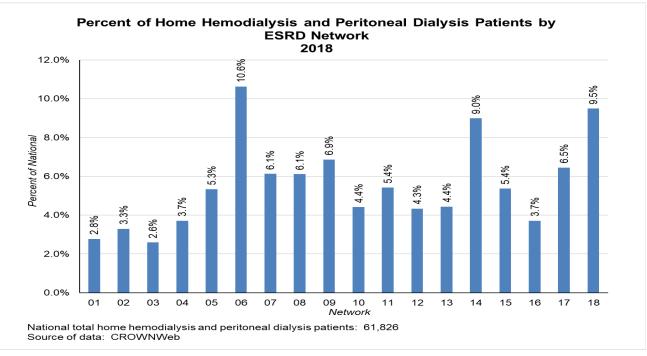


Chart C: Percent of Home Hemodialysis and Peritoneal Dialysis Patients by ESRD Network 2018

Transplant

During 2018, 1,393 kidney transplants were completed by eleven transplant centers in the state of Florida. As of December 31, 2018, there were 221,497 transplant patients nationally, of which 5.7% were in Network 7. (See Chart D)

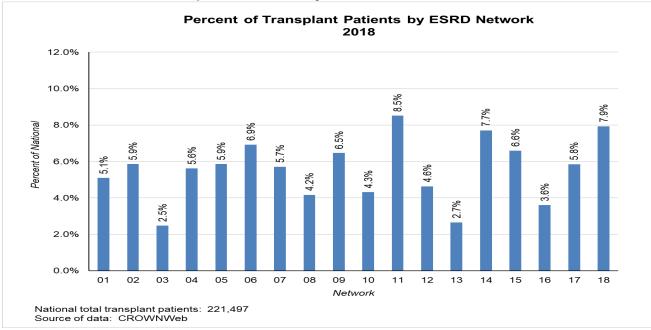


Chart D: Percent of Transplant Patients by ESRD Network 2018

ESRD Facilities

As of December 2018, Network 7's service area included a total of 497 ESRD facilities, including 484 dialysis facilities and eleven transplant facilities. (See Chart E). The majority of Florida's dialysis facilities were owned by two large dialysis organizations (LDOs): DaVita Kidney Care (DVA) and Fresenius Medical Care (FMC). These two corporations owned and/or operated 72.3% of Florida's 486 dialysis facilities as of the end of 2018. Of the LDO facilities, 43.2% were affiliated with DVA and 29.1% with FMC. Nationally, Network 7 comprised 6.5% of all dialysis facilities (See Chart F) and 4.8% of all transplant facilities (See Chart G)

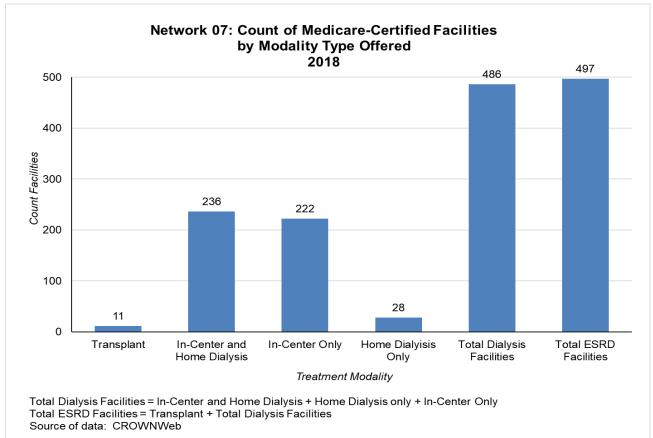


Chart E: Network 7 Count of Medicare-Certified Facilities by Modality Type Offered 2018

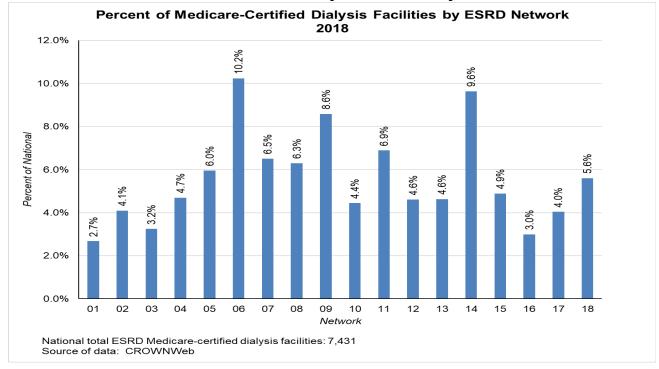
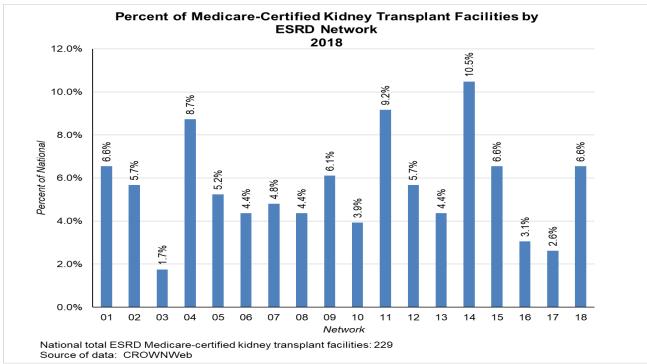




Chart G: Percent of Medicare-Certified Kidney Transplant Facilities by ESRD Network 2018





ESRD NETWORK GRIEVANCE AND ACCESS TO CARE DATA

Grievances

The Network responds to grievances filed by or on behalf of ESRD patients in its service area. Grievances may focus on staff issues, quality of care issues, and/or environmental issues and fall under several categories, including Clinical Area of Concern, General Grievance, and Immediate Advocacy. Immediate Advocacy grievances are addressed by the Network contacting the facility to resolve an issue within seven calendar days. General Grievances, in which the Network addresses more complex non-quality of care issues, are addressed over a 60-day period. Quality of Care grievances are addressed through records review and the grievant receives a final outcome letter. According to Chart H below, during 2018, 36% of contacts to the Network were for grievances, including 30% for Immediate Advocacy, 4% for Clinical Quality of Care, and 2% for General Grievances.

Facility Concerns

In addition to grievances, the Network also responded to facility concerns, which accounted for 24% of all contacts to the Network in 2018. Facility Concerns included contacts received from ESRD facilities and providers related to managing difficult patient situations, requests for technical assistance, and other concerns.

Access to Care Issues

The Network works with facilities and advocates for patients to avert potential Access to Care issues whenever possible. Access to Care concerns include patients at-risk for Involuntary Discharge (IVD) or Involuntary Transfer (IVT), and patients who have not been able to permanently establish themselves with an outpatient dialysis facility. During 2018, Access to Care issues accounted for 40% of contacts to the Network.

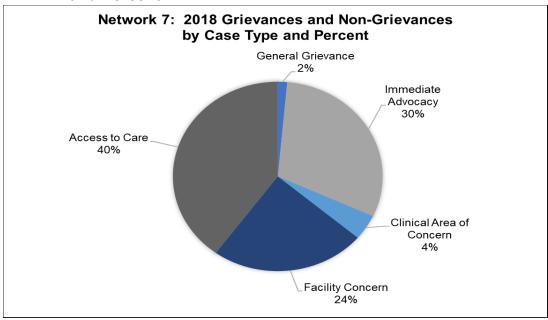


Chart H: Network 7: 2018 Grievances and Non-Grievances by Case Type and Percent

Source of data: Patient Contact Utility (PCU)



ESRD NETWORK QUALITY IMPROVEMENT ACTIVITY (QIA) DATA

Long-Term Catheter (LTC) QIA

During 2018, the Network conducted a QIA to reduce LTC use (catheter in use for 90 days or longer) in a cohort of 200 facilities with rates greater than 15.0%. The Network implemented enhanced interventions for a subset of 50 facilities, with approximately 3,386 patients, that had the highest LTC rates in the cohort.

Goals and Outcomes

The baseline LTC rate for the subset of 50 facilities, which was based on August 2017 CROWNWeb data, was 19.8%. By September 2018, the facilities reduced their aggregate LTC rate to 16.4%, which was a decrease of 3.4 percentage points. (See Chart I)

Barriers

Facility-reported barriers to reducing LTCs included:

- Patients refusing to have a permanent access placement timely.
- Patients with placement of multiple accesses that did not work.
- Lack of adequate surgeon availability to place permanent accesses or conduct timely access interventions.

Interventions

Interventions for the QIA included:

- Distributing patient education tools, including:
 - An explanation of the advantages of a permanent access versus a catheter.
 - The importance of hand hygiene.
 - Proper access care.
- Distributing resources to identify and maintain a facility Vascular Access (VA) manager.
- Encouraging use of a tracker for monitoring patient appointments.
- Collecting and trending facility data to conduct rapid cycle improvement.

Best Practices

Best practices identified by QIA facilities included:

- Developing a process to provide vascular access education to patients upon initiation of dialysis.
- Holding a celebration in the facility for each new permanent access placed.
- Conducting a meeting with the local surgeon office(s) to address timely evaluation and placement of permanent accesses.

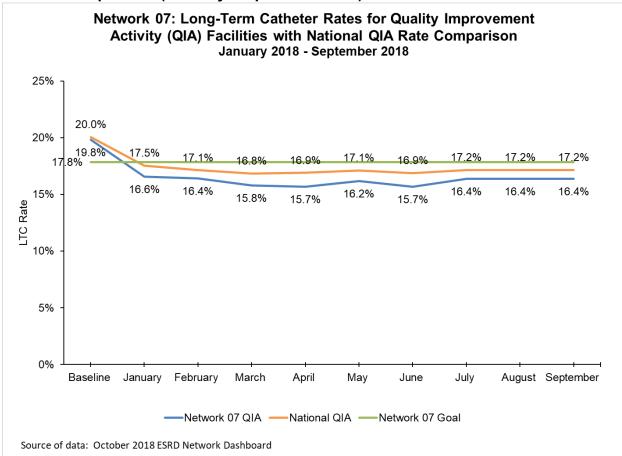


Chart I: Network 7: LTC Rates for QIA Facilities with National QIA Rate Comparison (January–September 2018)

Bloodstream Infection (BSI) QIA

During 2018, the Network conducted a QIA to reduce dialysis event rates, specifically BSIs, by improving infection control practices. The QIA was designed to support the National Action Plan to Prevent Healthcare-Associated Infections (HAIs) and the Centers for Disease Control and Prevention (CDC) Core Interventions for Dialysis BSI Prevention Program. The QIA included 200 facilities, impacting approximately 15,217 patients. While 200 facilities were included in the QIA, the measurement for Network success was based on the 20% of facilities in the cohort (n=80) with the highest BSI rates.

Goals and Outcomes

The Network used the National Healthcare Safety Network (NHSN) BSI pooled mean rate per 100 patient-months to target facilities for the QIA. The goal was to achieve at least a 20% relative reduction in the pooled mean rate of BSIs from January–June 2018 and to prevent at least 92 BSIs. By the conclusion of the QIA, the aggregate BSI rate decreased from 1.3 to 0.7, and 248 BSIs were prevented, exceeding the goal. (See Chart J)

Barriers

Facilities reported the following barriers to further reducing BSIs at their facilities:

- Lack of staff focus on infection prevention techniques and event reporting.
- Poor patient compliance with hand washing and catheter care.

Interventions

Interventions implemented during the QIA included:

- Directing facilities to have staff complete the following training courses:
 - Infection Prevention in the Dialysis Setting.
 - NHSN Dialysis Event Surveillance.
- Distributing patient education related to hand hygiene.
- Disseminating the interactive patient learning module, *Test your Hand Hygiene Knowledge*.
- Collecting and trending facility data to conduct rapid cycle improvement.
- Providing education on the 9 CDC core interventions.
- Having facilities complete CDC BSI prevention audit tools for staff.
- Posting the CDC's *Days Since Last BSI* poster.
- Providing additional education and sharing best practices gained through the ESRD National Coordinating Center's (NCC's) BSI QIA Learning and Action Network (LAN).
- Encouraging facilities to work toward obtaining access to a Health Information Exchange (HIE) in their area.

Best Practices

Facilities reported including patients in monthly hand hygiene audits to be a best practice, as well as using Clear Guard Antimicrobial Barrier Caps. Evaluation results indicated that facilities plan to continue using the patient education provided by the Network, as well the CDC infection control audits, for sustainability of gains made during the QIA. By September 30, 2018, 100% of all dialysis facilities reporting in NHSN had completed the *NHSN Dialysis Event Surveillance training*, and 49% of the facilities included in the group with the highest BSI rates had gained access to an HIE. (See Charts K and L)

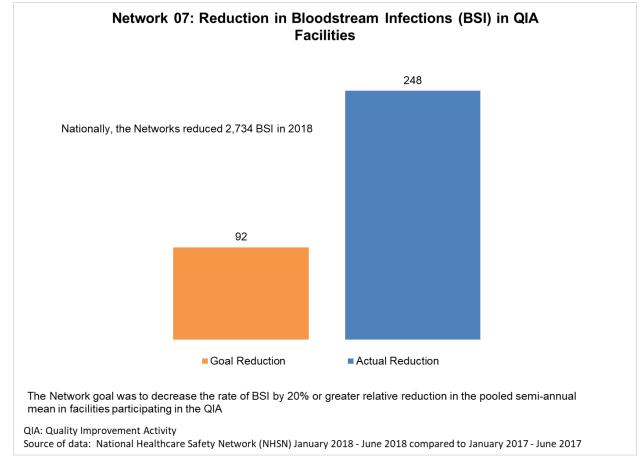


Chart J: Network 7: Reduction in BSIs in QIA Facilities

Chart K: Network 7: Percent of Dialysis Facilities that Have At Least One Person Who Has Completed the NHSN Dialysis Event Surveillance Training (January–September 2018)

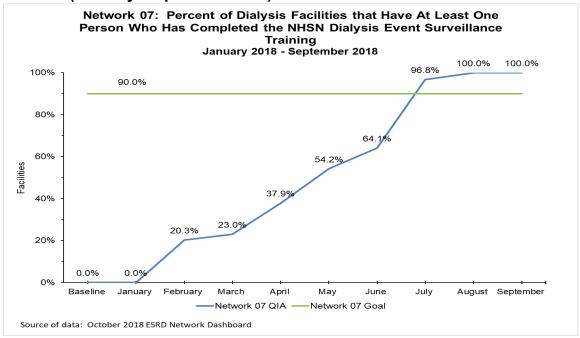
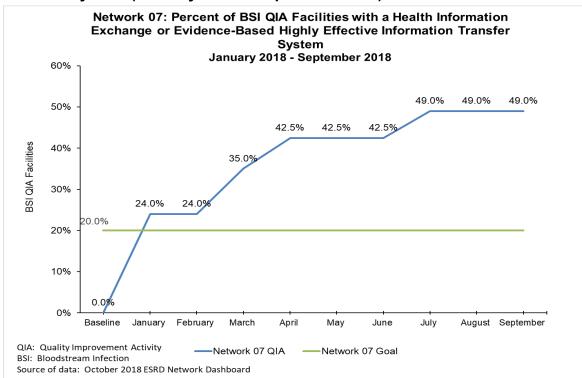


Chart L: Network 7: Percent of BSI QIA Facilities with a Health Information Exchange or Evidence-Based Highly Effective Information Transfer System (January 2018 – September 2018)



Transplant Waitlist QIA

In 2018, the Network conducted a QIA to support the CMS goal of increasing the rates of dialysis patients on a transplant waitlist by 10 percentage points over the baseline for a targeted group of dialysis facilities.

Goals and Outcomes

The Network identified 123 dialysis facilities for inclusion in the QIA, impacting approximately 9,300 hemodialysis patients. The baseline rate was 6.8%, and the final measure rate, as of September 2018, was 7.5%. (See Chart M)

Barriers

Barriers to meeting the QIA goals included:

- Patient refusals.
- Lack of a structured communication process between the dialysis facilities and transplant centers.
- Patients' inability to meet the criteria for transplant referral or complete the work-up.

Interventions

The Network addressed each of the barriers indicated above with the following interventions:

- To explore the large number of patient refusals, the Network created a resource that the facilities could use to ask patients why they were not interested in pursuing a transplant.
 - The network collected the patients' responses from facilities and the results were reviewed and discussed with Network Patient Subject Matter Experts (SMEs). Based on feedback from the SMEs, the Network began the development of two interventions:
 - A transplant referral guide.
 - Patient testimonials that address the risks vs. the rewards of receiving a transplant.
- The Network encouraged the QIA facilities to build a workable, structured communication process with the transplant centers with the goal of successfully exchanging information to expedite the referral process.
 - To achieve this, the Network shared best practices identified by QIA facilities and the ESRD NCC Transplant LAN.
- To ensure proper tracking and documentation of each patient's movement through the steps to transplant wait listing, the Network created and disseminated a Seven Steps to Transplant tracker for use by QIA facilities.
 - The tracker could also be used for ease in completing monthly QIA reporting to the Network.

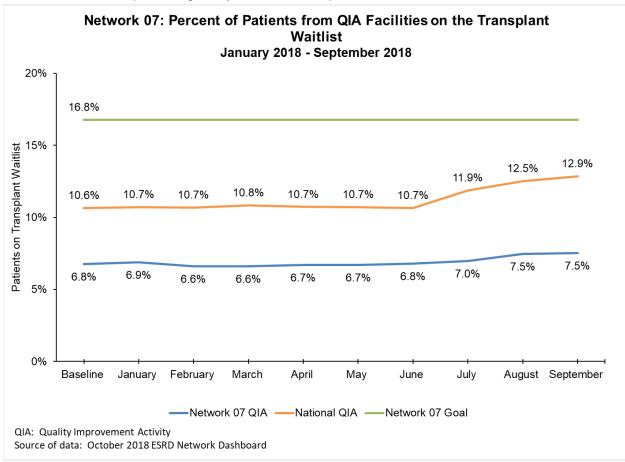
Best Practices

Best practices identified from the QIA include:

- Building better communication processes with transplant centers for exchanging information.
- Referring patients to more than one transplant center if they meet the criteria.
- Using a tracking tool to follow patients through the transplant waitlist process.
- Conducting a transplant Lobby Day and inviting a previously transplanted patient to attend.
- Using the *Why Not consider Transplant Questionnaire* to identify why patients are refusing to pursue transplant.

- Educating patients and staff on transplant, the waitlist process, and referral criteria.
- Assisting and supporting patients through the transplant waitlist process.

Chart M: Network 7: Percent of Patients from QIA Facilities on the Transplant Waitlist (January–September 2018)



Home Therapy QIA

In 2018, the Network conducted a QIA to support the CMS goal of increasing the number of ESRD patients dialyzing at home by 10 percentage points over the baseline for a target group of dialysis facilities.

Goals and Outcomes

The Network identified 118 dialysis facilities (30%) for inclusion in the QIA, impacting approximately 8,536 patients. The baseline rate was 0.5%, and the final measure, as of September 2018, was 4.9%. (See Chart N)

Barriers

Barriers to meeting QIA goals included a lack of:

- A formal tracking process for timely follow-up with patients in need of education and who had been referred.
- A home program to partner and collaborate with for the QIA.
- Patient and/or caregiver interest in home dialysis.

Interventions

The following interventions were implemented to address barriers over the course of the QIA:

- Using a home dialysis patient tracker to monitor patients through the steps to home dialysis.
- Collaborating with a home dialysis program for patient and staff education.
- Educating new and existing in-center patients regarding home dialysis.
- Hosting a home dialysis Lobby Day with assistance from a home program and including an existing home patient and/or caregiver.
- Collecting monthly reports from QIA facilities to show the progression of patients from referral to training and implementation of QIA activities.

Best Practices

Best practices identified through the QIA include:

- Using the home dialysis tracking tool created by the Network or an internal tracking tool.
- Continuing on-going communication with a partnering home program for timely patient follow-up.
- Administering the Match-D assessment tool.
- Educating patients at their level of readiness using the following materials:
 - Could Home Dialysis be a Choice for Me
 - My Dialysis, My Choice
- Conducting a Lobby Day using the Network's *Tips for Engaging Patients When Hosting a Lobby Day* resource.
- Developing support from the facility medical director and other nephrologists to transition patients through the seven steps to home dialysis training.

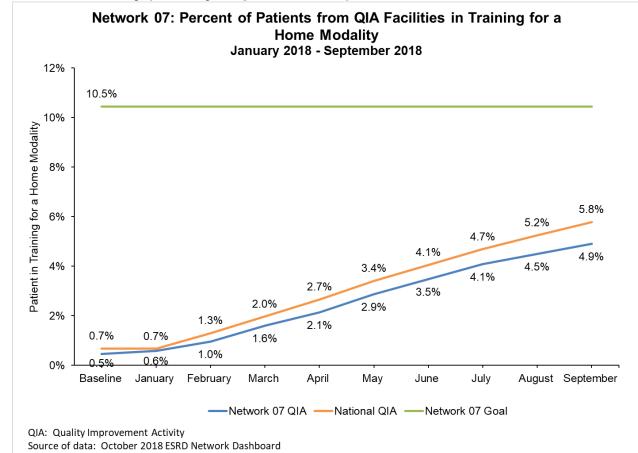


Chart N: Network 7: Percent of Patients from QIA facilities in Training for a Home Modality (January–September 2018)

Population Health Focused Pilot Project QIA: Positively Impact the Quality of Life of the ESRD Patient with a Focus on Pain Management

In 2018, Network 7 conducted a QIA that focused on improving pain management in 10% of the dialysis facilities in the Network service area.

Goals and Outcomes

The primary goal of the QIA was to achieve a 10% improvement in the completion of pain assessments in the Network service area and achieve a 100% zero rate of "no pain assessment completed, and no reason given" in CROWNWeb by the end of September 2018. The baseline rate for "no pain assessment and no reason given" for the 44 facilities was 68.5% based on October 2016–June 2017 CROWNWeb data. By QIA completion, the pain assessment rate for 'no pain assessment and no reason given,' decreased to 0.2%, representing a reduction of 68.3%.

A secondary goal of the QIA was to eliminate the disparity between the disparate population (race other than White), as compared to a non-disparate population (White), when measuring pain assessments documented as "no pain assessment completed, and no reason given." The baseline disparity rate among the 44 facilities was 6.11% based on October 2016–June 2017 CROWNWeb data. By the QIA's closure, the Network reduced the disparate rate from 6.1% to 0.1%, representing a 6.0% reduction. (See Charts O, P, and Q)

Barriers

Root cause analysis (RCA) on 44 facilities exhibited the following causes for poor performance on the completion of pain assessments, including a lack of:

- Facility leadership knowledge and inadequate staff training regarding purpose and method for completing pain assessments and follow-up plans.
- Facility processes to track, monitor, and ensure pain assessments and follow-up plans are completed and documented.
- A streamlined process for reporting of pain assessments in CROWNWeb, resulting in missed or incomplete pain assessments and lack of reporting per required timeframes.
- CROWNWeb batching errors.

Interventions

The QIA interventions included:

- Using a tracking and monitoring tool to ensure pain assessments are completed on all eligible patients.
- Collecting monthly feedback regarding pain assessments on patients reporting, including the type of pain and interventions to address symptoms of pain.
- Referring patients to a primary care provider (PCP) or specialist for pain management.
- Documenting appointments related to pain management in the electronic medical record.
- Educating staff about conducting pain assessments, to include:
 - Facility policy and procedure for conducting pain assessments.
 - Centers for Medicare & Medicaid Services (CMS) Quality Incentive Program (QIP) pain assessment reporting requirements.

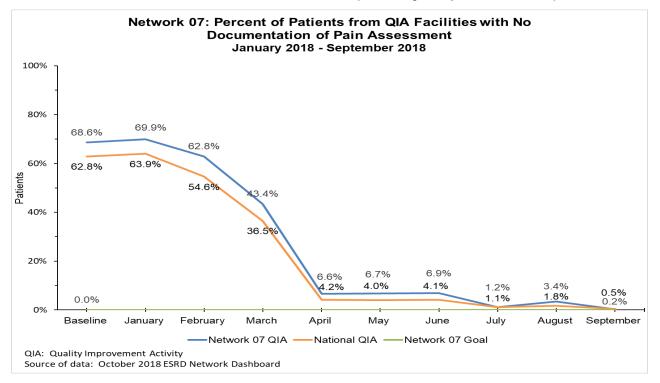
- Chronic vs. acute pain.
- Non-medication strategies for pain management.
- Instructing facilities to identify the timing of their batch and the template used to capture the data, to ensure that the most current pain assessment data was documented and batched into CROWNWeb.

Best Practices

Best practices identified by QIA facilities included:

- Ongoing monitoring and tracking of pain assessment follow-up plans for patients reporting pain.
- Educating staff and patients about non-pharmacological interventions for pain.
- Obtaining CROWNWeb access for a least one nurse.
- Referring patients to a PCP or specialty doctor for pain management.
- Conducting medication reviews to verify medication prescriptions for pain management.

Chart O: Network 7: Percent of Patients from QIA Facilities with No Documentation of Pain Assessment (January–September 2018)



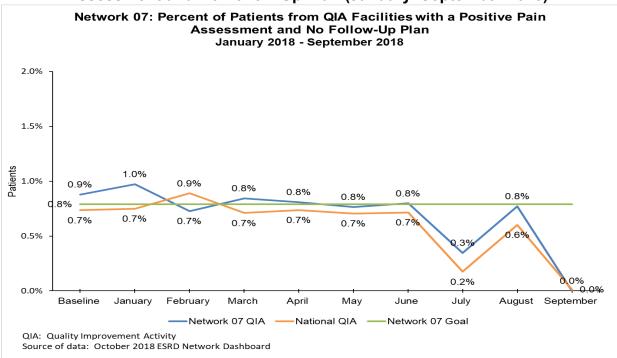
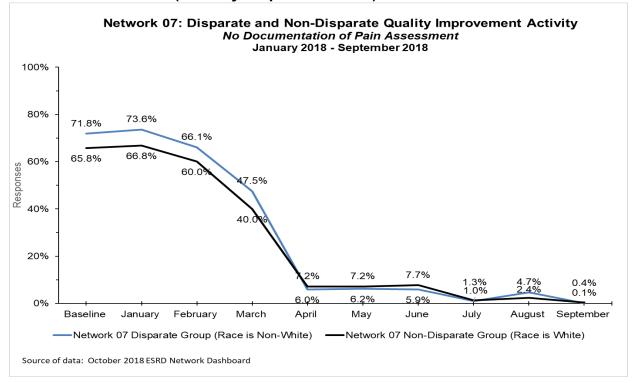
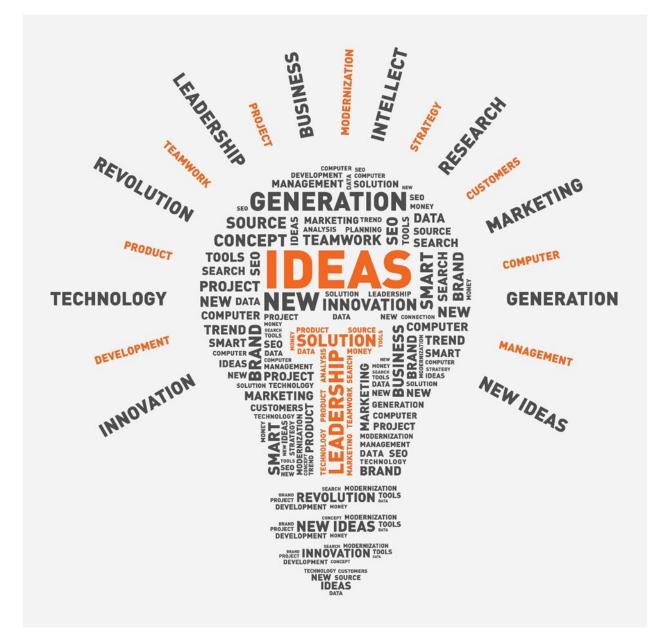


Chart P: Network 7 Percent of Patients from QIA facilities with a Positive Pain Assessment and No Follow-Up Plan (January–September 2018)

Chart Q: Network 7 Disparate and Non-Disparate QIA No Documentation of Pain Assessment (January–September 2018)





ESRD NETWORK RECOMMENDATIONS

Recommendations for Sanction

Section 1881(c) of the Social Security Act states that the ESRD Network can recommend to CMS the imposition of a sanction when an ESRD provider is not cooperating in achieving Network goals. The Federal Regulations that implement this statute are found in 42 CFR §405.2181. The Network strived to maintain a cooperative and collaborative partnership with ESRD providers in all activities in 2018. The Network regularly interacted with facilities regarding QIAs and projects, patient grievances, data reporting, and the provision of technical assistance and education.

In 2018, the Network did not identify any facilities that warranted a recommendation for sanctions.

Recommendations to CMS for Additional Services or Facilities

The Network shares available aggregate data with the CMS Regional office in Dallas, as requested, for use in determining Special Purpose Renal Dialysis Facility (SPRDF) approvals in anticipation of or in response to emergency situations. The information provided generally includes the number of dialysis patients, facilities, and stations available in a given geographic area. In 2018, the Network recommended the approval of one SPRDF due to the impact of Hurricane Michael.

During 2018, the Network identified the need for specialized dialysis services that are not currently provided by typical outpatient or home dialysis facilities for patients with tracheotomies. Identified, specialized services could include regionalized outpatient hemodialysis facilities that can provide enhanced monitoring for patients or HHD training in the home due to caregiver travel restraints.



ESRD NETWORK SIGNIFICANT EMERGENCY PREPAREDNESS INTERVENTION

ESRD Network 7 is tasked with providing support to dialysis facilities related to emergency preparedness, planning, and response. To ensure this support is provided, the Network:

- Conducts a risk assessment and submits an emergency plan annually to CMS.
- Monitors and tracks the open and closed status of facilities and the location of patients during the response to an emergency event.
- Works closely with the Kidney Community Emergency Response (KCER) Coalition and other stakeholders to ensure patients have access to dialysis before and after an emergency event.

Hurricane Michael, addressed below, was the only emergency event Network 7 responded to during 2018.

Hurricane Michael

Hurricane Michael made landfall in the Florida Panhandle on Wednesday, October 10, 2018. The storm caused widespread damage and flooding across 10 counties, with extensive power outages across the region in the days immediately following landfall. Hurricane Michael also caused damage to critical infrastructures and disruptions in systems and services within the impacted areas, including power, water, roads, transportation, communication, and 911 systems. Forty-one facilities in the Network service area reported changes to their operational status due to the storm, impacting over 2,615 dialysis patients. Multiple facilities required use of a water tanker and/or generator to re-open after the storm; one facility remained closed long-term.

In preparation for Michael, the Network distributed weather alerts, patient education, and links to community resources, including a link to all open shelters, to all facilities in the affected area. The Network participated in state of Florida preparedness calls and was in contact with the Big Bend Healthcare Coalition for pre-storm planning.

Response activities for Hurricane Michael included:

- Remaining in contact with the facilities in the affected area to assess and track operational status and identify patient access to care issues.
- Receiving and addressing patient and stakeholder calls related to facility operational status, including patients who evacuated and needed placement at a new facility.
- Collaborating with stakeholders to resolve patient access to care issues.
- Submitting situational updates to the KCER Coalition and CMS daily and participating in daily emergency status calls with key ESRD and emergency preparedness stakeholders.

ACRONYM LIST APPENDIX

This appendix contains an <u>acronym list</u> created by the KPAC (Kidney Patient Advisory Council) of the National Forum of ESRD Networks. You can access the acronym list on <u>The National Forum of ESRD</u> <u>Networks website</u>. We are grateful to the KPAC for creating this list of acronyms to assist patients and stakeholders in the readability of this annual report. We appreciate the collaboration of the National Forum of ESRD Networks especially the KPAC.