2009

Fistula First Breakthrough Initiative Strategic Plan

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TABLE OF CONTENTS

Section I
EXECUTIVE SUMMARY

The percentage of prevalent hemodialysis patients in the US with an arteriovenous fistula (AV fistula) as their primary vascular access was 32.4% (87,344 patients) at the beginning of 2003. By May 2009, this percentage had increased to 52.6% (179,113 patients). As a result, approximately 92,000 additional patients experienced improved adequacy, fewer hospitalizations, fewer infections, and a lowered mortality risk than those with other forms of vascular access.[1] The dramatic change in practice patterns that produced the improvement was due to the targeted efforts of many organizations and individuals, facilitated by the Fistula First Breakthrough Initiative (FFBI). However, the Centers for Medicare & Medicaid Services' (CMS) goal, based upon achievable practice, is a prevalent AV fistula utilization rate of 66%, which requires the identification of additional opportunities for improvement. This strategic plan aims to serve as the roadmap to CMS, providers of care, the renal community and professionals working with Chronic Kidney Disease (CKD) patients to achieve the goal of 66%.

In developing this plan, a Root Cause Analysis (RCA) team convened to identify underlying barriers that prevent AV fistula placement and use, and a Technical Expert Panel (TEP) convened to identify solutions to the root causes. The TEP, with membership from the surgical, interventional, and CKD communities, brought forward strategies that when implemented will have a positive impact on AV fistula rates nationally.

Identified strategies include:

Nephrologist as Leader

The nephrologist is the leader of the healthcare team and has responsibility for assuring that patients are prepared for dialysis, that prescriptions are appropriate, and that quality outcomes are achieved. Strategy 1 (Encourage and support nephrologists to take a leadership role and be accountable for vascular access management in all hemodialysis patients) calls for greater collaboration with the American Society of Nephrology as the primary provider of nephrology continuing education. It also supports expansion of nephrology fellowship training programs to include skills such as leadership training and quality improvement. Accountability is promoted in this strategy through the development and use of nephrology profiles of care.

Leveraging Partnerships

The CMS goal of 66% AV fistula utilization in prevalent hemodialysis patients and reduction in the quality deficit for incidence AV fistulas cannot be achieved exclusively by one organization. This goal can only be achieved by building upon existing relationships throughout the renal and Quality Improvement Organization (QIOs) communities as well as identifying and engaging new and existing partners, each of whom brings a variety of expertise, resources, and motivation to the effort. Strategy 2 (Partner to improve AV fistula placement and utilization rates) advances public awareness campaigns (such as GFR 30-20-10 and "Save Your Veins"), promotes the identification and use of educational resources from a variety of organizations, and supports an effective and dynamic website for sharing resources. The strategy also recognizes several key partners (such as National Kidney Disease Education Program (NKDEP) and the Society for Vascular Surgery) to disseminate specific messages to target audiences.

Hospital Systems

Hospitals are integral new partners to the FFBI. They represent an immense opportunity to affect the incident and prevalent AV fistula utilization rates for the newly diagnosed CKD patient, the CKD Stage 5 patient who presents for emergent hemodialysis therapy, and the patient who progresses rapidly to CKD Stages 4 - 5 while being treated for another condition. Strategy 3 (Modify hospital systems to promote AV fistula placement) calls for development of a new Change Concept addressing identification of CKD while hospitalized, discharge planning that promotes AV fistula placement, appropriate referral of patients identified in the hospital setting, and vessel preservation. It builds upon relationships between hospitals and QIOs and dovetails with CMS's emphasis on patient safety, care transitions to reduce re-hospitalizations, and surgical site infection prevention, and recognizes vascular catheter-associated infection as a CMS-identified hospital-acquired infection.

Patient Self-Management

Managing chronic illness is time-consuming and complex, but the use of self-management support programs is expected to reduce health costs and improve outcomes. Strategy 4 (Promote patient self-management throughout the stages of CKD) acknowledges the patient-practitioner partnership as a new chronic disease paradigm. This partnership involves collaborative care and self-management education and is another strategy that lends itself to the development of a new Change Concept. While traditional patient education offers information and technical skills, self-management education teaches problem-solving skills. Network Patient Advisory Committees (PACs) can serve as partners in this strategy.

Addressing Access Problems

Several of the challenges encountered in the FFBI efforts around the country have been with AV fistulas that fail to mature, revision of failing AV fistulas, and conversion of a central venous catheter (CVC) to an AV fistula. Various protocols exist or are being developed to address these issues. Strategy 5 (Promote fast-track protocols for rapid identification and referral of vascular access problems, which include failure to mature, revision of the failing AV fistula, and placement of an AV fistula) recommends development and deployment of protocols to rapidly address these problems.

Practitioner Training and Credentialing

Many specialties care for CKD patients, including primary care providers, vascular access surgeons, nephrologists, interventionalists, nurses, and dialysis technicians. To provide patients with the best care possible, practitioners need to be well educated on the standards, guidelines, policies, and procedures associated with their particular domain of care. They should have the appropriate credentials and attend appropriate continuing education programs to keep their skills current. Practitioners must then incorporate new knowledge and new skills into their practice. Strategy 6 (Promote training, experience, and credentialing of healthcare professionals in the area of hemodialysis vascular access management) identifies the training needed for these practitioners, specifically vascular access surgeons who perform procedures and dialysis technicians who provide care during each hemodialysis session.

FFBI Change Concepts

The current FFBI Change Concepts were developed and implemented in 2003, and the steady increase in the national AV fistula prevalence rate is attributed to the implementation of these Change Concepts. Each of the 18 ESRD Networks has employed the Change Concepts to develop, evaluate, and redesign quality improvement projects addressing the identified challenges in their specific geographic region. Many of the Change Concepts have worked well, but some need refinement to make them more robust. Strategy 7 (Expand and endorse the current Change Concepts for education and promotion throughout the renal, surgical, and interventional communities) recommends changes to 10 of the 11 concepts and the creation of two (2) new change concepts: Modify Hospital Systems and Patient Self-Management.

In addition to the seven (7) strategies, two (2) policy recommendations were made:

Pay-for-performance

To promote safe, efficient, effective, patient-centered, timely, and equitable vascular access care for individuals with CKD Stage 5, it is recommended that financial performance incentives be utilized.

Assure Data Flow

Accurate data, reliably collected, available in a timely fashion, and analyzed in meaningful ways, serve in understanding challenges, setting goals and tracking progress. Data play a central and enabling role in improving the prevalent AV fistula rate and support each of the preceding strategies.

Each of the strategies and policy recommendations has been made by the TEP working in collaboration with the clinical consultants and the FFBI contractor. The strategies and policy recommendations include specific tactics and actions for implementation across many healthcare systems that care for CKD patients. Collaboration and coordination within all of these systems are crucial to ensure the strategies are implemented in a manner that will positively impact practice patterns and behaviors to move the AV fistula utilization rate to 66% nationally. Healthcare and community systems must support this quality improvement initiative to ensure that all eligible hemodialysis patients are dialyzing with an AV fistula.

A. Fistula First Breakthrough Initiative History and Structure

Arteriovenous fistulas (AV fistulas) are considered the gold standard for hemodialysis vascular access based on their superior patency, low complication rates, improved adequacy, lower cost to the healthcare system, and decreased risk of patient mortality. As part of the End Stage Renal Disease (ESRD) Networks Statement of Work (SOW) beginning in July 2003, the Centers for Medicare & Medicaid Services (CMS), the ESRD Networks, and key provider representatives jointly recommended adoption of a National Vascular Access Improvement Initiative (NVAII). The primary goal of this Continuous Quality Improvement (CQI) project was to increase the appropriate use of AV fistulas for hemodialysis access and to reach or exceed the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (K-DOQI) practice guidelines of 50% in incident patients and 40% in prevalent patients. Due to the implementation of this quality improvement initiative, this goal was reached in August 2005, 10 months earlier than anticipated.

The focus of the original NVAII was to address clinical and organizational improvements that would lead to placement and use of AV fistulas. ESRD Networks, dialysis providers, medical specialists, hospitals, and clinics all share responsibility for improving dialysis care by increasing appropriate and successful AV fistula placement. The ESRD Networks played a major role in catalyzing change, creating efficient ways to share knowledge and resources and building strong alliances with the facilities and medical professionals in their regions.

An interdisciplinary working group supported by a team from the Institute for Healthcare Improvement (IHI) identified and developed 11 major Change Concepts. The Change Concepts focused on modifications that could be made immediately to give all eligible hemodialysis patients the opportunity to receive an AV fistula. The current Change Concepts are presented in Appendix A.

In 2005, the NVAII was recognized by CMS as a breakthrough initiative and became known as the Fistula First Breakthrough Initiative (FFBI); the national prevalent AV fistula goal was increased to 66%. As part of the initiative, the FFBI Coalition was formed and remains active today. Going forward, the FFBI Coalition structure will be reconfigured with added partners who can impact all systems involved in the placement of AV fistulas.

"The work of the ESRD Networks and their partners has led to substantial increases in US AV fistula rates which translate into saved lives, improved quality of life for dialysis patients, and reduced cost for Medicare."
-IHI

Section III
INTRODUCTION

A. Need for a Strategic Plan

One of the primary goals of, and a challenge faced by, the FFBI project is implementation of sustainable system changes that support increased AV fistula placement and use. A system change modifies healthcare processes or procedures so that providers can more easily incorporate best-demonstrated practices into their daily routines. System changes can improve care processes within a single system or across systems. Meaningful and sustainable changes within systems require:

- A clear, shared vision of purpose and goals;
- Intentional fostering of partnerships and relationships; and
- Organizations working together to leverage resources to build knowledge, skills, and processes.

In the first phase of the FFBI project, a clear and shared vision was articulated through the wide distribution and marketing of the evidence-based guidelines setting forth the advantages of AV fistulas. A collaborative structure for the spread of ideas, fostered partnerships, and tools and resources (as presented in the Change Concepts) was developed and implemented, allowing ESRD Networks and others to build knowledge, skills, and processes. System changes during this phase targeted vascular access surgeon behavior (increased training on AV fistula placement), reimbursement (G code for vessel mapping and revised Relative Value Unit (RVU) for AV fistula placement), dialysis facility implementation of various Change Concepts, and data flow (development of a Fistula First Dashboard and feedback reports).

While the CMS goal of achieving a prevalent AV fistula utilization rate of 66% remains unmet, additional systems within and beyond the dialysis facility community require modification to assure continued and sustainable improvement. One example is systems addressing the transition of chronic kidney disease (CKD) patients from primary care to nephrology to surgery, as well as the interactions between these sites of care, which include the acute care hospital, the dialysis facility, and in some cases the interventional center. Changes to these systems will positively impact several of the ongoing issues associated with improved AV fistula rates, specifically central venous catheter (CVC) usage and failure of AV fistulas to mature.

ESRD Networks, working with Quality Improvement Organizations (QIOs) and FFBI Coalition members, can affect system change by:

- Identifying desirable system changes and guiding the implementation of system changes through technical assistance and promotion of best practices;
- Promoting existing Change Concepts at the dialysis facility level;
- Developing new Change Concepts to address hospital systems and patient self-management;
- Supporting data reporting systems that enable monitoring, benchmarking and feedback; and
- Providing quality improvement training.

The purpose of this strategic plan is to continue the process of putting sustainable system changes into place so that all appropriate hemodialysis patients routinely receive timely and functional AV fistulas.

B. Current Situation and Trends

The percentage of prevalent hemodialysis patients in the US with an AV fistula as their primary vascular access was 32.4% (87,344 patients) at the beginning of 2003. By May 2009 this percentage had increased to 52.6% (179,113 patients). As a result, approximately 92,000 additional patients experienced improved adequacy, fewer hospitalizations, fewer infections, and a lowered mortality risk than

those with other forms of vascular access.[1] The dramatic change in practice patterns that produced the improvement was due to the targeted efforts of many organizations and individuals facilitated by the FFBI. However, the CMS goal, based upon achievable practice, is a prevalent AV fistula utilization rate of 66%, which requires the identification of additional opportunities for improvement. The QIOs working on a CMS CKD sub-national project have a goal to reduce the gap between the statewide baseline AV fistula rate and 66% for incident hemodialysis beneficiaries.*

There is notable variation among the ESRD Networks as well as variation among states within ESRD Networks, signifying that opportunities for improvement are still present. The data for May 2009, show a range of AV fistula rates among the ESRD Networks from 48.1% to 63.8%; arteriovenous graft (AV graft) rates from 12.8% to 28.5%; and central venous catheter (CVC) rates from 7.1% to 13.5%.[2] One (1) ESRD Network has 40% of its facilities achieving AV fistula prevalence utilization rates of 66% or greater, implying that there are best-demonstrated practices to be understood and implemented in underperforming regions.[2]

Opportunities for Improvement

Several adverse trends have emerged which present opportunities for continued improvement and which, if addressed, will improve the AV fistula rate. One is the AV fistula which fails to mature. It is estimated that between 23% and 46% of AV fistulas placed fail to mature[3] and are either never used or do not have timely revisions. This problem has given rise to free-standing vascular access centers that specialize in the management of dialysis accesses. Services provided by these centers vary but primarily include maturation procedures such as angioplasty to relieve stenosis, ablation of competing veins, vessel mapping prior to AV fistula placement, thrombectomy (declotting), and intervention for some cases of steal syndrome.

Concerns that increased AV fistula placement rates have led to an increased prevalence in CVCs are not validated by data,[4] but the high number of patients who present for their first hemodialysis treatment with a CVC is of concern. Data indicate that approximately 82% of new patients start dialysis with CVCs.[5] This can be impacted by earlier nephrology referral and care, but change requires partnerships with professional organizations that reach nephrologists and referring physicians (internists, family practitioners, cardiologists, and endocrinologists, in particular) to increase awareness of the importance of timely referral for AV fistula creation before hemodialysis is initiated. Programs being implemented by several of the large dialysis organizations (Fresenius' "Catheter Last" and DaVita's "Cath-away" initiatives) should have a positive influence on the problem and lead to improvements in converting CVCs to a more appropriate vascular access.

Regulatory and Legislative Initiatives

Several regulatory and legislative initiatives have potential to positively affect the AV fistula rates moving forward. In April 2008, CMS published updated Conditions for Coverage for dialysis facilities. These regulations modernize Medicare's ESRD health and safety conditions, are patient-centered, and reflect improvements in clinical standards of care. In addition, these regulations require the use of more advanced technology and outline a framework to incorporate performance measures viewed by the scientific and medical communities to be related to the quality of care provided to dialysis patients.[6]

Under the new Conditions for Coverage, dialysis facilities are required to "develop, implement, maintain, and evaluate an effective, data-driven, quality assessment and performance improvement (QAPI) program with participation by the professional members of the

* The CMS goal of achieving 66% incident patients with AVFs in place as of the first outpatient dialysis treatment is a performance measure for the QIOs that have sub-national CKD contracts. The denominator is limited to adult patients who are entitled to Medicare prior to initiating dialysis and who have a CKD diagnosis at least 6 months prior to starting dialysis.

interdisciplinary team."[6] There are nine (9) clinical indicators that are required to be monitored and assessed to determine the facilities' performance and identify their opportunities for improvement. One of these clinical indicators is vascular access.

An additional requirement outlined in the Conditions for Coverage is electronic data submission using a web-based application called CROWNWeb. This application will enable dialysis providers to input patient data directly into a registry system. The availability of data in this system will allow ESRD Networks and other authorized users to analyze, trend, and report comparative data on many indicators of care, including vascular access outcomes. In preparation for a Pay-for-Performance model of care, these data will potentially assist in the development of policies for payment that include case mix adjustments. CROWNWeb is currently in the testing phase and should be operational with all providers in early 2010.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) has several provisions that impact the care of patients with CKD. Section 152(b) provides Medicare coverage for kidney disease patient education services for CKD Stage 4 individuals. Coverage for these services is designed to provide individuals with comprehensive information regarding the management of comorbidities, prevention of uremic complications, and available options for renal replacement therapy; provide individuals with the opportunity to actively participate in the choice of therapies; and provide information tailored to individual patient needs.

Section 153(b) of MIPPA calls for the development of a dialysis bundled payment system to be implemented by 2011. The payment system for facility reimbursement directs Medicare to make adjustments based on case mix, including co-morbidities, length of time on dialysis, age, race, ethnicity, and other appropriate factors. The Act also calls for the development of quality incentives with a reduction in payment to providers who fail to achieve specific measures, one of which will address vascular access through maximizing the placement of AV fistulas.[7]

While AV fistulas are the gold standard for the dialysis patient in terms of decreased morbidity and mortality with corresponding improvement in quality of life, they also represent significant cost savings. The United States Renal Data System (USRDS) noted in 2006, that the per patient per year expenditure for a dialysis patient with a CVC was $77,093, compared to $71,616 for a patient with an AVG and $59,470 for a patient with an AV fistula.[8] Therefore, the annual per patient cost savings of an AV fistula as compared to an AV graft was $12,269, and the cost savings as compared to a CVC was $17,746. These cost savings could be recognized in the development of a Pay-for-Performance program to provide incentives for quality care.

C. Role of the ESRD Networks, QIOs, and Renal Partners

One of the hallmarks of the FFBI has been the collaboration of diverse groups to achieve a similar aim. The FFBI Coalition membership includes, but is not limited to…

- ESRD Networks
- QIOs
- CMS
- National Institutes of Health
- USRDS
- Medical Education Institute (MEI)
- Renal Physicians Association (RPA)
- Society for Vascular Surgery (SVS)
- American Society of Nephrology (ASN)
- American Nephrology Nurses Association (ANNA)
- National Renal Administrators Association (NRAA)
- American Association of Kidney Patients (AAKP)
- American Kidney Fund (AKF)
- National Kidney Foundation (NKF)
- Fresenius
- DaVita
- WellPoint
- Kaiser

In total, over 40 associations are represented and contribute to the project's successes.

As contractors to CMS, both the ESRD Networks and the QIOs are charged with improving the care of the beneficiaries they serve. This is accomplished through building collaborative relationships and providing technical assistance to providers of direct services. As such, they are in an exceptional position to implement many aspects of this strategic plan. Specifically, the 11 QIOs that currently hold CKD sub-national project contracts have been directed by CMS to initiate measures to reduce the onset of renal failure through prevention and to improve the rate of AV fistulas in incident patients. ESRD Networks are charged with promoting increased AV fistulas in the prevalent population. The ESRD Networks and QIOs will work with current and emerging FFBI stakeholders to implement the Strategic Plan.

D. How the Plan was Developed

In late February 2009, the FFBI contract was awarded to the Mid-Atlantic Renal Coalition (ESRD Network 5). The overarching purpose of the FFBI contract for 2009–2010 is to "assist all 18 ESRD Networks in building upon the vascular access quality improvement activities in their SOW to advance the development, implementation, monitoring, and marketing of the FFBI." The ultimate goal of the FFBI is to reach a prevalent AV fistula utilization rate of 66% nationally for ESRD Networks and assist QIOs to reduce the gap between the statewide baseline AV fistula rate and 66% for incident hemodialysis patients.

The FFBI contractor was charged with:

- Conducting a thorough analysis of the current process for AV fistula placement;
- Assessing the current weaknesses of and barriers to AV fistula placement;
- Examining the patient, physician, dialysis facility, and other healthcare entity facilitators that impact AV fistula placement; and
- Developing and implementing a strategic plan that will move the AV fistula utilization rate to 66% for ESRD Networks and assist QIOs to reduce the gap between the statewide baseline AV fistula rate and 66% for incident hemodialysis patients.

A Root Cause Analysis (RCA) team was convened to identify current reasons for placement of an access other than an AV fistula. A flow diagram that displayed the paths related to decisions affecting AV fistula placement was used by the team as part of its Failure Modes and Effects Analysis (FMEA). The flow diagram is presented as Appendix B.

To perform the FMEA, the RCA team defined a loss as "any event or condition affecting the placement of an access other than an AV fistula." As a result, the team identified four (4) opportunity points at which there is a high probability of engaging the patient in decision-making related to vascular access. These opportunity points, or modes, include:

- Determining appropriateness of patients for AV fistula;
- Vessel preservation;
- Follow-up to monitor development of AV fistula; and
- Secondary procedure for AV fistula revision.

Following the FMEA, the RCA team drilled down into opportunity areas to identify root causes affecting the placement of an AV fistula. The result was a logic tree that exceeded 250 branches, with 139 of them deemed root causes. The RCA team membership is listed in Appendix C.

A Technical Expert Panel (TEP) was convened to develop strategies to address the 139 root causes identified by the RCA. The recommended strategies were prioritized according to their potential to impact AV fistula rates and have been synthesized and included in this document. The TEP membership is listed in Appendix D.

Section IV
STRATEGIES AND POLICY RECOMMENDATIONS

A. TEP Recommendations Overview

The TEP was charged with assessing the findings of the RCA team and making strategic recommendations that would be developed into an operational plan to increase the AV fistula utilization rate to 66% in prevalent hemodialysis patients for ESRD Networks and to assist QIOs in reducing the gap between the statewide baseline AV fistula rate and 66% for incident hemodialysis patients. Working in groups and discussing the 139 causes for failure to place an AV fistula, the TEP members identified and prioritized 17 strategies. Since a number of these represented duplication and some were multi-dimensional, seven (7) strategies and two (2) policy recommendations were developed. These are listed below and further described in the plan.

The TEP identified the priority areas during the meeting, but were also provided an additional opportunity to review the TEP recommendations draft report via email. Communication among the TEP allowed for group discussion and consensus. They were asked to re-evaluate their priorities based on the report and upon further reflection, most of the TEP members modified their priority list.

The strategies listed in this report reflect the priorities based upon what the members consider to be achievable and what would have the greatest opportunity to impact the improvement in AV fistula rates. The strategies are listed in priority order defining those to be worked on first. The tactics listed in the operational table reflect those tactics that are actionable in the timeframe of the FFBI contract. The narrative discussion of strategies is intended to be an overview with background and provide examples of possible operational tactics. A full set of actionable tactics are presented in the Operational Plan Table (page 31). The two (2) policy recommendations are items on which CMS must provide direction before priority setting can be addressed.

B. Strategies

Strategy 1: Nephrologist as Leader

Encourage and support nephrologists to take a leadership role and be accountable for vascular access management in all hemodialysis patients.

The nephrologist manages the CKD patient who is progressing to renal failure, and as such is responsible for the care provided to that patient once dialysis is initiated. As the leader of the interdisciplinary dialysis team, the nephrologist is responsible for assuring that patients are prepared for dialysis, that prescriptions are appropriate, and that quality outcomes are achieved. The nephrologist is the professional who coordinates patient care and initiates referral for other required medical services. This role requires leadership, coordination of care transitions, and guidance of all technical aspects associated with vascular access placement and maintenance.

The revised Conditions for Coverage represents a sustainable system change that assigns greater accountability to the medical director, a nephrologist, for overall care of the patients in the dialysis facility. This includes providing leadership to the professional team with respect to quality assessment and performance improvement (QAPI) and ensuring that appropriate patient care policies are developed and implemented and that patient assessments include evaluations of dialysis access type and maintenance. The RPA recognizes the importance of nephrology leadership and states in its *Position Paper on Dialysis Facility Medical Director Responsibilities* that "...medical directors must possess and employ

good leadership skills in order to maintain a high-performing and safe dialysis facility."[9]

Leadership is an acquired skill, and multiple venues exist to obtain leadership training. One such system is the continuing education provided to nephrologists through the ASN, a key driver in nephrology continuing education. The Society's annual Renal Week meeting is attended by 10,000 individuals from around the world. ASN also offers Renal Weekends, which are shorter, geographically dispersed sessions covering core concepts from Renal Week. The FFBI Coalition will collaborate with ASN to develop and present a session on the technical aspects of vascular access, which will also address knowledge deficiencies among nephrologists. These include:

- Leadership training;
- Vessel mapping (arterial and venous);
- Communicating with patients who are reluctant to have an AV fistula placed or a temporary CVC converted to a permanent access;
- Establishing relationships with primary care providers;
- Communicating guidelines on when primary care providers should refer patients for nephrology consults; and
- Establishing care transition approaches.

The FFBI Coalition will engage other professional associations, such as the RPA, NKF, and American Society of Diagnostic and Interventional Nephrology (ASDIN) for endorsement of these educational offerings. These professional organizations also have coordinated educational programs for their members and components of leadership, vascular access management, and coordination of care can be included on an ongoing basis.

As a long-term approach, nephrologists must receive specific training in their nephrology fellowship programs that will provide them with the necessary skills to be leaders in the dialysis environment. Efforts can be devoted to encouraging fellowship programs to include educational components designed for the physician who intends to work in the dialysis setting. Inclusion of didactics on quality improvement, leadership, and communication skills are necessary for this group of physicians as these courses will prepare them to take a leadership role as they transition into the dialysis community. Additionally, these programs should include training in vascular access types, evaluation of vascular access development, long-term vascular access monitoring, and therapies to treat vascular access patency problems. This type of system change can have a long-term impact on beneficiary care.

There needs to be improved communication between the nephrologist, as leader of the vascular access management team and the vascular access surgeon. One mechanism for facilitating this communication is to provide surgeon-specific outcome data to the nephrologist that includes AV fistula placement rates and functionality of the AV fistula for each surgeon. To ensure that the latest techniques are available in their practice areas, nephrologists should assist surgeons and interventionalists in identifying educational opportunities to improve AV fistula placement and management.

> *"…Medical directors must possess and employ good leadership skills in order to maintain a high-performing and safe dialysis facility."*
> *- RPA*

Nephrologists are held accountable for dialysis outcomes through the Medicare survey and certification process, and the ESRD Networks communicate with State Survey Agencies (SSA) about the quality improvement activities in their areas. The SSAs also receive the Dialysis Facility Reports developed by the University of Michigan Kidney Epidemiology and Cost Center with comparative data on selected clinical indicators that allow SSAs to target their activities to providers who are outliers in given areas, such as those with low rates of AV

fistulas. However, to assure greater accountability, nephrologist specific profiles are required which is addressed further in the policy recommendation on assuring data flow.

Strategy 2: Leveraging Partnerships

Partner to improve AV fistula placement and utilization rates.

A partnership is a mutually beneficial relationship between two (2) organizations in which they work together to achieve common goals. By identifying and engaging new and existing partners, each of whom brings a variety of expertise, resources, and motivation to the project, system-wide improvement toward the utilization rate of 66% AV fistulas can be achieved for ESRD Networks and can assist QIOs in reducing the gap between the statewide baseline AV fistula rate and 66% for incident hemodialysis patients. System changes can be made through organizations working together to leverage resources to build knowledge, skills, and processes. Listed below are several examples.

In identifying and selecting partners, the FFBI Coalition considered accessibility to CKD patients. In addition, the need to include community members who have an interest in or responsibility for providing and/or assuring the quality of care provided to CKD patients were identified. Partners include renal stakeholders, ESRD Networks, dialysis organizations, renal associations, and QIOs, as well as those outside of the renal community (i.e., hospital associations, primary care associations, QIO statewide Coalition organizations, vascular access surgeons, surgical associations, interventionalists, interventional organizations, community organizations, and not-for-profit disease-focused foundations). QIOs are promoting early referral of CKD patients to nephrologists as a key intervention, building upon the premise that increased frequency of patient care by nephrologists contributes to higher AV fistula outcomes. Studies have found that late referral to a nephrologist is a major determinant in the use of a CVC at initiation of dialysis.[10] These partners will assist the FFBI Coalition in educating the community and reinforcing the message to primary care providers on the importance of early recognition, improved prevention and treatment of CKD complications, and early referral to a nephrologist and/or vascular access surgeon for vascular access in CKD Stages 3-4 patients who are progressing toward CKD Stage 5.

CKD patients have multiple co-morbidities including hypertension, diabetes, coronary artery disease and congestive heart failure. Primary care providers are well-positioned to treat these patients with multiple problems including CKD. These providers may not be aware of the evidence-based guidelines for the treatment of CKD, and the National Kidney Foundation's K-DOQI Guidelines can assist in this regard.

Primary care providers often have long-standing relationships with patients and their families. This trusting relationship is essential when caring for the newly diagnosed CKD patient. While the nephrologist can manage the nephrology-related aspects of care, the primary care provider needs to continue to be involved to assist with patient and family communication. The primary care provider can reinforce the recommendations of the nephrologist as the patient nears CKD Stage 5. These practitioners can be great advocates to encourage appropriate vascular access placement in patients needing dialysis therapy. Co-management of the CKD patient can be promoted by the QIOs, which provide needed access to primary practitioners.

Campaigns to promote automated Glomerular Filtration Rate (GFR) reporting for primary care practitioners and the community will guide patients to see a nephrologist before CKD Stage 5. QIOs are currently working to promote education on GFR reporting, tracking, and trending for primary care providers for the purpose of early detection, treatment, and timely referral to nephrologists. The National Kidney Disease Education Program (NKDEP) has been successful in ensuring automated GFR reporting with every creatinine ordered in all patients greater than 18 years of age. Additionally, the development of a 30-20-10 GFR campaign will

help with early referral and placement of an AV fistula in all appropriate patients prior to their first dialysis treatment. The 30-20-10 campaign is defined as:

- Referral to the nephrologist when the GFR is ≤30
- Referral to the vascular access surgeon for access placement when the GFR is ≤20
- Initiation of hemodialysis when the GFR is ≤10

The campaigns success will hinge on establishing and nurturing partnerships with primary care providers, patients, vascular access surgeons, interventionalists, and community organizations. Reaching practitioners can best be accomplished through coordination with professional associations. For example, vascular surgeons have multiple associations including the Society for Vascular Surgeons (SVS), American College of Surgeons (ACS), American Surgical Association (ASA), and various state-level societies.

Partnerships with primary care associations, such as the American Academy of Family Physicians (AAFP), the Association of Primary Care Physicians (APCP), the American Academy of Nurse Practitioners (AANP), and the American Academy of Physician Assistants (AAPA) will offer another venue for education (e.g., an article in *American Family Physician*, a peer-reviewed journal which reaches over 178,000 physicians).

Another partnership to cultivate is with the American Association of Diabetes Educators (AADE). This group of practitioners has a long-established and well-respected history of educating patients with diabetes. This is an important group as nationally 43% of dialysis patients are diabetic and diabetes is the leading cause of renal failure.[11] Collaborating with this group to provide education on CKD that includes planning for dialysis, if needed, is one more venue to promote the FFBI and improve AV fistula rates.

Educated consumers and caregivers have a greater capacity to understand the importance of their role and make better-informed decisions. Therefore, it is essential to educate the community on CKD and the importance of vascular access in CKD Stage 5. ESRD Networks and QIOs will play a major role in working with providers to ensure that patients and members of their support system receive initial education at first diagnosis and throughout progression of CKD Stages. As part of MIPPA patients and members of their support system can be educated on vascular access through the six (6) CKD educational sessions reimbursed by Medicare.

The NKDEP, a FFBI Coalition partner, is focused on improving care for CKD patients and has resources to educate consumers on the benefits of timely referral to a nephrologist and on how to avoid becoming part of the 45% of patients who start dialysis without exposure to a nephrologist.[2] Examples of partners who can assist with the distribution of educational materials to consumers include the NKF, AAKP, AKF, pharmaceutical companies, insurance companies, and public health departments.

Strategy 3: Hospital Systems

Modify hospital systems to promote AV fistula placement.

Most individuals utilize a hospital system for healthcare during their lifetime, some for planned procedures and some for emergent events. Hospital stays provide an additional opportunity for early diagnosis of CKD and/or treatment. Hospital discharge planning and care coordination are integral parts of hospital systems' infrastructures. Hospital discharge planning and case management assist patients in arranging necessary care following a hospital stay and can be utilized to assure that CKD Stages 4 and 5 patients obtain an appropriate vascular access.

Hospitals are integral new partners to the FFBI and modifying this system is an effective way to sustain long-term viability for AV fistula placement. Working with hospitals represents an immense opportunity to affect the incident

and prevalent AV fistula utilization rates for the newly diagnosed CKD patient, the CKD Stage 5 patient who presents for emergent hemodialysis therapy, and the patient who progresses rapidly to CKD Stages 4 or 5 while being treated for another condition. Enhancement of the discharge planning process that is already in place in hospital systems can be accomplished with minimal time and effort, from development to implementation.

For some newly diagnosed CKD Stage 3 and all newly diagnosed CKD Stages 4-5 patients, referral to a nephrologist for an evaluation of their kidney function during their hospital stay, or as part of their discharge plan, will ensure appropriate medical management of this newly discovered co-morbid condition. One example of utilizing an existing hospital system is using electronic pharmacy systems to facilitate referral from the pharmacist to the attending physician when certain classes of drugs are ordered that are contra indicated and/or known to be nephro-toxic. Requirements to check drug orders against the patient's GFR to assure that ordered medications do not have an adverse effect on patients with CKD (as defined by GFR) and receive appropriate medication, also allows for an alert to be generated for the admitting physician to arrange a consult for nephrology care if not already provided.

Another system change for hospitals addresses vessel preservation. Guidelines to reduce or eliminate the use of peripherally inserted central catheter (PICC) lines in patients with a GFR less than 45 are needed. One aspect of the guidelines would be the need for the nephrologist to approve all PICC line placements in these patients. Availability and use of vessel preservation guidelines will ensure there are adequate vessels for construction of an AV fistula if needed.

CKD patients who are co-managed by their primary care providers and a nephrologist, and who progress to CKD Stage 5, are less acutely ill than those who are not followed for any medical care and are more likely to have an AV fistula in place prior to their first dialysis treatment.[12] For the CKD Stages 4 or 5 patient who presents for emergent hemodialysis therapy and the patient who progresses rapidly to CKD Stage 5 while being treated for another condition, vessel mapping and placement of a permanent access prior to discharging to an outpatient dialysis facility will net considerable gains in the incident and prevalent AV fistula rates. Vessel mapping must be provided by a practitioner experienced in AV fistula placement and knowledgeable about vessel mapping protocols.

This strategy lends itself to the development of a new Change Concept directed at hospitals which will include coordination with risk management, hospital administration, and discharge planners. QIO partners have access to the 5,700 registered US hospitals[13] and can help to promote implementation of this strategy. This Change Concept should recognize and address limitations to the reimbursement system, such as the diagnosis-related group (DRG), length of stay requirements and lack of coverage for elective readmissions for many patients without existing health insurance coverage.

Strategy 4: Patient Self-Management

Promote patient self-management throughout the stages of chronic kidney disease.

Created as a term in 1969, the concept of patient-centered medicine evolved as a prescription for how physicians should interact and communicate with patients. A patient-centered physician is described as someone who tries to enter the patient's world, to see the condition through the patient's eyes. Key elements of the patient-centered approach include viewing the patient as a person, rather than focusing strictly on the disease, and building a therapeutic relationship that is based on both the patient and physician perspectives.[14]

In 2003, the Institute of Medicine (IOM) defined self-management support as "the systematic provision of education and supportive interventions by healthcare staff to increase patients' skills and confidence in managing their health problems, including regular assessment of

progress and problems, goal setting, and problem-solving support."[15]

According to the National Assessment of Adult Literacy, only 12% of adults have proficient health literacy and may lack the skills needed to manage their own health and prevent disease.[16] Therefore, it is essential to incorporate health literacy principles into patient self-management programs. Managing a chronic illness is time-consuming and complex, and chronically ill patients are required to manage many factors that contribute to their health outcomes. Patients with chronic illnesses need support and information to become effective managers of their own health. Additionally, patient centeredness needs to be encompassed into their self-management programs. Better patient outcomes are achieved through the use of evidence-based techniques that emphasize empowerment, collaborative goal setting, and problem-solving skills and understand the patient's perception of the disease. To meet these needs, it is necessary for patients to have:

- Basic information about their disease;
- An understanding of and assistance with building self-management skills; and
- Ongoing support from members of the practitioner team, family, friends, and the community.

The patient-practitioner partnership is an important chronic disease paradigm. This partnership involves collaborative care and self-management education and is another strategy that lends itself to the development of a new Change Concept.

Modifying a process, such as implementing a standardized assessment of patient self-management needs and activities to improve the practitioner's ability to support patients, is another example of sustainable system change. These assessments include questions about the patient's self-management knowledge, skills, supports, and barriers. Self-management education supplements traditional patient education by supporting patients to live the best possible quality of life. It instills patient self-confidence to help them carry out behaviors necessary to reach a desired goal. While traditional patient education offers information and technical skills, self-management education teaches problem-solving skills. This model is reinforced when patients succeed in solving patient-identified problems.

The family and other respected figures in the patient's life play an important role in how patients handle and make decisions about their healthcare. Providers need to be sensitive to the role that families and communities play in different cultures. In some cultures, it is customary for the family to assume responsibility for decisions about an individual's health, while in others, it is expected that the family will at least be consulted. Improved practitioner understanding of the patient's culture and the role his/her family will play in his/her healthcare management will enhance the patient's ability to be successful in self-managing his/her chronic disease.

All ESRD Networks have Patient Advisory Committees (PACs) to assist them in identifying areas of patient concern. These committees will be advocates in the development of a self-management Change Concept that incorporates basic information, such as disease understanding and management and the risks/benefits of catheters and AV fistulas. These committees can also identify areas of care the CKD Stage 5 patients can self-manage in the dialysis facility. Some specific responsibilities that patients can assume in the dialysis facility are:

- Weighing themselves pre- and post-treatment;
- Examining their access to determine patency (look, listen, feel);
- Cleaning their access;
- Learning self-cannulation;
- Learning buttonhole cannulation;
- Understanding monitoring and interventional tools that are available to maintain access patency; and
- Understanding clinical lab values and how they relate to their treatment plan.

QIOs work within the physician practice settings on quality improvement indicators and serve as

another venue for providing technical support to detect and treat patients with CKD. QIOs may assist physician practices in assembling appropriate patient educational materials and teaching modalities for CKD self-management that are culturally and linguistically sensitive.

The promotion of patient self-management, particularly during the late stages of CKD, will empower patients to chose the optimal appropriate vascular access and participate in the management of their vascular access.

Strategy 5: Addressing Access Problems

Promote fast-track protocols for rapid identification and referral of vascular access problems which include failure to mature, revision of the failing AV fistula, and placement of an AV fistula.

Data show that AV fistulas are associated with increased event-free patency and reduced morbidity and mortality at a significantly lower cost. However, one of the major obstacles associated with increasing the AV fistula utilization rate is the AV fistula that fails to mature. While the ESRD Networks find the current FFBI Change Concept #9 (monitoring and maintenance to ensure adequate access function) to be successful, some challenges remain to receiving full benefit. These include:

- Lack of care coordination among the vascular access surgeon, the interventionalist, the nephrologist, and the dialysis team;
- Lack of active follow-up to ensure the best access for the patient; and
- Patients inadequately trained to manage their accesses.

To address these challenges, dialysis facility systems must be changed to include the development and implementation of fast-track protocols. These are standard treatment protocols based on current evidence-based medicine and guidelines that are designed to accelerate identification and response to vascular access problems. Protocols are a series of action steps for a particular patient based upon the medical needs of the patient.

The purpose of the fast-track protocol is to speed physician response to emerging patient vascular access problems and allow the care team to rapidly implement the appropriate plan of care. Many physicians find that protocols are especially helpful to remind them of critical actions, e.g., to perform a physical exam on a patient's newly placed AV fistula four (4) weeks post-operatively to assess maturation for future intervention. Introduction of fast-track protocols for monitoring newly created AV fistulas to identify those that are not maturing will result in salvaging a greater number of these accesses. Interventions must not be viewed as a surgical failure, but seen as one more tool for establishing functional AV fistulas. The literature suggests that 20% to 50% of the failure-to-mature accesses can be salvaged.[17]

Time from placement of a vascular access to its use is a subject requiring additional investigation and analysis, given the European experience where AV fistula rates are higher than in the US. Surgeons and nephrologists in the United States have generally waited longer to allow AV fistula cannulation than physicians in other countries. Although the Dialysis Outcomes and Practice Pattern Study (DOPPS) found cannulation within two (2) weeks of AV fistula construction increased the risk of access failure, cannulation after two (2) weeks did not change AV fistula outcomes.[18,19]

Established AV fistulas require frequent routine monitoring to ensure continued patency. A failing AV fistula places the patient at risk for inadequate dialysis, which can lead to numerous complications and increased morbidity and mortality. Additionally, if the access fails, the patient will receive a CVC until a new permanent access can be placed. Development and implementation of fast-track protocols for routine monitoring of AV fistulas by the interdisciplinary team can prevent this. Utilization of fast-track protocols will result in early identification of cannulation or blood flow problems, with appropriate prompt referral for evaluation by either the interventionalist or the

vascular access surgeon, and increase the salvage of AV fistulas that are beginning to fail.

Many patients with AV grafts have repeated interventions for stenosis and thrombosis that net short-term results. These patients often have angioplasty or surgery, sometimes on a monthly basis, and often present to the dialysis facility, days after an intervention, with a clotted access and must undergo yet another procedure before they can receive their treatment.[20] Eventually these AV grafts fail completely, and consequently, the patient receives a CVC. Each intervention places the patient at risk for development of complications. Development and implementation of fast-track protocols that address the maximum number of interventions to be performed on an existing AV graft will benefit the patient greatly. These protocols must include a plan for placement of a new vascular access, preferably an AV fistula, before the current one fails, thereby eliminating the need for the patient to have a CVC.

There are multiple complications associated with long-term CVC use. While a small percentage of patients have no other means of viable access, a large percentage of patients choose this access for other reasons. When a patient has had a CVC for greater than 90 days, the revised Medicare Conditions for Coverage (Subpart C 494.90 - V550 - V551 and 494.110 – V633) mandate that a plan or an explanation as to why there is no plan be documented in the patient's medical record. A specific fast-track protocol to address patients who present to the outpatient facility with a CVC must be adopted in every facility. This protocol will trigger the physician, who during rounding observes that a patient is due to have a CVC removed, to engage and advise the patient accordingly. Engaging the patient in this type of timely discussion during routine rounding will build a collaborative patient-centric relationship and better prepare the patient to care for his/her access in and out of the dialysis facility. The fast track protocol will include patient education on CVCs as a temporary access only and have a positive impact on the AV fistula and CVC rates, while assisting facilities in complying with the Conditions for Coverage.

Strategy 6: Practitioner Training and Credentialing

Promoting training, experience, and credentialing of healthcare professionals in the area of hemodialysis vascular access management.

Many specialties care for CKD patients, including primary care physicians, vascular access surgeons, nephrologists, interventionalists, nurse practitioners, physician assistants, nurses, and technicians. To provide patients with the best care possible, practitioners need to be well educated on the standards, protocols, policies, and procedures associated with their particular aspect of care. They should have the appropriate credentials and attend appropriate continuing education programs to keep their skills current. Practitioners must then incorporate this new knowledge and new skills into their practice.

Credentialing is the process of formal recognition and verification of a medical professional's technical competence and performance based on evaluation and monitoring of clinical practice and medical decision-making by adherence to their applicable professional standard. Credentialing verifies an individual's license, experience, certification, education, training, malpractice, and adverse clinical occurrences.[21] It defines the scope of practice and the services a practitioner may provide. Influencing the credentialing process of practitioners providing services to CKD patients ensures these professionals have the most current skills and knowledge to care for their patients and represents a systems change that is sustainable over time.

Vascular access surgeons are trained in the diagnosis and management of disease affecting all parts of the vascular system (with the exception of brain and heart, which are addressed by other surgical subspecialties). In recent years, more general surgeons as well as vascular surgeons and transplant surgeons are performing procedures for AV fistulas. While this has addressed some of the access to care

issues, the outcomes for patients due to lack of education on the part of and experience by some surgeons are questionable.[22] Requirements must include additional training and experience for the surgeons who intend to perform AV fistula placement and care. These surgeons must receive training on all available techniques for AV fistula placement, including those that are more difficult to perform. Surgical education and experience, combined with a good physical assessment and vessel mapping will increase the number of patients deemed appropriate for an AV fistula and lead to an increased number of AV fistulas placed and used. Credentialing of vascular access surgeons will assure competence in the technical aspects of AV fistula placement, management of the AV fistula that fails to mature, secondary AV fistulas, and timely CVC reduction.

Interventionalists are defined as all medical practitioners who perform radiological-based procedures involving evaluation and salvage of vascular access. They must be fully trained and compliant with vessel mapping oriented toward helping the vascular access surgeon find a potential fistula site. The interventionalist must be trained in the proper techniques to handle any abnormality leading to delayed maturation. These techniques include maturation angioplasty, ligation or coil ablation of side-veins if indicated, and outflow angioplasty. As new techniques are available, interventionalists must attend continuing education programs to update their skills to enable them to provide the best care possible for the CKD patients.

As the AV fistula placement rate continues to increase, the skill level of the patient care technicians and nurses must increase. These front line dialysis facility staff work with patients and their vascular accesses each hemodialysis session. They need to have knowledge and proficient skills for physical assessment, cannulation, and monitoring for continued patency of vascular access. The revised Conditions for Coverage (Subpart D 494.140 – V695) mandate all patient care technicians caring for CKD Stage 5 patients become certified within 18 months of employment. This provides an opportunity for incorporating vascular access cannulation and care as a competence of certification. Professional associations that provide the educational content and serve as the testing agency for certification are members of the FFBI Coalition and will be encouraged to include credentialing requirements that advance good cannulation skills, vascular access management, and care.

The availability of CKD educational programs has increased and greater awareness of these programs by the primary care and nephrology practitioners has resulted in additional referrals. A new group of practitioners has emerged to augment these educational programs: CKD educators. While not all patients with a CKD diagnosis will progress to CKD Stage 5, CKD educators need to include information on optimal vascular access planning should patients progress to CKD Stage 5. This allows for patient empowerment and educated decision-making and ensures that vessel preservation, vessel mapping, and eventually placement of an AV fistula occur. Ensuring CKD educators are teaching all aspects of care will affect both incident and prevalent AV fistula rates. An additional benefit will be the reduction in CVC use at the patient's first dialysis treatment.

Continuing education is essential for healthcare practitioners. New evidence, best-demonstrated practices, and discoveries emerge at a rapid pace in the healthcare arena. To provide the best possible care for patients, healthcare practitioners must be aware of all the current treatments and procedures available in their areas of expertise. Many states and professional organizations require CEUs for practitioners to be re-licensed and certified. Collaboration with these organizations to include FFBI programs will ensure the most up-to-date information is available and incorporated into practice. The availability of these programs will have a positive impact on the AV fistula rate.

Strategy 7: FFBI Change Concepts

Expand and endorse the current Change Concepts for education and promotion throughout the renal, surgical, and interventional communities.

The renal community is now several years into the FFBI project. The current FFBI Change Concepts were developed and implemented in 2003, and the steady increase in the national AV fistula rates is attributed to the implementation of these Change Concepts. Each of the 18 ESRD Networks has employed the Change Concepts to develop, evaluate, and redesign quality improvement projects to address the identified challenges in its specific geographic region.

The FFBI Change Concepts have worked well and have been the catalyst for increasing the AV fistula rates in the US. These change concepts have been used by Networks and widely distributed to dialysis facilities through training sessions and national and local educational programs, with feedback reports, and via the Fistula First website. However, as new technologies and best-demonstrated practices emerge, there is a need to refine the Change Concepts. The ESRD Networks and the TEP have recommended refinement to the current Change Concepts to make them more robust.

Concept #2 – Timely referral to nephrologists: include more information regarding undiagnosed CKD that precludes early referral.

Concept #3 – Early referral to surgeon for "AV fistula only" evaluation and timely placement: address continued resistance among some physicians to placement of AV fistulas.

Concept #4 – Surgeon selection based on best outcomes, willingness, and ability to provide access services: discuss and examine insurance issues (e.g., must use preferred providers) and develop mechanisms for obtaining surgeon specific outcomes data.

Concept #5 – Full range of appropriate surgical approaches to AV fistula evaluation and placement: promote vessel mapping standards.

Concept #6 – Secondary AV fistula placement in patients with AV grafts: develop "Sleeves Up" QAPI for dialysis facilities.

Concept #7 – AV fistula placement in patients with CVCs where indicated: improve educational materials for patients who choose to keep their CVCs.

Concept #8 – Cannulation training for AV fistulas: promote increased training through professional organizations.

Concept #9 – Monitoring and maintenance to ensure adequate access function: develop "non-maturation of AV fistula" QAPI module for dialysis facilities.

Concept #10 – Education for caregivers and patients: improve training made available to nephrologists, vascular access surgeons, dialysis facility staff, patients, and caregivers.

Concept #11 – Outcomes feedback to guide practice: develop vascular access surgeon and nephrologists profiling methodology.

For continued success, sustainment, and improvement of outcomes, projects often need new ideas to continue the momentum. Expansion and endorsement of the Change Concepts are required and will provide the roadmap for the FFBI project to move forward to meet the CMS goal of 66% of prevalent patients utilizing an AV fistula.

C. Policy Recommendations

Policy Recommendation 1: Pay-for-Performance

A fundamental strength of traditional fee-for-service payment is that it closely matches payment to actual resource use. Payment is established based on services the patient

receives. This strength of traditional fee-for-service payment has also become its fundamental weakness, it fails to create financial incentives that encourage and enable improvements in quality. Further, it rewards the use of more interventions and procedures in expensive inpatient settings and/or the use of less medically recommended practices.

Vascular access placement and management is an ideal environment for Pay-for-Performance (P4P). P4P has the potential to address some of the problems in the current Medicare fee-for-service model, as well meet the goals, requirements, and considerations outlined by the Institute of Medicine (IOM) and the Medicare Payment Advisory Committee (MedPAC). To promote safe, efficient, effective, patient-centered, timely, and equitable care for individuals with CKD Stage 5, it is recommended that financial performance incentives be utilized. Alignment of these efforts among the vascular access surgeons, nephrology practitioners, dialysis facilities, and other institutional providers assures that AV fistulas are the first choice for every medically suitable patient.

A vascular access P4P program can be budget neutral. Savings projected from increased AV fistula utilization rates and decreased rates of alternative accesses such as CVCs and AV grafts will be primarily realized in the hospital setting. This will occur through reduced hospitalizations related to vascular access complications and reduced costs for treatment of those complications, both of which are more expensive to the Medicare program in the hospital setting. Additionally, the dialysis facility's missed treatment rates related to hospitalizations for access complication will decrease. The dialysis facility will realize an increase in revenue by having the patient dialyze in the outpatient center versus the hospital. This is another cost savings to the Medicare program. Data indicate a potential cost savings to the Medicare program in excess of $500 million if the AV fistula prevalent rates are achieved.[23] Performance payments should be made near the time of service rendered, preferably at 6-month intervals, depending on the size of the practice or facility.

Policy Recommendation 2:
Assure Data Flow

Accurate data, reliably collected and validated, available in a timely fashion, and analyzed in meaningful ways, serve to aid the renal community in understanding challenges, setting goals, and tracking progress. Data play a central and enabling role in improving the prevalent AV fistula rate and support each of the preceding strategies. Through data, practitioners and policy makers are able to identify opportunities for improvement, stimulate changes, and assess the results of actions. Data and data analysis allow for management of the change process by fact and are essential to achieving the CMS goal of 66% of prevalent patients utilizing an AV fistula. Important to the FFBI are:

- Data availability and timeliness
- Clinical measures and standardized reports
- Data-driven quality improvement
- Developmental analysis
- Progress tracking
- Data sharing between ESRD Networks and their QIO counterparts

Data Availability

Currently available dialysis facility-level vascular access data, which are aggregated to the Large Dialysis Organization (LDO), state, and ESRD Network levels, allow for examination of the prevalent vascular access rates at dialysis facilities and exploration of access rates within and across regions and organizations. CMS Form 2728 data provide an additional glimpse into pre-CKD Stage 5 care and vascular access received by incident hemodialysis patients at the time of hemodialysis initiation. Together, these data sources have supported the FFBI success to-date. The aggregate data provide the basis for the FFBI Dashboard, managed by the Network Information Technology Systems (NWITS) contractor as well as the provider feedback reports available to ESRD Networks through

SIMS. 2728 data provide additional information for ad-hoc analysis, which is performed by the ESRD Networks to better understand pre-dialysis care. CKD QIOs are also utilizing the 2728 data in their CKD work.

The preceding two (2) data sources remain useful but fall short of providing the full range of information needed. Noticeably absent are longitudinal patient-level data on types of vascular access (i.e., in-use) since the CKD Stage 5 onset. Also absent are relevant data allowing the performance of nephrologists and vascular access surgeons to be transparent. To partially correct this problem, CROWNWeb was developed and is currently in Phase II of implementation. Among other data, CROWNWeb will track patient-level vascular access (in-use) data and access changes over time, which will become available to the ESRD Networks for analysis. During initial implementation, limited standardized reports will also be available to dialysis facilities for easy access and use in quality improvement. Because SIMS will cease to exist and CROWNWeb will form the backbone of the data warehouse to support the FFBI, in the future attention must be directed to: (1) assuring a smooth transition and accurate and comprehensive data migration from SIMS to CROWNWeb and (2) making use of newly available data to support quality improvement assessments and surveillance objectives.

Assuring the availability and usefulness of FFBI data during the transition and beyond will require a number of activities and the collaboration of multiple entities. Strategically important working relationships are those among CMS and its various contractors. Equally important are gathering information from end users to assure that emerging information systems meet their needs; turning data into useful information; and distributing the resultant information to support quality improvement.

The FFBI contractor, through the FFBI Coalition Data Committee, will give additional consideration to the comprehensiveness of vascular access data to meet the analytical needs in addressing the root causes of failure in order to reach the prevalent AV fistula utilization rate of 66%, e.g., data related to AV fistula failure to mature, failure of previously functional AV fistulas and revision, placement of secondary AV fistula, and clinically important contra-indications for AV fistula placement. Recommendations for refinements to the data elements or additions will be communicated to CMS and/or CMS contractor for incorporation into later versions of CROWNWeb, as feasible. Attention must also be directed to developing a process and assigning responsibilities for data validation within CROWNWeb. There is a potential role for Networks in future Statements of Work (SOWs).

Currently under-utilized data sources must also be investigated as a means to support the FFBI. These include Medicare claims data that may be useful in assessing vascular access surgeon and nephrologist performance, vein mapping procedure rate, examining the complexity of AV fistulas being placed, and measuring access complication and placement rates. Even in the absence of immediately available claims data for analysis, tracking tools will be identified by the FFBI contractor that can be used by nephrologists and dialysis facility staff to, for example, track vascular access surgeon performance, including internal access placement/revision rates.

Measures and Standardized Reports

Current vascular access measures, available through CROWNWeb, must be reviewed to determine their usefulness in identifying opportunities for improvement and tracking progress. New clinical measures, along with supporting data elements, must also be developed by the FFBI Coalition. Based on this work, end-user needs for rapidly accessible standardized reports using the CROWNWeb data and associated clinical measures will be determined and reports will be designed in collaboration with ESRD Networks and dialysis providers.

To be rapidly accessible, reports must become a part of CROWNWeb. Therefore, specifications for standardized reports will be communicated

to CMS for incorporation into CROWNWeb. This will entail identifying both the strengths and weaknesses of currently available reports (i.e., available through SIMS), retaining aspects of current reports found to be useful, and adding new reports or new components to existing reports. Attention can be directed to including competitive comparisons and benchmarking to stimulate improvement. Reports will also allow facilities to trend performance over time.

The FFBI Dashboard, which provides aggregate AV fistula rates at the ESRD Network, state, LDO, and national levels and is available online, will be maintained during the transition and improved going forward. Opportunities exist to augment the Dashboard with additional useful information, e.g., reporting CVC and AVG rates. Because the ESRD Networks are the primary end users of the Dashboard, their suggestions for improvement will be solicited, and recommendations for an improved FFBI Dashboard will be forwarded to CMS.

To support competition based on quality, profiling reports showing physician, vascular access surgeon, facility, and payer performance for AV fistula, AV grafts, and CVCs will be recommended for public reporting by CMS.

Data-Driven Quality Improvement

ESRD Networks and QIOs will be called upon to use benchmark and trending data to gather stories or best-demonstrated practices about successful care processes and system changes found to be useful in achieving the CMS goal. They will be further called upon to disseminate these stories or best practices to spread innovations. ESRD Networks must also pursue strategies to provide technical assistance to facilities found to have opportunities for improvement and track the results of change efforts as their QIO counterparts are doing within provider settings (i.e., physician practices, hospitals).

Developmental Analysis

In addition to standardized reports available through CROWNWeb and the FFBI Dashboard, there is a need for additional analyses to support quality improvement, and these will be identified and performed. For example, analysis to explore appropriate inclusions/exclusions to calculate the prevalent AV fistula rate will be conducted. Further analyses to assist the ESRD Networks in understanding barriers and targeting quality improvement interventions must be taken or performed by FFBI Coalition partners and designated CMS contractors.

Progress Tracking

Finally, data collection and analysis will play an important role in assessing the implementation and outcomes of this strategic plan, including the degree to which this strategic plan is implemented and the success of the ESRD Networks in achieving their intermediate contractual goals and stated CMS goal of 66% prevalent AV fistula usage. Results of these efforts must be identified, and questions asked and answered (e.g., “Do Network QI interventions of various types make a difference in improving facility AV fistula rates?”).

Examining progress over time will identify the need to change course, as necessary. Tracking and response will be carried out within the framework of the familiar Plan-Do-Study-Act cycle.

A. Spread Plan

Spread refers to the diffusion, through adaptation, of better ideas throughout the social system. Since the inception of the FFBI project, the dissemination of ideas has occurred via communication through a social system of partners in the renal community that incorporates, among others, dialysis facilities, nephrologists, vascular access surgeons, and interventional radiologists. A spread plan to move the AV fistula rate to the CMS goal of 66% includes utilizing an existing social system, maintaining an organization infrastructure, promoting better ideas and best-demonstrated practices, and deploying a communication strategy.

Dialysis facilities, ESRD Networks, QIOs, patients, acute care facilities, and healthcare professionals are linked to one another through a complex structure of relationships. A strong, integrated social system, as represented by the original FFBI Coalition, can be credited with the improvements in AV fistula rates since the inception of the FFBI. Partners in this social system include professional representatives from the following entities:

- CMS
- Healthcare insurers
- Patients and patient organizations
- ESRD Networks
- Quality Improvement Organizations
- State regulatory agencies
- Nephrologists
- Vascular access surgeons
- Interventional radiologists
- Dialysis facilities and their professional staff
- Renal professional organizations

Recommended as part of this strategic plan is the addition of new partners to the FFBI Coalition. These new partners include:

- Primary care providers and their professional organizations
- Hospital organizations
- Acute care facilities
- Community-based health programs
- Community education programs (e.g., American Association of Diabetes Educators (AADE))

In addition to a social system, an organizational infrastructure to support spread is necessary. This includes leadership commitment and support at all levels. As part of the original FFBI project, this infrastructure was developed, still exists, and plays an important role in the implementation of this strategic and operational plan. There is a "core" group consisting of the FFBI contractor, clinical consultants, and CMS Project Officer and Government Task Leader who meet on a weekly basis to discuss the project and identify critical steps in implementation. This group will be expanded to incorporate critical opinion leaders and physician/vascular access surgeon champions to assure oversight of implementation. The FFBI Coalition has specific workgroups, which will be re-organized into working committees to meet the current needs of the FFBI project. Committees will be responsible for specific strategies and tactics identified in the operational plan. Membership to these committees will be drawn from the multiple organizations committed to working on the project. Sustainability of the work is important and will be addressed with the Networks and QIOs that will be requested to provide primary leadership to the newly created committees. Additionally, ad hoc committees may be engaged for specific projects as needed.

This strategic plan brings forward seven (7) specific strategies and two (2) policy recommendations for development and implementation. Some of the strategies recommend the development of new Change Concepts while others recommend enhancement

of the existing Concepts. In addition to the recommendations in the strategic plan, better ideas and identification of best-demonstrated practices includes practical knowledge and experience about how to successfully implement change. The collection of better ideas has grown over time and will continue to expand as stakeholders (especially new stakeholders) gain experience. The FFBI website is a successful knowledge management tool for collecting and disseminating information and will be instrumental in spread.

Successful communication entails using a variety of methods and messages to spread broad awareness of AV fistula issues, opportunities for improvement, examples of successful applications, and technical information throughout the system. Successful communication strategies will be tailored to the needs of the various medical professionals and stakeholders. Part of the communication strategy will be to help people understand how the changes relate to their particular settings. Additionally, each of the FFBI committees will include a marketing component to implement the change ideas and deploy the information to the community at large.

In summary, successful spread will include specific actions aimed at communicating, sharing and implementing the strategies and tactics developed and documented in the FFBI Strategic plan. The FFBI Coalition will utilize all avenues and opportunities identified to communicate the strategies to current and new partners. Below is a list of actions to achieve the spread of the FFBI Strategic plan:

- Engage existing and new partners;
- Identify and engage early adaptors who have achieved the CMS goal on a sustained basis;
- Enhance the current Change Concepts and add new ideas;
- Identify and employ social marketing across provider types to manage buy-in;
- Develop and implement communication plans via the FFBI Coalition marketing components, the FFBI website and other avenues and opportunities;
- Utilize the FFBI website as a knowledge management tool;
- Leverage Network and QIO lessons learned;
- Capitalize on best demonstrated practices and successful system changes by encouraging facilities to test, adapt and reinvent practices to suit local circumstances; and
- Coach for sustainability.

B. Managing Buy-In

The strategic plan builds upon a social marketing model that employs the application of traditional marketing techniques to a social issue. The focus is on behavior and is centered on a target audience having a primary role in the process. Marketing management decisions are classified into four (4) categories:

- Product
- Place
- Price
- Promotion

The product of the FFBI project is the scientifically based premise that an AV fistula is the superior vascular access for at least 66% of prevalent hemodialysis patients. The organizations and individuals who promote this product are acquainted with the science behind the message and have assisted with the development of tools and resources, which assist the healthcare system in achieving acceptable AV fistula rates. ESRD Networks and QIOs working collaboratively with community stakeholders (healthcare professionals, government agencies, professional associations, membership organizations, dialysis providers, acute care hospitals, interventional centers, etc.) provide a system for distributing the message, thereby creating the place where marketing occurs.

Managing buy-in at the healthcare institution level is accomplished through broad distribution of the strategic plan and by creating a shared understanding of the cost, or price, to the organizations embracing AV fistulas. What are the additional time constraints on the part of the dialysis facility staff to discuss access options

with patients in order to convert CVCs to AV fistulas? What are the cost implications to the hospital for assuring that every newly identified CKD patient has an appropriate vascular access or plan? How much additional time is required on the part of the physician to obtain new skills and knowledge to manage the CKD patient or to learn a new surgical technique?

Positive attributes of adopting the product include:

- Increased revenue to the dialysis provider when patients do not require repeated hospitalizations due to access problems;
- Reduced hospital readmissions due to infections when fewer patients are discharged with CVCs;
- Better management of CKD patients when transition of care is appropriate between the primary care provider and the nephrologist; and
- Improved patient health.

Identifying these costs and promoting the greater benefits of AV fistulas are important aspects of managing buy-in. Managing buy-in requires on-going communication, engagement of patients and families, understanding and dealing with practice variation, and providing an infrastructure to facilitate these responsibilities.

FFBI Coalition workgroups, meetings, the FFBI website, routine communication with ESRD Networks, QIOs, and renal community partners will all be used to manage buy-in of the strategic plan.

C. QIO/ESRD Network Collaboration Plan

There are currently 11 QIOs with CKD sub-national contracts that extend until August 2011. The goal of their work is to detect the incidence and decrease the progression of CKD and improve care for Medicare beneficiaries through:

- Provider adoption of timely and effective quality of care interventions;
- Participation in quality incentive initiatives;
- Beneficiary education; and
- Key linkages and collaborations for system change at the state and local level.

The focus areas for quality improvement in CKD include:

- Annual testing to detect the rate of kidney failure due to diabetes;
- Slowing the progression of disease in hypertensive individuals with diabetes through the use of angiotensin converting enzyme inhibitor (ACE inhibitor) and/or an angiotensin receptor blocking (ARB) agent;
- AV fistula placement and maturation (as a first choice for AV access where medically appropriate) for individuals who elect, as a part of timely renal replacement counseling, hemodialysis as their treatment option for kidney failure.

The ESRD Networks currently hold contracts to perform work through December 2010. They are charged with implementing quality improvement projects with dialysis providers in the area of vascular access with the goal of achieving an AV fistula rate of 66% utilization in prevalent hemodialysis patients.

Collaboration opportunities between the QIOs and ESRD Networks to be acted upon jointly, include:

- Promoting utilization of CMS-approved vascular access quality improvement tools and activities, including providing appropriate educational, promotional, and/or other communication resources not already available through traditional channels.
- Achieving CKD Stage 5 treatment changes which may include process improvements, such as adoption by hospitals of standards of care that promote use of AV fistula and vessel mapping, evaluation, and preservation.
- Influencing effective hospital discharge planning to facilitate the earliest possible placement of an AV fistula.
- Communicating successes and identifying best practices.

- Providing recommendations to CMS for improvements in the program which may influence the ability to achieve goals.

A. Monitoring Progress

Monitoring is a key element of quality improvement during project implementation. The meticulous creation of a plan is no guarantee for its success. The willingness to be flexible and respond quickly to changing circumstances is crucial. While it is important to compare a project's progress with its planned intent ensuring that the project is on track to reach its goal, attention also must be focused on results. Evaluation of impact is needed to document periodically whether defined strategies and implemented activities lead to expected results. Each of the seven (7) strategies has a defined metric or metrics that will be used to monitor progress.

B. Continuous Learning

The strategic plan is built upon an analysis of latent root causes that prevent the placement of an AV fistula in all appropriate patients, but there are emerging themes requiring additional exploration and analysis. These include a better understanding of international practices in countries that demonstrate significantly higher AV fistula rates, the role of health disparities, and the continued awareness of the need for dissemination of best-demonstrated practices.

International Practice

The Dialysis Outcomes and Practice Patterns Study (DOPPS) examined international patterns in vascular access use, patient characteristics, and practices associated with vascular access use from 1996 to 2007. According to the DOPPS study, since 2005, an AV fistula was used by 67-91% of prevalent patients in Japan, Italy, Germany, France, Spain, the United Kingdom, Australia, and New Zealand, and by 50-59% of prevalent patients in Belgium, Sweden, and Canada. From 1996 to 2007, AV fistula use rose from 24% to 47% in the US.[24]

As the FFBI moves into the next phase, it is important to keep abreast of trends at the international level. The international perspective may provide useful information, new improvements in care, new techniques, and/or best-demonstrated practices.

Health Disparities

Health disparities are differences in the incidence, prevalence, mortality, burden of diseases, and other adverse health conditions or outcomes that exist among specific groups. Health disparities can affect groups based on gender, age, ethnicity, socioeconomic status, geography, sexual orientation, disability or special healthcare needs. To support learning and targeting of interventions, data will be analyzed to identify areas where disparities may exist. These analyses are valuable in pursuit of the CMS goal of 66% of prevalent patients utilizing an AV fistula for ESRD Networks and for QIOs to reduce the gap between the statewide baseline AV fistula rate and 66% for incident hemodialysis patients.

Best-Demonstrated Practices

A best-demonstrated practice is an innovative idea that one or a handful of people or organizations have implemented that has demonstrated quantitative evidence of success and can be deployed to others for their adaptation based on local circumstances. A best practice is not simply what others are doing, but what others are doing to achieve success.

The June 2009 FFBI Dashboard shows a range of AV fistula rates among the ESRD Networks from 48.5% to 64% with a national average of 52.9%. Additionally, there are facilities in each of the ESRD Networks that are reaching the prevalence utilization rate of 66%. Therefore, it is important for ESRD Networks to continue to identify best-demonstrated practices among top performers in their areas that can be adapted for

use in underperforming regions. A major objective for the FFBI is to seek out and spread best-demonstrated practices. QIO counterparts must reduce the gap between the statewide baseline AV fistula rate and 66% for incident hemodialysis patients by the 28th month of their 3-year contract with CMS and are also seeking out and sharing best practices.

C. Review and Refinement

In order to manage changes in opportunities, resources, and information, strategic plans require review and refinement as they are implemented. Frequent plan review and performance tracking via established measures are necessary. This type of review system allows for early intervention as problems arise. It is critical to examine each strategy, its tactics, and its actions to determine if the plan is on track to meet the desired goal.

The FFBI strategic plan is written to allow for innovative solutions to new challenges in the placement and care of the AV fistula. Review of the strategic plan will occur at each step in the operational plan. Each of the strategies has metrics, and each of the tactics in the operational plan has milestones to assess progress and results. Identification of issues and barriers will allow for refinement and deployment of new tactics based on the information learned. As new regulations and/or new K-DOQI guidelines emerge, they will be reviewed for applicability to the tasks set forth in the operational plan.

D. Next Steps

Those working to improve AV fistula utilization rates will need to remain mindful of changes to the healthcare system moving forward. For example, as providers in various settings respond to incentives in the American Recovery and Reinvestment Act (ARRA) to adopt and use electronic health records (EHRs), there will be a role for Networks and QIOs to assist them as they select an EHR vendor, redesign work flows, train staff, and respond to the myriad challenges and opportunities for quality improvement and efficiency enhancements. The FFBI Coalition will assist with identifying opportunities to leverage EHR capabilities to improve the care provided to patients with CKD. The FFBI strategic plan presents specific tactics and actions for implementation across many healthcare systems that will result in sustainable system changes. Coordination among all partners is essential, and CMS leadership is required. Next steps include:

- Gaining buy-in among FFBI Coalition members;
- Further specifying the tasks for Networks and QIOs;
- Committing to a data-driven approach; and
- Implementing the strategic plan and monitoring progress.

A. Overview

Each of the strategies developed was discussed in depth by the TEP, and a suggested list of activities was generated. The operational plan prioritizes the strategies and identifies the activities that will assist the renal community in reaching the CMS goal of utilizing 66% AV fistulas in prevalent patients. It includes metrics, tactics, responsible parties, timeframes, and milestones. The operational plan is intended to be a dynamic document that is flexible enough to allow for new ideas as FFBI Coalition members and partners share expertise and best-demonstrated practices.

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B. Operational Plan Table

Priority	**Strategy 1: Nephrologist as Leader** *Encourage and support nephrologists to take a leadership role and be accountable for vascular access management in all appropriate hemodialysis patients.*	**Metrics:** • **Percent of patients seen by a nephrologist between 6 and 12 months pre-dialysis, dialyzing with an AV fistula at first outpatient dialysis. (Data source: Form 2728)** • **Percent of patients seen by a nephrologist > 12 months pre-dialysis, dialyzing with an AV fistula at first outpatient dialysis. (Data source: Form 2728)**		
	Tactics	**Responsible Party**	**Timeframe**	**Milestones**
1	Apply nephrologist profiling methodology to develop feedback reports (as referenced in Policy Recommendation: Assure Data Flow)	ESRD Networks	July 2009 – June 2010	Feedback reports deployed June 2010
2	Apply surgeon profiling methodology to develop feedback reports for AV fistula placement and functionality rates for the nephrologists (as referenced in Policy Recommendation: Assure Data Flow)	ESRD Networks	September 2009 – January 2010	Access Medicare claims data - September 2009 Develop algorithm and reporting format November 2009 Apply algorithm to data set and produce reports - December 2009 Produce and distribute vascular access surgeon profiles – January 2010
3	Develop training modules for inclusion into Nephrology Fellowship programs for: • QAPI for Vascular Access • Leadership • Medical director responsibilities under the Conditions for Coverage • AV fistula placement, management and monitoring • Assisting in 1-2 permanent AV fistula placement procedures • Physical exam skills for the maturing AV fistula • AV fistula cannulation training	FFBI Coalition, American Society of Nephrology, Renal Physicians Association, Association of American Medical Colleges, American Board of Internal Medicine	September 2009 – September 2011	Beginning September 2011, Nephrology Fellowship Syllabus Includes new training modules Agenda item for Renal Physicians Association Fellow meeting 2010

Priority	**Strategy 1: Nephrologist as Leader** *Encourage and support nephrologists to take a leadership role and be accountable for vascular access management in all appropriate hemodialysis patients.*	**Metrics:** • **Percent of patients seen by a nephrologist between 6 and 12 months pre-dialysis, dialyzing with an AV fistula at first outpatient dialysis. (Data source: Form 2728)** • **Percent of patients seen by a nephrologist > 12 months pre-dialysis, dialyzing with an AV fistula at first outpatient dialysis. (Data source: Form 2728)**		
	Tactics	**Responsible Party**	**Timeframe**	**Milestones**

4	Expand nephrologist training and continuing education programs to include:
	• Leadership training
	• AV fistula placement, assessment, management, and continuous monitoring skills
	• Communication skills to discuss vascular access placement and care with patients and families (patient empowerment and cultural differences)
	  • Develop and deploy a list of talking points for:
	  ▪ Nephrologist
	  ▪ Primary care providers
	  ▪ Vascular access surgeon
		FFBI Coalition, American Society of Nephrology, Renal Physicians Association, American Nephrology Nurses Association, NANT, National Renal Administrators Association	October 2009 and Ongoing	Agenda item for Renal Physician Association and American Society of Nephrology meetings beginning March 2011

5	Collaborate with American Society of Nephrology to develop and provide breakout sessions during "Renal Week" on technical aspects of vascular access to include: • Leadership skills • Vessel mapping guidelines (arterial and venous mapping) • Develop a list of talking points to communicate AV fistula placement with patients who are reluctant to have one placed or convert to AV fistula • Develop a list of talking points to communicate with primary care providers on co-managing CKD Stages 3-5 patients • Referral of patients with AV graft or CVC for AV fistula (patients may need to see more than one surgeon depending on skill level) • AV fistula maturation (When to refer for an intervention) • Physical exam skills for the maturing AV fistula • AV fistula cannulation training • Ethics of referral patterns; referring patients to providers that produce desired outcomes	FFBI Coalition, American Society of Nephrology, Renal Physicians Association	November 2009 and Ongoing	Placeholder received on November 2010 American Society of Nephrology Meeting Agenda by February 2010

Priority	**Strategy 2: Leveraging Partnerships** *Partner to improve AV fistula placement and utilization rates.*	**Metrics:** • **Percent of incident patients with an AV fistula placed. (Data Source: FFBI Dashboard)** • **Percent of prevalent patients with an AV fistula placed. (Data Source: FFBI Dashboard)**		
	Tactics	**Responsible Party**	**Time Frame**	**Milestones**
1	• Promote appropriate CKD diagnosis and referral patterns through standardized and mandatory reporting of eGFR on all patients >18 years old with every creatinine ordered. • Collaborate with National Kidney Disease Education Program to promote automatic reporting of GFRs < 60 in standard format on all patients >18 years old with every creatinine ordered. This should be a national standard and should include appropriate educational guidance for the various levels (30–20–10). (An examination of the states currently requiring eGFR lab reporting will be done.) • Promote standardization of calibration of creatinine results to an isotope dilution mass spectrometry reference measurement. (Procedure requires coordination by method manufacturers and clinical laboratories to use the correct MDRD equation to calculate eGFR and to communicate associated clinical issues to clinical providers and pharmacists). • In collaboration with the Laboratory Working Group review serum creatinine measurement and develop recommendations for reporting eGFR. (The current variability in serum creatinine measurement renders all estimating equations for GFR, including the MDRD study equation, less accurate in the normal and slightly elevated range of serum creatinine concentrations (<133 µmol/L, <1.5 mg/dl) which are most important for detecting chronic kidney disease (<60 ml/min/1.73 m2). • Explore current practice among insurance companies to provide "notification" letters to beneficiaries when certain triggers are identified. (E.g. eGFR <60).	National Kidney Disease Education Program, FFBI Coalition	September 2009 – April 2010	eGFR reported on all patients ≥ 18 years old with every creatinine ordered by April 2010

Priority	**Strategy 2: Leveraging Partnerships** *Partner to improve AV fistula placement and utilization rates.*	**Metrics:** • **Percent of incident patients with an AV fistula placed. (Data Source: FFBI Dashboard)** • **Percent of prevalent patients with an AV fistula placed. (Data Source: FFBI Dashboard)**		
	Tactics	**Responsible Party**	**Time Frame**	**Milestones**
2	Leverage MIPPA to educate CKD patients • Develop vascular access content to be included in the six (6) reimbursed CKD education sessions • Promote Fistula to patients and families prior to CKD Stage 5 • Promote patient self-management for all stages of CKD patients	CMS, FFBI Coalition, American Society of Nephrology, Renal Physicians Association, American Nephrology Nurses Association, National Renal Administrators Association, patients	TBD	Content developed and deployed by (TBD)
3	Develop 30 – 20 – 10 GFR awareness program • Including marketing strategy for deployment (patients, families, primary care providers, dialysis community, public health fairs) • Develop educational component for patients and families, promoting 30 – 20 – 10 GFR awareness campaign (DVD, web-based) • Include information into the National Kidney Foundation KEEP program	FFBI Coalition, National Kidney Foundation, AAKP, AKF, National Kidney Disease Education Program, Quality Improvement Organizations, ESRD Networks, Hospital Associations and Organizations, Community-based organizations (Deployment: National Kidney Foundation, pharmaceutical professionals)	September 2009 – June 2010	Program developed and educational materials available by July 2010
4	Conduct educational sessions promoting the 30 – 20 – 10 GFR awareness campaign and early referral with: • Professional societies for Primary care practitioners, nephrologists and vascular access surgeons • Professional societies for Physician Assistants and Nurse Practitioners	ESRD Networks, Quality Improvement Organizations contact associations to get item on agendas	January 2010 and Ongoing	Education sessions begin in July 2010

Priority	**Strategy 2: Leveraging Partnerships** *Partner to improve AV fistula placement and utilization rates.*	**Metrics:** • **Percent of incident patients with an AV fistula placed. (Data Source: FFBI Dashboard)** • **Percent of prevalent patients with an AV fistula placed. (Data Source: FFBI Dashboard)**		
	Tactics	**Responsible Party**	**Time Frame**	**Milestones**
	• American Diabetic Association • American Hospital Association • American Medical Society • Insurers and private payers • Hospital Associations • Include articles in appropriate journals promoting the 30-20-10 campaign			
5	Partner with national and regional surgical and surgical educational societies to develop training modules for inclusion into surgical fellowship programs and continuing education programs to include: • Vessel mapping (arterial and venous) techniques to help surgeons make the best possible choice for an AV fistula that will mature • AV fistula placement, management, and monitoring (including more difficult AV fistula procedures) • Physical exam skills for the maturing AV fistula to include recognition of AV fistulas that fail to mature • Appropriate interventional techniques aimed at salvaging and not abandonment of the AV fistula	American Association of Program Directors in Surgery American College of Surgeons, American Society of Transplant Surgeons, American Surgical Association, Association for Academic Surgery, Association of Surgical Education, Central Surgical Association , Eastern Vascular Surgery Society, Midwest Surgical Association , Midwest Surgical Society, Midwestern Vascular Surgical Society, New England Society for Vascular Surgery,	January 2010 and Ongoing	Educations sessions begin in November 2010

Priority	**Strategy 2: Leveraging Partnerships** *Partner to improve AV fistula placement and utilization rates.*	**Metrics:** • **Percent of incident patients with an AV fistula placed. (Data Source: FFBI Dashboard)** • **Percent of prevalent patients with an AV fistula placed. (Data Source: FFBI Dashboard)**		
	Tactics	**Responsible Party**	**Time Frame**	**Milestones**
		New England Surgical Society, North Pacific Surgical Association, Pacific Coast Surgical Association, Rocky Mountain Vascular Surgical Society, Society for Vascular Surgery, Society of University Surgeons, Southeastern Surgical Congress, Southern California Vascular Surgical Society, Southern Surgical Association, Southwestern Surgical Congress, The Peripheral Vascular Surgery Society, Western Surgical Association,		
6	• Partner with National Kidney Disease Education Program and American Association of Diabetes Educators to include CKD education with diabetes education, provided by diabetes educators • National Kidney Disease Education Program developed collaboration with the American Association of Diabetes Educators • National Kidney Foundation, AARP, renal-related businesses (dialysis equipment and pharmaceutical companies) , faith-based community	FFBI Coalition, National Kidney Disease Education Program, American Association of Diabetes Educators, Quality Improvement Organizations, ESRD	November 2009 and Ongoing	CDK education being taught in diabetes education classes by June 2010

Priority	**Strategy 2: Leveraging Partnerships** *Partner to improve AV fistula placement and utilization rates.*	**Metrics:** • **Percent of incident patients with an AV fistula placed. (Data Source: FFBI Dashboard)** • **Percent of prevalent patients with an AV fistula placed. (Data Source: FFBI Dashboard)**		
	Tactics	**Responsible Party**	**Time Frame**	**Milestones**
	organizations, retail partners, insurance companies (e.g., consumer newsletters)	Networks, National Kidney Foundation, Community Collaborative (RWJ)		
7	Develop and deploy guidelines for vessel preservation • Promote "Save Your Veins" campaign, developed by one of the Quality Improvement Organizations • Provide a wrist band for patients who have a GFR <60 • Include need for consistent reporting that can ultimately be used by all to make appropriate and applicable decisions	Quality Improvement Organizations, ESRD Networks, FFBI Coalition, hospitals	September 2009 and Ongoing	Campaign deployed nationally by February 2010
8	Update FFBI website educational materials • Content • Current relevance • Educational level (literacy – ease of understanding) • Offer several languages • Include National Kidney Disease Education Program educational materials on CKD and Dialysis (link to National Kidney Disease Education Program website)	FFBI Coalition	July 2009 - October 2009	FFBI website with new design, functional with current information by October 2009
9	Deploy Fistula First educational materials to: • Primary care offices • Hospitals (discharge planners and emergency departments) • Case managers (hospital and insurance companies) • Urgent care centers • Public health facilities • Certified diabetes educators • CKD programs • Diabetes support groups • Laboratories (vessel preservation) • Public health fairs	FFBI Coalition, Quality Improvement Organizations, ESRD Networks	October 2009 – February 2010	Fistula First materials available in the identified locations and on the FFBI website by February 2010

Priority	**Strategy 3: Hospital Systems** *Modify hospital systems to promote AV fistula placement.*	**Metrics:** **To be further refined** ▪ **Percent of patients with AV fistulas placed in hospital setting (Data Source: Medicare Claims)**		
	Tactics	**Responsible Party**	**Timeframe**	**Milestones**
1	Develop new Change Concept to modify hospital systems ▪ Develop and deploy CKD Stage 3 discharge toolkit for hospitals. The toolkit would include: o Discharge plan for newly diagnosed CKD Stage 3 patients o Criteria for referral to the nephrologist o Vessel preservation guidelines/information (FFBI white paper) o Coordination of care plan with primary care providers o CKD Stage 3 self-management brochure ▪ Develop and deploy CKD Stages 4-5 discharge toolkit for hospitals. Reiterate the lack of reimbursement for patients who return with a hospital-acquired catheter infection. The toolkit would include: o Discharge plan for CKD Stage 4-5 patients o Vessel mapping guidelines o AV fistula placed or plan for AV fistula placement o Criteria for referral to vascular access surgeon (if AV fistula not placed) o Education on the use of the term "temporary" CVCs instead of permanent CVCs o CKD Stage 4-5 self-management brochure	FFBI Coalition, Quality Improvement Organization, ESRD Networks, Hospital Associations, Case Management and Discharge Planning Associations	November 2009 – March 2010	Toolkit ready for deployment by March 2010
2	Explore hospital electronic pharmacy systems to send an alert from the pharmacist to the attending physician when certain medications are ordered that are contraindicated and/or known to be nephro-toxic.	FFBI Coalition, Quality Improvement Organization, ESRD Networks, Hospital Pharmacy's, Hospital Associations	January 2010 – December 2010	Electronic alerting active by December 2010

Priority	**Strategy 4: Patient Self-Management** *Promote patient self-management throughout the stages of chronic kidney disease.*	**Metrics:** • **Percent patients initiating dialysis with an AV fistula after receiving patient education per MIPPA (Data Source: Medicare Claims)** • **Median level of patient self management (Data Source: Survey questionnaire such as CAHPS)**		
	Tactics	**Responsible Party**	**Timeframe**	**Milestones**
1	Develop and Deploy Self-Management Change Concept to include: ▪ CKD Stage 3 patients: o Know your GFR o Save your Veins o Treatment modalities for CKD Stage 5 o Participating with the care team in determining vascular access action plan o Understanding risks and benefits associated with CVCs, AV grafts, and AV fistulas o Dietary guidelines o Routine annual screenings (e.g., colonoscopy's, mammogram's, pap smears, PPDs) o Vaccinations (e.g. Flu, pneumovax, hepatitis series) o Smoking cessation ▪ CKD Stage 4-5 patients: o Collaborate with ESRD Network Patient Advisory Committees (PACs) to identify AV fistula patients who participate in self-management at the facility. Record interviews with patients to post to the FFBI website and make available to dialysis facility educators as training aids. o Self management includes: ▪ Patient cleans access ▪ Self-cannulation (buttonhole cannulation if appropriate) ▪ Examination of access (look, listen, feel) ▪ Understanding of numbers (clinical lab values) ▪ Understanding of monitoring and interventional tools that are available to ensure vascular access patency (Nephrologists will be educated on this topic as noted in Strategy 1, dialysis facility staff will be educated on this topic as noted in Strategy 6)	ESRD Networks, National Kidney Disease Education Program, Quality Improvement Organizations, FFBI Coalition, National Kidney Foundation, Centers for Medicare & Medicaid Services, Medical Education Institute, Chronic Kidney Disease Patients	September 2009 – June 2010	Deployment of Change Concept Package by June 2010

Priority	**Strategy 5: Addressing Access Problems** *Promote protocols for rapid identification and referral of vascular access problems, which include failure to mature, revision of the failing AV fistula, and placement of an AV fistula.*	**Metrics:** • **Percent of patients having monitoring and surveillance of AV fistula and AV grafts for access dysfunction through physical examination (Data source: CROWNWeb)** • **Percent of patients having monitoring and surveillance of AV fistula and AV grafts for access dysfunction through pre-pump arterial pressure (Data source: CROWNWeb)**		
	Tactics	**Responsible Party**	**Timeframe**	**Milestones**
1	Develop and deploy a protocol to address patients who present to the outpatient facility with a CVC only • Include talking points for facility staff and physician • Include patient education on benefits of AV fistula	FFBI Coalition, ESRD Networks, Renal Physicians Association, Society for Vascular Surgery, American Nephrology Nurses Association, National Association of Nephrology Technologists	October 2009 – February 2010	Protocol developed and deployed to facilities by February 2010
2	Develop and deploy protocols for monitoring newly created AV fistula to identify those that are not maturing to include objective imagining/testing. (Enhancement to Change Concept 9 is noted in Strategy 7) • Maturation • Time to initial use	FFBI Coalition, ESRD Networks, Renal Physicians Association, Society for Vascular Surgery, American Nephrology Nurses Association, National Association of Nephrology Technologists	October 2009 – January 2010	Protocol developed and deployed to facilities by January 2009
3	Develop and deploy protocols for routine monitoring of existing AV fistulas • Monitor for continued patency • Monitor for development of stenosis • Monitor for aneurysms and pseudo-aneurysms	FFBI Coalition, ESRD Networks, Renal Physicians Association, Society for Vascular Surgery, American Nephrology Nurses Association, National	November 2009 - February 2010	Protocol developed and deployed to facilities by February 2010

Priority	**Strategy 5: Addressing Access Problems** *Promote protocols for rapid identification and referral of vascular access problems, which include failure to mature, revision of the failing AV fistula, and placement of an AV fistula.*	**Metrics:** • **Percent of patients having monitoring and surveillance of AV fistula and AV grafts for access dysfunction through physical examination (Data source: CROWNWeb)** • **Percent of patients having monitoring and surveillance of AV fistula and AV grafts for access dysfunction through pre-pump arterial pressure (Data source: CROWNWeb)**		
	Tactics	**Responsible Party**	**Timeframe**	**Milestones**
		Association of Nephrology Technologists		
3	Develop and deploy protocols for routine monitoring of AV fistulas	FFBI Coalition, ESRD Networks, Renal Physicians Association, Society for Vascular Surgery, American Nephrology Nurses Association, National Association of Nephrology Technologists	November 2009 - February 2010	Protocol developed and deployed to facilities by February 2010
4	Develop and deploy protocols that list the maximum number of interventions on an existing access	FFBI Coalition, ESRD Networks, Renal Physicians Association, Society for Vascular Surgery, American Nephrology Nurses Association, National Association of Nephrology Technologists	November 2009 - June 2010	Protocol developed and deployed to facilities by June 2010
5	Appoint a workgroup to develop a protocol on time from vascular access placement to use	FFBI Coalition, Quality Improvement Organizations, ESRD Networks, Renal Physicians Association,	January 2010 – April 2010	Protocol developed and deployed to facilities by April 2010

Priority	**Strategy 5: Addressing Access Problems** *Promote protocols for rapid identification and referral of vascular access problems, which include failure to mature, revision of the failing AV fistula, and placement of an AV fistula.*	**Metrics:** • **Percent of patients having monitoring and surveillance of AV fistula and AV grafts for access dysfunction through physical examination (Data source: CROWNWeb)** • **Percent of patients having monitoring and surveillance of AV fistula and AV grafts for access dysfunction through pre-pump arterial pressure (Data source: CROWNWeb)**		
	Tactics	**Responsible Party**	**Timeframe**	**Milestones**
		American Nephrology Nurses Association, National Association of Nephrology Technologists, Surgical Societies		

Priority	**Strategy 6: Practitioner Training and Credentialing** *Training, experience and credentialing of healthcare professionals in hemodialysis vascular access management.*	**Metrics:** **To be Determined** ***This metric will be determined by the FFBI Coalition, once work is started on this strategy.**		
	Tactics	**Responsible Party**	**Timeframe**	**Milestones**
1	Develop and deploy clinical protocols for primary care providers on when to refer patients with CKD diagnosis to the nephrologist	FFBI Coalition, Renal Physicians Association, American Society of Nephrology, American Board of Internal Medicine, ESRD Networks, Quality Improvement Organizations, renal stakeholders, American Nephrology Nurses Association, pharmaceutical reps	September 2009 - June 2010	Guidelines approved by July 2010
2	Collaborate with professional organizations to establish credentialing requirements that include initial and continuing education, and hands-on training for AV fistula placement, monitoring and care for:	FFBI Coalition, American Society of Nephrology, Renal Physicians	September 2009 - June 2011	Requirements established by June 2011

Priority	**Strategy 6: Practitioner Training and Credentialing** *Training, experience and credentialing of healthcare professionals in hemodialysis vascular access management.*	**Metrics:** **To be Determined** ***This metric will be determined by the FFBI Coalition, once work is started on this strategy.**		
	• Nephrologists • Vascular access surgeons • Interventionalists • CKD educators • Nurses • Patient care technicians	Association, American Nephrology Nurses Association, Society for Vascular Surgery		
3	Collaborate with the Society for Vascular Surgery, the American College of Surgeons, and regional surgical societies to reach the various surgical specialties at their national, regional and local meetings to offer educational sessions on FFBI to include: • Vessel mapping (arterial and venous) • AV fistula placement, management and monitoring • Physical exam skills for the maturing AV fistula	FFBI Coalition, Society for Vascular Surgery, American College of Surgeons, regional surgical societies	September 2009 - December 2010	Education sessions begin in January 2011
4	Develop training modules for inclusion into surgical training programs for: • Vessel mapping (arterial and venous) • AV fistula placement, management and monitoring • Physical exam skills for the maturing AV fistula	FFBI Coalition, Society for Vascular Surgery, American College of Surgeons, regional surgical societies	October 2009 – June 2011	Beginning September 2011 surgical syllabus include new training modules
5	Expand dialysis facility training and continuing education programs for nurses and PCTs to include: • Permanent vascular access placement, assessment, management, and continuous monitoring skills • Communication skills to discuss vascular access placement and care with patients and family members • Cannulation skills (to include buttonhole and self-cannulation) • Cultural competence	FFBI Coalition, American Nephrology Nurses Association, National Association of Nephrology Technologists,	October 2009 – February 2010	Beginning February 2010, training and testing materials will include new training modules
6	Collaborate with the Society for Interventional Radiology and the American Society of Diagnostic and Interventional Nephrology at their national, regional and local meetings to offer educational sessions on FFBI to include: • Vessel mapping (arterial and venous) oriented toward helping the vascular access surgeon find a potential fistula site • Proper techniques to handle any abnormality leading to delayed	FFBI Coalition, American Society of Diagnostic and Interventional Nephrology, Society for Interventional Radiology	September 2009 - September 2011	Beginning September 2011 training materials include new training modules

Priority	**Strategy 6: Practitioner Training and Credentialing** *Training, experience and credentialing of healthcare professionals in hemodialysis vascular access management.*	**Metrics:** **To be Determined** ***This metric will be determined by the FFBI Coalition, once work is started on this strategy.**		
	maturation including: ○ Maturation angioplasty ○ Ligation or coil ablation of side-veins ○ Outflow angioplasty			

Priority	**Strategy 7: FFBI Change Concepts** *Expand and endorse the current Change Concepts for education and promotion throughout the renal, surgical, and interventional communities.*	**Metrics:** **FFBI Dashboard/AV fistula prevalent rate.**		
	Tactics	**Responsible Party**	**Timeframe**	**Milestones**
1	• Include new tools and resources under each existing Change Concept, as needed, during website redesign. • Develop approval process for additions and deletions of information on the FFBI website	FFBI Coalition (Website Redesign Workgroup)	July 2009 and Ongoing	Launch of new website by October 2009
2	Enhance Change Concept #6 ▪ Develop a "Sleeves Up" QAPI for implementation at the facility level to promote physical examination of AV graft patients and assists facilities in staying compliant with the Conditions for Coverage.	ESRD Networks, FFBI Coalition, renal stakeholders	September 2009 - November 2009	QAPI available for deployment by December 2009
3	Enhance Change Concept #7 ▪ Require standardized monthly review, tracking, and permanent access plan reporting of each catheter patient from the dialysis unit director and staff ▪ Publish white paper on CVCs	FFBI Coalition, ESRD Networks, renal stakeholders	September 2009 - November 2009	Deployment of enhanced Change Concepts
4	Enhance Change Concept #9 ▪ Develop a "non-maturation of AV fistula" QAPI that includes posters of good and bad scenarios for facilities ▪ Disseminate to all dialysis facilities	FFBI Coalition, ESRD Networks, renal stakeholders	September 2009 - November 2009	Deployment of enhanced Change Concepts
5	Enhance Change Concept #5 ▪ Include focus on interventional strategies – full range of appropriate surgical and interventional approaches to AV fistula evaluation and placement ▪ Include vascular access vessel mapping guidelines (arterial and venous mapping)	ESRD Networks, Quality Improvement Organizations, FFBI Coalition, American Society of Diagnostic and Interventional	September 2009 - December 2009	Vessel mapping guidelines posted to FFBI website by February 2010

Priority	**Strategy 7: FFBI Change Concepts** *Expand and endorse the current Change Concepts for education and promotion throughout the renal, surgical, and interventional communities.*	**Metrics:** **FFBI Dashboard/AV fistula prevalent rate.**		
	Tactics	**Responsible Party**	**Timeframe**	**Milestones**
	▪ Publish vessel mapping white paper ▪ Disseminate vascular access vessel mapping guidelines to: o Primary Care Providers o Nephrologists o Vascular access Ultrasound technologists o Vascular access surgeons	Nephrology		
6	Enhance Change Concept #8 ▪ Partner with National Association of Nephrology Technologists and American Nephrology Nurses Association to leverage Conditions for Coverage requiring technician certification to include cannulation credentialing, certification, and requirements, including: o Adherence to K-DOQI Guidelines "Maturation and Cannulation of AV fistula "Rule of 6s" o Different levels of cannulation (novice to master) o Buttonhole cannulation o Teaching self-cannulation	National Association of Nephrology Technologists, American Nephrology Nurses Association, FFBI Coalition	September 2009 - November 2009	Deployment of enhanced Change Concepts
7	Enhance Change Concept #10 ▪ Include Strategy 1, Tactics 2-4 ▪ Include Strategy 2, Tactics 7-9 ▪ Include Strategy 3, Tactic 1 ▪ Include Strategy 4, Tactic 1	ESRD Networks, FFBI Coalition, Quality Improvement Organizations	September 2009 – September 2011	Deployment of enhanced Change Concepts
8	Enhance Change Concept #2 ▪ Include the 30-20-10 campaign into this Change Concept (See Strategy 2, Tactic 4) ▪ Include Strategy 6, Tactic 1	ESRD Networks, FFBI Coalition, Quality Improvement Organizations	November 2009 and Ongoing	Deployment of enhanced Change Concepts
9	Enhance Change Concept #3 ▪ Include Strategy 6, Tactics 2-4	ESRD Networks, FFBI Coalition, Quality Improvement Organizations	September 2009 – June 2011	Deployment of enhanced Change Concepts

Priority	**Strategy 7: FFBI Change Concepts** *Expand and endorse the current Change Concepts for education and promotion throughout the renal, surgical, and interventional communities.*	**Metrics:** **FFBI Dashboard/AV fistula prevalent rate.**		
	Tactics	**Responsible Party**	**Timeframe**	**Milestones**
10	Enhance Change Concept #4 ▪ Include Strategy 6, Tactics 2-4	ESRD Networks, FFBI Coalition, Quality Improvement Organizations	September 2009 – June 2011	Deployment of enhanced Change Concepts
11	Enhance Change Concept #11 ▪ Please see Policy Recommendation 2: Assure Data Flow	ESRD Networks, FFBI Coalition, Quality Improvement Organizations	TBD	TBD

Policy Recommendation 1: Pay-for-Performance			
Tactics	**Responsible Party**	**Timeframe**	**Milestones**
Develop the "business case" to present to CMS showing the cost benefit of a P4P program. (While this would be an initially expensive undertaking, over time the costs will be recaptured in savings to the program.)	FFBI Coalition	October 2009 - January 2010	Business case presented to CMS by February 2010
Consider whether incentives could be provided for patients who present to dialysis with a working AV fistula and would acknowledge the time and effort required to make this possible at the patient, vascular access surgeon, primary care provider and nephrology level.	CMS	TBD	TBD
Develop New "G" code, for Reimbursement for Education & Prevention Activities for primary care providers	CMS & FFBI Coalition	TBD	TBD
Expand G code(G0365) for vessel mapping to remove the payment limitations	CMS & FFBI Coalition	TBD	TBD
Recommend objective imaging testing to assess fistula maturation at an early stage by duplex ultrasound. Payment for this service would require a modification of the NCD for CPT 93990 by CMS	CMS & FFBI Coalition	TBD	TBD
• Address length of stay pressures and the DRG system and lack of coverage for many patients without health insurance and presenting in CKD Stage 5. • Address how vessel mapping and access placement can happen prior to discharge from the hospital for these patients.	CMS & FFBI Coalition	TBD	TBD

Policy Recommendation 2: Assure Data Flow			
Tactics	**Responsible Party**	**Timeframe**	**Milestones**
Establish routine communications among CMS and CMS contractors with responsibilities related to FFBI. Recommendations will include those related to data elements, methods to assure accurate and reliable data, clinical quality measures, and standardized reports. **(Data Availability)**	CMS	Ongoing	Routine calls between pertinent parties for purposes of mutual information exchange beginning in September 2009
• Develop process to validate data in CROWNWeb • Employ process to validate data in CROWNWeb. **(Data Availability)**	CMS ESRD Networks	TBD	Work with CMS to put more robust data validation processes in place
Assure availability of relevant vascular access clinical measures and standardized reports in CROWNWeb. **(Data Availability)**	CMS and/or CMS contractor, FFBI Data Committee	April 2009 – February 2010	Complete environmental scan of Networks' use of current SIMS provider-specific feedback reports and their recommendations for improvement – June 2009 Provide recommendations CMS and/or CMS contractor for improvements to provider-specific reports being transitioned from SIMS to CROWNWeb – July 2009 Provide recommendations to CMS and/or CMS contractor for new data

Policy Recommendation 2: Assure Data Flow			
Tactics	**Responsible Party**	**Timeframe**	**Milestones**
			elements, clinical measures, and standardized reports for incorporation into CROWNWeb – December 2009
Maintain and improve FFBI Dashboard during transition from SIMS to CROWNWeb. **(Measures and Standardized Reports)**	CMS and/or CMS contractor with technical assistance from FFBI Data Committee	December 2009 – February 2010	Complete environmental scan of Networks' use of current FFBI Dashboard and their recommendations for improvement – October 2009 Provide recommendations to CMS and/or CMS contractor for improvements to FFBI Dashboard – November 2010
Develop and deploy vascular access surgeon profiling methodology. **(Measures and Standardized Reports)**	CKD Quality Improvement Organizations , and associated ESRD Networks, consulting with FFBI Data Committee	August 2008 – July 2011	Access Medicare claims data - September 2009 Develop algorithm and reporting format - February 2010 Apply algorithm to data set and produce reports – July 2010

Policy Recommendation 2: Assure Data Flow			
Tactics	**Responsible Party**	**Timeframe**	**Milestones**
			Produce and distribute vascular access surgeon profiles – January 2011
Develop and deploy nephrologist profiling methodology. **(Measures and Standardized Reports)**	FFBI Data Committee, ESRD Networks, CKD Quality Improvement Organizations	July 2009 – January 2010	Access national Form 2728 data - August 2009 Develop algorithm to produce nephrologist profiles – December 2009 Provide algorithm to Networks for further distribution within their regions – January 2010
Report vascular access outcomes for AV fistula, AV Grafts, and CVCs for all Medicare providers publicly. **(Measures and Standardized Reports)** • Physicians • Vascular access surgeons • Facilities • Payers	CMS	TBD	TBD
Identify QI approaches associated with improved performance. **(Data-driven quality improvement)**	ESRD Networks, FFBI Data Committee	June 2009 – February 2010	Development of data collection tool – November 2009 Collect Data – December 2009 Completion of "What

Policy Recommendation 2: Assure Data Flow			
Tactics	**Responsible Party**	**Timeframe**	**Milestones**
			Works" analyses – February 2010
Conduct data-driven quality improvement. **(Data-driven quality improvement)**	ESRD Networks	Ongoing	Identify top performers with respect to prevalent AV fistula rate and those achieving the greatest improvement – September 2009 Identify poorly performing facilities with respect to prevalent AV fistula rate – September 2009 Gather QI stories from top performers and most improved and distribute to stimulate the spread of good ideas – December 2009 Provide technical assistance to poorly performing facilities – June 2010 (ongoing activity)
Analyze data at the patient level to inform improvement efforts. **(Developmental Analysis)**	CMS or CMS-designated contractor	July 2009 – February 2010 March 2010 – December 2010	Using existing data sources, develop methodology to apply exclusions to the AV fistula rate – January

Policy Recommendation 2: Assure Data Flow			
Tactics	**Responsible Party**	**Timeframe**	**Milestones**
			2010 Vet methodology among clinical stakeholders – June 2010 Using CROWNWeb data, adapt and/or apply methodology to produce AV fistula rates – December 2010
Monitor performance of ESRD Networks in achieving contractual goals. **(Progress Tracking)**	CMS and/or CMS contractor	Ongoing	Availability of Dashboard with Network performance rates following transition to CROWNWeb – January 2010

Section VIII
APPENDICES

A. Fistula First Change Package

B. Decision to Place AVF Flow Chart

C. Root Cause Analysis Team

D. Technical Expert Panel

Appendix A

Fistula First Change Package

Clinical and organizational recommendations based on best practices for increasing AV fistula use and improving hemodialysis patient outcome

1 Routine CQI review of vascular access

- Designate staff member in dialysis facility responsible for vascular access CQI (RN if feasible but can be any renal care professional). Incorporate vascular access into facility-based CQI process.
- Assemble multi-disciplinary vascular access CQI team in facility or hospital.
  - Minimally: Medical Director and VA CQI Coordinator.
  - Ideally: Representatives of all disciplines, including access surgeons and interventionalists.
- Investigate and track all non-AVF access placements and AVF failures.

2 Timely referral to nephrologist

- Primary care physicians utilize pre-ESRD/CKD referral criteria to ensure timely referral of patients to nephrologists, ideally prior to Stage 4 CKD.
  - Establish meaningful criteria for PCPs who may not perform GFR or creatinine clearance testing (i.e. serum creatinine criteria, conversion formula for GFR)
- Nephrologist documents AVF plan for all patients expected to require renal replacement therapy, regardless of RRT being considered.
- Designated nephrology staff person educates patient and family on benefits of AVF and to protect vessels, when possible using bracelet as reminder.

3 Early referral to surgeon for "AVF only" evaluation and timely placement

- Nephrologist/skilled nurse performs appropriate evaluation and physical exam prior to surgery referral.
- Nephrologist refers for vessel mapping where feasible, ideally prior to surgery referral.
- Nephrologist refers patients to surgeons for "AVF only" evaluation, no later than Stage 4 CKD (GFR<30). Surgery scheduled with sufficient lead-time for AVF maturation.
- Nephrologist defines AVF expectations to surgeon, including vessel mapping.
- If pre-ESRD placement of AVF does not occur, nephrologist ensures that patient receives AVF evaluation and placement (if feasible) at the time of initial hospitalization for temporary access (e.g. catheter).

4 Surgeon selection based on best outcomes, willingness, and ability to provide access services

- Nephrologists communicate expectations to surgeons regarding AVF placement and training in current AVF surgical techniques, based on K/DOQI Guidelines and best practices.
- Nephrologists refer to surgeons willing and able to meet AVF expectations based on K/DOQI and best practices.
- Surgeons are continuously evaluated on frequency, quality, and patency of access placements. Data collection and outcomes tracking ideally initiated and reported at the dialysis center as part of ongoing CQI process, and can be aggregated at the Network level.

5 Full range of appropriate surgical approaches to AVF evaluation and placement

- Surgeons utilize current techniques for AVF placement including vein transpositions.
- Surgeons ensure mapping is performed for any patient candidate not deemed suitable for AVF based solely on physical exam.

6 Secondary AVF placement in patients with AV grafts

- Nephrologists evaluate every AV graft patient for possible secondary AV fistula, including mapping as indicated, and document plan in patient's record.
- Dialysis facility staff and/or rounding nephrologists examine outflow vein of all forearm graft patients ("sleeves up") during dialysis treatments (minimum frequency=monthly) to identify patients who may have suitable upper outflow vein for elective secondary AVF conversion in upper arm. Inform nephrologist and surgeon of need to evaluate identified outflow vein for AVF conversion.
- Nephrologist refers to surgeon for evaluation/placement of secondary AVF before failure of AVG.

7 AVF placement in patients with catheters where indicated

- Regardless of prior access (e.g. AV graft), nephrologists and surgeons evaluate all catheter patients as soon as possible for AVF, including mapping as indicated.
- Facility implements protocol to track all catheter patients for early removal of catheter.
- Nephrologists make every effort not to admit patients to clinic with "catheter only"

8 Cannulation training for AV fistulas

- Facility identifies and uses best cannulators and best teaching tools (e.g., videos) to teach AVF cannulation to all appropriate dialysis staff.
- Dialysis staff uses specific protocol for initial dialysis treatments with new AVFs and assigns the most skilled staff to such patients.
- Facility offers option of self-cannulation to patients who are interested and able.

9 Monitoring and maintenance to ensure adequate access function

- Nephrologists and surgeons conduct post-operative physical evaluation of AVFs in 4 weeks to detect early signs of failure and refer for diagnostic study and remedial intervention as indicated.
- Facilities adopt standard procedures for monitoring, surveillance, and timely referral for the failing AVF.
- Nephrologists, interventional radiologists, and surgeons adopt standard criteria, and a plan for each patient, to determine the appropriate extent of intervention on an existing access before evaluating and mapping for an AVF.

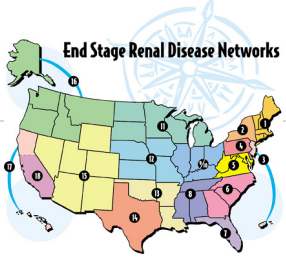
10 Education for care givers and patients

- Routine facility staff in-servicing and education program in vascular access.
- Continuing education for all caregivers to include periodic in-services by nephrologists, surgeons, and interventionalists.
- Facilities educate patients to improve quality of care and outcomes (e.g., prepping puncture sites, applying proper pressure at needle sites without clamps, AVF brochures, etc.).

11 Outcomes feedback to guide practice

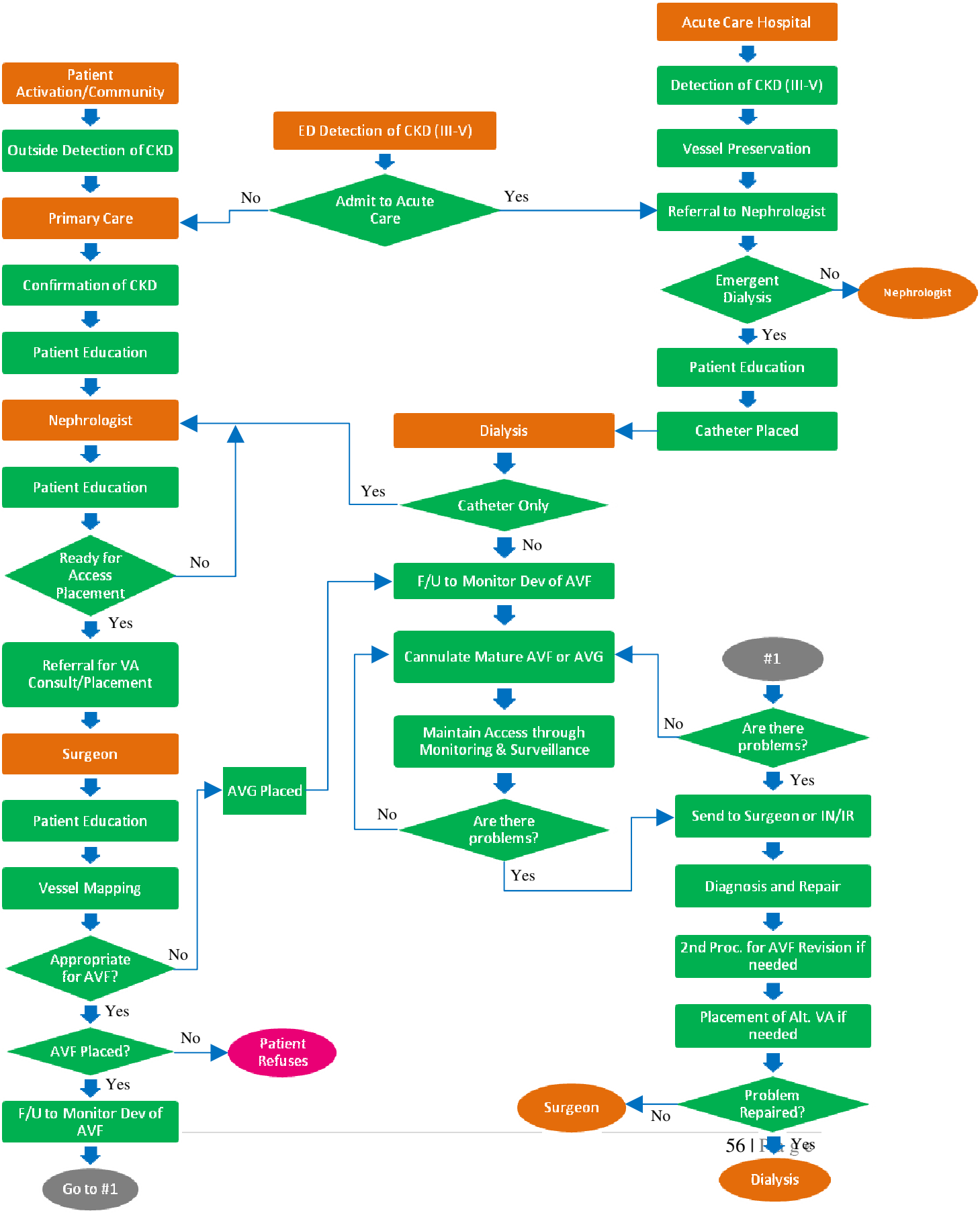
- Networks work with dialysis providers to provide specific outcomes feedback to all decision-makers, including incident and prevalent rates of AVF, AVG, and catheter use.
- Review data monthly or quarterly in facility staff meetings. Discuss and evaluate data trended over time for incident and prevalent rates of AVF, AVG, and catheter use. Track and disseminate all vascular access-related outcomes.

For further information, contact your ESRD Network. A complete listing of ESRD Networks can be found at: http://www.esrdnetworks.org/. *Fistula First* is an initiative of the Centers for Medicare and Medicaid Services and the Department of Health and Human Services. Project assistance provided by the Institute for Healthcare Improvement.



Appendix B

Decisions in AV Fistula Placement Flow Chart



Appendix C

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Appendix D

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