



**A STRATEGIC BLUEPRINT
FOR ADVANCING
KIDNEY CARE QUALITY**



ABOUT KIDNEY CARE PARTNERS

Kidney Care Partners was founded in May 2003 as a coalition of patient advocates, dialysis professionals, care providers, and manufacturers dedicated to working together to improve quality of care for individuals with Chronic Kidney Disease.

MISSION STATEMENT

Members of the kidney care community have formed an alliance—Kidney Care Partners. Their goal is to involve patient advocates, care professionals, providers and manufacturers. Their mission, individually and collectively, is to ensure:

- Chronic kidney disease patients receive optimal care;
- Chronic kidney disease patients are able to live quality lives;
- Dialysis care is readily accessible to all those in need; and
- Research and development leads to enhanced therapies and innovative products.

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EXECUTIVE SUMMARY

According to the U.S. Renal Data System, in 2011 approximately 615,000 adults, plus more than 9,000 children, lived with End-Stage Renal Disease and required dialysis or a transplant to live. African Americans, Hispanic Americans, Pacific Islanders, American Indians, and older Americans have a disproportionate risk for kidney disease. Additionally, people with diabetes, hypertension, and a family history of kidney disease are at higher risk.

Despite community-wide improvements, Kidney Care Partners (KCP) felt kidney care quality would benefit from a strategic blueprint that identified the essential areas for improvement. KCP's vision for this report is that the identification of a comprehensive, yet parsimonious, core set of strategic recommendations will help patients with kidney disease live [Life to the Fullest](#). KCP believes care can and should be improved to

- improve survival,
- reduce hospitalizations,
- improve health-related quality of life, and
- improve patient experience with care.

In *A Strategic Blueprint for Advancing Kidney Care Quality*, KCP identifies the key areas central to making an impact on these goals (Table A), and we recommend focusing on 32 strategic opportunities to do so (Table B). Specifically:

- KCP has supported the overall intent of the **QIP**, which includes both transparency and payment components. KCP believes improving it in four areas—the measure development process, measure harmonization, inclusion of arteriovenous grafts in the measurement program, and careful deployment and improvement of ICH CAHPS—can make a marked difference in achieving the four goals.
- KCP recognizes that **internal quality improvement (IQI)** activities such as deploying standardized protocols, identifying and disseminating best practices, and benchmarking are highly effective drivers of improving care. KCP recommends IQI activities focus on the following: vascular access, incident patients, modality choice, fluid management, nutrition management, patient comprehension, patient experience with care, care coordination and care transition, infections, co-morbidities management, depression, staff engagement, medication management, and end-of-life care.
- **Research** is essential to improving the quality of care for patients with kidney disease. KCP recommends priority be placed on research related to: bone mineral metabolism and the QIP, fluid management, reducing rehospitalizations, reducing sudden death, patient communication tools, quality of life assessment, and patient engagement.
- **System innovation** can transform quality of care. KCP recommends focusing on integrated care and alternative dialysis strategies (e.g., longer duration or more frequent dialysis) to positively affect one or more of the four goals.
- Federal **policy** is a significant driver of health care quality in any sector, but especially for kidney care quality. KCP recommends that federal policies: support the advancement of quality in the delivery of care to patients with kidney disease, provide incentive payments

KCP's goals for high-quality kidney care are to:

- **improve survival,**
- **reduce hospitalizations,**
- **improve health-related quality of life, and**
- **improve patient experience with care.**

In A Strategic Blueprint for Advancing Kidney Care Quality, KCP identifies the key areas central to making an impact on these goals . . . and we recommend focusing on 32 strategic opportunities to do so.

as part of the QIP, encourage health information exchange and health information technology for dialysis care, incorporate a new technology adjustment that is not budget neutral, and permit dialysis facilities to be reimbursed for providing education for pre-ESRD patients.

A Strategic Blueprint for Advancing Kidney Care Quality is a multi-stakeholder, consensus document intended to provide a near-term roadmap on the key actions that, if undertaken through collaboration and partnership, can significantly improve kidney care quality. KCP sees the Blueprint as serving as a guidepost for public and private sector stakeholders to expand upon and/or identify their own priorities.

Table A. Domains for Kidney Care Quality

CARE COORDINATION*

- Care Transitions
- Integrated Care
- Medication Management
- Rehospitalization

DISEASE MANAGEMENT

- Adequacy
- Anemia
- Bone Mineral Metabolism
- Comorbidities Management (e.g., diabetes, peripheral vascular disease, cardiovascular disease)
- Renal Replacement Modality Selection
- Fluid Management
- Immunization
- Nutrition
- Vascular Access

INFRASTRUCTURE

- Care Models
- Health Information Exchange/Data Coordination
- New Technology: Health Information Technology
- New Technology: Device/Machine
- New Technology: Pharmaceuticals
- Telehealth/Medicine
- Workforce

PALLIATIVE & END-OF-LIFE CARE

PATIENT ENGAGEMENT AND EDUCATION

- Adherence to Dialysis Rx, Medications, Diet, etc.
- CKD Stage 4 Pre-Dialysis Education
- Dialysis Patient Education
- Frequency and Duration of Dialysis
- Modality Options Selection
- Nutrition

PATIENT SATISFACTION AND PATIENT EXPERIENCE WITH CARE

PEDIATRIC-SPECIFIC ISSUES

QUALITY OF LIFE

- Depression
- Functional Status
- Rehabilitation and Employment
- Transplantation Referral and Access

SAFETY

- Adverse Events
 - Healthcare-Associated Infections
-

*Including care coordination for Acute Kidney Injury.

Table B. Summary of Strategic Opportunities to Improve Kidney Care Quality

In *A Strategic Blueprint for Advancing Kidney Care Quality*, each KCP recommendation is intended to advance progress toward one or more of our goals for kidney care quality: improved survival, reduced hospitalizations, improved health-related quality of life, and improved patient experience with care.

Public Reporting and the Quality Incentive Program

- Measure Development Process. Improve the rigor and transparency of the federal government’s measure development process and address validity concerns about CROWNWeb data.
- Measure Harmonization. Align the specifications used in the QIP with corollary measures in other federal and private-sector programs.
- Arteriovenous (AV) Grafts. Explicitly include AV grafts in the QIP’s current performance measure strategy, not just AV fistulas and central venous catheters.
- ICH-CAHPS. Deploy ICH-CAHPS as an outcome measure only after developing a careful and thoughtful strategy. Modify the survey so its results are more timely and actionable, as well as one that assesses the experience of all dialysis patients, not just those receiving in-center treatments.

Internal Quality Improvement

- Vascular Access. Supplement straight enumeration of the types of vascular access with IQI activities that will provide a more refined assessment of the precise improvement points on which to focus.
- Incident Patients. Increase deployment of IQI programs targeted to the broader spectrum of clinical and social needs of incident patients.
- Modality Choice. Focus on: 1) increasing physician knowledge about and comfort with discussing all modality options, and 2) educating patients so they can be involved in shared decisionmaking to make informed choices.
- Fluid Management. Disseminate and deploy evidence-based best practices related to extracellular volume monitoring and intensified dialysis regimens.
- Nutrition Management. Focus IQI activities on iterative nutritional status assessments, counseling and, when indicated, nutritional supplementation.
- Patient Comprehension. Identify an IQI-only measure of patient comprehension so that existing patient education efforts, as well as the efficacy of different approaches, can be evaluated.
- Patient Experience with Care. Deploy IQI activities that focus on near-term approaches that provide timely feedback and yield actionable information.
- Care Coordination and Care Transitions. Develop and disseminate standardized protocols, checklists, and communication tools (e.g., on hospital admission, on discharge from a hospital to the dialysis facility or to a skilled nursing facility, related to medication reconciliation, access plan, etc.).
- Infections. Systematically adopt the Centers for Disease Control and Prevention’s protocols, audit tools, and checklists to reduce healthcare-associated infections.
- Co-Morbidities Management. Use innovative care delivery, standardized protocols, checklists, worksheets, automatic reminders, and other patient engagement technologies to improve management of and complications from co-morbidities.
- Depression. Systematically assess and identify best practices for approaches to address depression.
- Staff Engagement. Share best practices aimed at staff retention, engagement, and professionalism.
- Medication Management. Establish a culture of safety designed to mitigate risk, and use root cause analyses when adverse events occur. Ensure patients maintain an accurate and up-to-date medication list.
- End-of-Life Care. Increase awareness and understanding of the benefits and importance of palliative and hospice services among health care professionals to ensure appropriate and timely referrals.

Research

- Bone Mineral Metabolism and the QIP. Address the gap in suitable measures for the QIP, as well as the underlying evidence base on the effectiveness of interventions related to bone mineral metabolism.
- Fluid Management. Emphasize research related to: 1) an accurate way to assess dry weight and determine appropriate ultrafiltration rates, 2) innovative methods for assessing extra-cellular volume, 3) avoidance of sodium loading, and 4) the utility of more frequent/extended hemodialysis.
- Reducing Rehospitalizations. Pursue research on the underlying factors behind repeated readmissions of patients with chronic kidney disease.
- Reducing Sudden Death. Expand research on the underlying factors that contribute to sudden death in patients with ESRD and the impact of potentially modifiable risk factors.
- Patient Communication Tools. Undertake research on deploying 21st century communication tools to improve patient education, experience with care, engagement/activation, and comprehension.

- Quality of Life Assessment. Improve patient surveys of quality of life and functional status so they are useful for assessing facility-wide quality.
- Patient Engagement. Pursue research on improving engagement of and shared decisionmaking by patients with ESRD and their families and caregivers.

System Innovation

- Integrated Care. Place a high priority on decreasing health care delivery fragmentation and increasing care coordination through the pursuit of integrated care models or other proposals.
- Alternative Dialysis Strategies. Pursue projects through federal agencies that examine patient, health care professional, provider, economic, and system factors related to alternative treatment schedules.

Policy

- Advancing Quality. Advance federal policies that support quality in the delivery of care to patients with kidney disease.
 - Incentive Payments. Provide incentive payments under the QIP, consistent with other value-based purchasing programs for other health care sectors.
 - Health Information Exchange (HIE) and Health Information Technology (HIT). Examine current federal policy to promote HIE in order to encourage the adoption and utilization of effective HIT for dialysis care.
 - New Technology. Using existing authority, establish a new technology adjustment to the ESRD prospective payment system that is not neutral.
 - Patient Education. Enact legislation that permits dialysis facilities to be reimbursed for providing education sessions for pre-ESRD patients in the Medicare program.
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INTRODUCTION

Currently, about 26 million American adults have chronic kidney disease (CKD).¹ According to the U.S. Renal Data System (USRDS), in 2011 approximately 615,000 of these individuals, plus more than 9,000 children, lived with End-Stage Renal Disease (ESRD) and required dialysis or a transplant to live.² African Americans, Hispanic Americans, Pacific Islanders, American Indians, and older Americans have a disproportionate risk for kidney disease. Additionally, people with diabetes, hypertension, and a family history of kidney disease are at higher risk.³

Data demonstrate that outcomes and quality of care for patients with kidney disease have improved,^{4,5,6} but few would argue that additional improvements are not within reach. For nearly a decade, Kidney Care Partners (KCP; Appendix A) has provided community-wide leadership in kidney care quality. Most recently, it undertook two specific, comprehensive, proactive initiatives: In 2005 it convened the Kidney Care Quality Alliance to develop performance measures, worked with the Centers for Medicare and Medicaid Services (CMS) to harmonize like measures, and received National Quality Forum (NQF) endorsement for its measures in the area of vascular access, influenza immunization, and patient education.⁷ In 2009, KCP launched a voluntary quality improvement initiative, the Performance Excellence and Accountability in Kidney Care (PEAK) Campaign, to reduce first-year mortality by 20%.⁸

The federal government also has focused increasingly on promoting health care quality through performance measurement for a broad range of health care providers and professionals, including the dialysis organizations. Unlike “pay for participating” or “pay for public reporting” programs, however, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA; Pubic Law 110-275) subjected dialysis facilities to the first (and to date only) penalty-based, value-based purchasing program. Under the Quality Incentive Program (QIP), payment to a facility is reduced by up to 2% if the entity does not meet or exceed a total

performance score for specific performance measures selected by the Secretary of Health and Human Services (HHS).

Despite community-wide improvements and the success of KCP’s KCQA and PEAK programs—and those of its [member organizations](#)—a growing realization emerged that the QIP specifically, and kidney care quality, generally, would benefit from a strategic blueprint that identified the key areas and strategies to accelerate improvement in the quality of care for patients with kidney disease, among the most vulnerable of patient populations. This report presents KCP’s strategic vision for kidney care quality.

CONTEXT OF THE BLUEPRINT

Over the past two years KCP has urged CMS to work with the community to identify a clear and transparent process to identify and prioritize domains to be addressed by the QIP and measure development.⁹ At the same time, KCP recognized:

- All stakeholders share responsibility to drive improved health and health care;
- The QIP is only one approach to improve quality; and
- The blueprint should have an appropriate contextual and organizing framework that resonates with the kidney care community, CMS, and the broader health care quality community.

Given these principles, KCP’s vision for the Blueprint is to identify the strategic opportunities that would help patients with kidney disease live a full and productive life.¹⁰

Contextual and Organizing Framework

KCP^{*} reviewed eight documents as potential contextual and organizing frameworks for the

*The KCP Blueprint Steering Committee conducted this review: Akhtar Ashfaq, Amgen; Donna Bednarski, ANNA; Dolph Chianchiano, NKF; Edward Jones, RPA; Chris Lovell, DCI; Franklin Maddux, FMC; Allen Nissenson, DVA; Gail Wick, AKF.

Blueprint.¹¹ We concluded the Blueprint is best positioned if placed in the context of the national quality dialogue, which centers on HHS' National Quality Strategy (NQS)¹² with its three aims:

- Better care (improve the overall quality of care by making health care more patient-centered, reliable, accessible, and safe),
- Healthy people and communities (improve the health of the U.S. population by supporting proven interventions to address behavioral, social, and environmental determinants of health in addition to delivering higher-quality care), and
- Affordable care (reduce the cost of quality health care for individuals, families, employers, and government),

as well as six priorities:

- Make care safer by reducing harm caused in the delivery of care.
- Ensure that patients and families are engaged as partners in their care.
- Promote effective communication and coordination of care.
- Promote the most effective prevention and treatment practices for the leading causes of mortality.
- Work with communities to promote wide use of best practices to enable healthy living.[#]
- Make quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models.

Framing Kidney Care Quality

Translating the NQS to a strategic blueprint to achieve high-quality kidney care requires identifying:

- the desired outcomes, or **goals**, for kidney

[#]KCP noted that this priority's intent is to focus on community and population health and, given the breadth of material to be covered, set it aside for this project.

care;

- the key kidney-specific **domains** that should be addressed to achieve those goals; and
- the **drivers of transformation** through which improvements in a domain will result in advancement toward one or more goals.

Goals

To address the aims and priorities of the NQS, KCP has identified the following four quality goals for patients with late-stage CKD or ESRD:

- Improve survival.
- Reduce hospitalizations.
- Improve health-related quality of life.
- Improve patient experience with care.

Domains

The NQS, by design, lays out a high-level vision. To add granularity for kidney care, KCP has identified nine primary domains, some of which are further parsed to multiple subdomains. Collectively, these (sub)domains comprise those aspects of kidney care that can be addressed to impact one or more of the four goals. Table 1 sets forth the domains and subdomains; the primary-level domains are:

- Care Coordination,
- Disease Management,
- Infrastructure,
- Palliative and End-of-Life Care,
- Patient Engagement and Education,
- Patient Satisfaction & Patient Experience with Care,
- Pediatric-Specific Issues,^{**}
- Quality of Life, and
- Safety.

^{**}KCP members ultimately did not identify macro-level issues unique to the pediatric population at this time, but did note that micro-level issues (e.g., specific measurement targets within a particular [sub]domain) exist and need to be accounted for.

Table 1. Domains for Kidney Care Quality**CARE COORDINATION***

Care Transitions
 Integrated Care
 Medication Management
 Rehospitalization

DISEASE MANAGEMENT

Adequacy
 Anemia
 Bone Mineral Metabolism
 Comorbidities Management (e.g., diabetes, peripheral vascular disease, cardiovascular disease)
 Renal Replacement Modality Selection
 Fluid Management
 Immunization
 Nutrition
 Vascular Access

INFRASTRUCTURE

Care Models
 Health Information Exchange/Data Coordination
 New Technology: Health Information Technology
 New Technology: Device/Machine
 New Technology: Pharmaceuticals
 Telehealth/Medicine
 Workforce

PALLIATIVE & END-OF-LIFE CARE**PATIENT ENGAGEMENT AND EDUCATION**

Adherence to Dialysis Prescription, Medications, Diet, etc.
 CKD Stage 4 Pre-Dialysis Education
 Dialysis Patient Education
 Frequency and Duration of Dialysis
 Modality Options Selection
 Nutrition

PATIENT SATISFACTION AND PATIENT EXPERIENCE WITH CARE**PEDIATRIC-SPECIFIC ISSUES****QUALITY OF LIFE**

Depression
 Functional Status
 Rehabilitation and Employment
 Transplantation Referral and Access

SAFETY

Adverse Events
 Healthcare-Associated Infections

*Including care coordination for Acute Kidney Injury.

Drivers of Transformation

Identifying the domains important to kidney care quality is a key first step, but this alone is insufficient to achieve the four goals. Addressing *how* to best effect change that can result in meaningful improvement also is necessary. The NQF's National Priorities Partnership notes that leadership and commitment to apply drivers of transformation to key areas can make significant strides to improve health care quality.¹³ In the context of the Blueprint, KCP has identified five transformation drivers for kidney care quality:

- Federal Government's QIP,⁵
- Internal Quality Improvement,
- Research,
- System Innovation, and
- Policy.

While the recommendations that follow are discrete and targeted for organizational purposes, KCP recognizes the inter-relationships among many of them and acknowledges that an integrated approach and evolution to what IOM refers to as “the learning health care system” is desirable—i.e., we should strive toward a system that generates and applies the best evidence for collaborative health care choices and shared decisionmaking between patients and providers as a natural outgrowth of patient care, while ensuring innovation, quality, safety, and value.¹⁴

Public Reporting and the QIP

As noted, increasingly Congress and the Administration have turned to value-based purchasing and public reporting programs that link payment to performance measurement within specific care settings or across settings in the case of Accountable Care Organization models¹⁵ or the proposed ESRD Seamless Care Organizations (ESCOs).¹⁶ USRDS, CMS through Dialysis Facility

Compare, and the Dialysis Outcomes and Practice Patterns Study Program have long publicly reported longitudinal information about the quality of kidney care. More recently, the QIP has encompassed both public reporting as well as the government's only penalty-based program. This approach, withholding a portion of payment unless a certain level of performance is attained, places greater burden on dialysis organizations compared to reward-based, reporting-only uses of performance measurement (e.g., Hospital Compare or the Physician Quality Reporting System).^{***}

Performance measurement and public accountability through public reporting and value-based purchasing are widely viewed as important drivers to improve health care quality.^{17,18} KCP has supported the overall intent of the QIP, which includes both transparency (through reporting on Dialysis Facility Compare and mandated, facility-specific posting of performance) and payment policy, while also making recommendations for improvement to CMS.¹⁹ Going forward strategically for the QIP: What performance measures exist and should be included for key (sub)domains? Are there evidence-based, high-leverage opportunities that exist, but that require measure development? How should such measure development occur?

Internal Quality Improvement

Internal quality improvement (IQI) refers to activities such as deploying standardized protocols, identifying and disseminating best practices, and benchmarking. IQI also may involve performance measures for longitudinal tracking within an organization/physician practice or to analyze the outcomes of different interventions—i.e., measurement other than for public accountability purposes.^{###} The broad range of IQI activities are

⁵Other government value-based purchasing programs such as the Physician Quality Reporting System and proposed ESCO initiative obviously have a bearing on kidney care quality. For the most part, however, KCP has opted to focus on the QIP in this document.

^{***} In other programs, hospital claims related to avoidable readmissions and for serious reportable events (“never events”) are reduced.

^{###} Performance measures used only within an organization have significantly less rigorous technical requirements than those used for public reporting and/or payment. As demonstrated though the history of NQF projects, the vast

well-documented as being highly effective drivers of transformation.²⁰

Clearly, IQI activities in nearly any of the kidney care (sub)domains can result in higher quality. The strategic recommendations in the Blueprint focus on those (sub)domain(s) that have the highest potential yield to improve one or more of the four goals.

Research

As in any field, new knowledge and its dissemination are essential to improving the quality of care for patients with kidney disease. NQF demands a robust evidence base gathered through research to assess the importance, validity, and reliability of measures it endorses (for the most part a requirement CMS adopts for use in the QIP). Similarly, research is necessary to inform how IQI initiatives should be structured, and research on the effectiveness of IQI per se is important. Interesting and important research issues can be identified for all of the (sub)domains, but the Blueprint's focus is on specific knowledge gaps for which research could advance understanding in the particular (sub)domain and make a significant improvement in survival, hospitalization, patient experience with care, and/or quality of life.

System Innovation

Research can serve as the foundation from which treatments, best practices, clinical guidelines, and performance measures are derived. Innovation can similarly serve as a transformation driver for quality improvement. In this report, innovation refers to potential system delivery changes, potential technological advances, or potential policy changes explored through small-scale projects or testing because they might be promising based on the existing knowledge base, but for which widespread adoption might be premature. For example, CMS's previous ESRD Disease Management Demonstration and its proposed ESCOs are examples of innovation to address care coordination.

majority of IQI measures are not suitable for immediate translation for accountability—i.e., public reporting and/or payment applications.

Policy

Federal policies, and to a far lesser extent some state policies, affect care delivery—and hence have the potential to be a significant driver of health care quality in any sector. For kidney care quality, the impact is enormous, since Medicare is the primary payer. From a strategic viewpoint, the Blueprint addresses federal policies (regulatory or statutory) that could be reasonably eliminated or modified in order to improve kidney care quality.

Reimbursement for dialysis services—what is included/excluded in the bundled payment, specific adjusters for low volume or case mix, etc.—are not the focus of this Blueprint. KCP's specific views on payment issues and the ESRD Prospective Payment System (PPS) are available elsewhere,²¹ although obviously payment policies ultimately intertwine with quality, access, and outcomes.

SCOPE AND ORGANIZATION OF THE STRATEGIC BLUEPRINT

The KCP Blueprint's scope encompasses improving quality for patients with late-stage CKD and ESRD. Related areas that are not included are prevention (e.g., community- and population-focused healthy living and well-being) and transplantation, except as it applies to modality options. KCP does not mean to imply that prevention (and HHS' National Prevention Strategy)²² and transplantation are not important, but limited the scope of the Blueprint to allow greater focus on the vulnerable late-stage CKD and ESRD populations.

The KCP Blueprint is intended as a **strategic** document to accelerate kidney care quality improvement, not a **tactical** document that identifies actions that different stakeholders could or should take regarding implementation of the recommendations.

Finally, while a necessary first step was identifying and reviewing the key areas on which to focus (Table 1) and by reviewing the state-of-the-art of all (sub)domains, **the recommendations in the body of this report are organized around the transformation drivers. They primarily focus on the domains where application of the transformation**

driver(s) can feasibly, significantly, and in the near-term impact one or more of the four goals: improve survival, reduce hospitalizations, improve quality of life, and improve patient experience with care; they are not in priority order. KCP discussed actions for other (sub)domains and recognized the inter-relationships that exist among them. We do not mean to diminish the importance of any single domain by not focusing on it in detail. Rather, KCP sought to focus on the leverage points with the highest potential value. We further note that the knowledge, competency, and professionalism of all staff is integral to providing high-quality care and so crosses the domains and recommendations in this Blueprint. Ensuring an educated workforce through fellowships, certification, and continuing education is essential.

STRATEGIC OPPORTUNITIES TO IMPROVE KIDNEY CARE QUALITY

As just noted, this Blueprint is intended to strike a balance between being strategic and focused versus covering all the domains of kidney care quality. This section emphasizes how leveraging the five transformation drivers provides key strategic opportunities, especially in the areas of vascular access; renal replacement modality choice; patient education, engagement, and shared decisionmaking; care coordination and care transitions; fluid management; and hospitalization and rehospitalization.

Public Reporting and the QIP

The federal government funds health care quality-related research, as well as biomedical and clinical research that can improve kidney care quality. The federal government's main approach to quickly improving frontline quality, however, is through performance transparency and value-based purchasing—for kidney care quality chiefly the QIP for dialysis facilities, the Physician Quality Reporting System (PQRS), and the proposed (and currently unidentified) performance measures for ESCOs. Additionally, other non-federal public reporting and payment-related quality programs exist. This report primarily focuses on strategic opportunities related to the QIP.

Through rulemaking, CMS has finalized the QIP measures and structure for payment year 2016. The areas encompassed are: anemia management, vascular access, dialysis adequacy, vascular access-related infections/patient safety, bone mineral metabolism, and patient experience with care. KCP has commented in detail on CMS's specific proposals for the QIP for payment year 2016, including the current domains, measure specifications, and lifecycle of measures to be included or retired.²³ In this Blueprint, we identify how the QIP could more effectively drive transformation if certain key opportunities were pursued.

Strategic Opportunities to Improve the QIP

QIP-Measure Development Process. A meaningful QIP requires valid, reliable, and evidence-based performance measures that examine areas with the highest impact on outcomes. Even for legislatively mandated or suggested areas, however, a robust set of measures does not exist. The measurement gaps for ESRD care must be addressed by new measure development, but the federal government's current approach is lacking in rigor and transparency and must be improved before the void can be filled. As well, the validity of data from CROWNWeb must be addressed.

QIP-Measure Harmonization. To maintain the integrity of the program, the specifications for kidney care measures used in the QIP must align with corollary measures in other federal programs—e.g., with PQRS measures and with the proposed ESRD Seamless Care Organizations (ESCOs) measures—as well as other programs—e.g., among PQRS, physician maintenance of certification (MoC), and ESRD Network-led initiatives.

QIP-Including Grafts. The QIP's current strategy to use two measures that focus on arteriovenous (AV) fistulas and central venous catheters (CVC) is suboptimal, and potentially damaging. AV grafts should be

explicitly included. Changing the current state of vascular access in the United States provides a significant opportunity to decrease mortality, decrease hospitalizations, and improve quality of life.

QIP-Deploying ICH-CAHPS. HHS currently includes In-center Hemodialysis (ICH)-CAHPS, a patient experience with care measure developed by the Agency for Healthcare Quality, in the QIP as a process measure. Using ICH-CAHPS as an outcome measure requires a careful and thoughtful strategy. ICH-CAHPS also should evolve to assess the experience of all dialysis patients, not just those receiving in-center treatments. As well, it should be more timely and actionable.

Overcoming the Barriers to Realize the Strategic Opportunities

Advancing each of the strategic opportunities related to the QIP naturally gears toward CMS as the party that can best effect change, given the QIP is a federal program. Other parties, however, can play important roles (other than advocating changes to CMS) and are noted as appropriate.

Ensuring Development of Valid, Reliable, and Evidence-based Performance Measures

A meaningful QIP requires valid, reliable, and evidence-based performance measures. The measurement areas encompassed by the QIP for payment year 2015 are anemia management, vascular access, dialysis adequacy, vascular access-related infections, and bone mineral metabolism. Expanding beyond these areas requires development of new measures.

Although the measurement gaps for ESRD care must be addressed by measure development, the federal government's current approach is lacking in rigor and transparency and must be improved before the void can be filled. Specifically, KCP has serious concerns about the execution of the federal government's current measure development. KCP has provided details elsewhere to CMS, including specific recommendations on how the process can

be improved,²⁴ but also summarizes them here because development of new measures is essential to build-out the QIP to achieve the NQS and KCP's four goals.

First, the constitution of the individual Technical Expert Panels (TEPs) convened result in discussions that do not meaningfully (if at all) consider the day-to-day operations and data collection realities of dialysis facilities. Second, the process seems pre-determined to endorse pre-identified measures, as opposed to stimulating an open dialogue for responding to comments and recommendations of TEP members. Third, the output does not always correspond with the discussions many of the TEP members understood to have occurred, leading to measures that were inconsistent with the direction the TEP suggested or, in at least two cases, measures neither recommended by the TEP nor specified for the public comment period. Additionally, the process is not transparent. For example, meeting materials are not provided to stakeholders; no opportunity to listen in and provide public comment at the meetings is offered; and follow-up conference calls are completely opaque. Finally, the primary data source going forward, CROWNWeb, must be validated.

We believe the current, suboptimal approach and execution thereof has led to suboptimal outputs, the majority of which in the past have not advanced through NQF—a process that KCP generally supports for vetting measures prior to adoption in the QIP. CMS should address the deficiencies in the execution of its current measure development process before moving forward.

Aligning Performance Measure Specifications and Incentives

To maintain the integrity of the QIP, the specifications for the measures used must align with corollary measures in other federal programs—e.g., with PQRS measures and with forthcoming ESCO measures. Alignment also must be achieved across other programs—e.g., between PQRS and physician MoC.

Working with NQF, measure developers, and the kidney care community, CMS should ensure that measures used in the PQRS, ESCOs, and QIP are fully harmonized: the domains, the measures and their definitions, and the specifications and data elements (and their interpretation) all must be harmonized. Anything short of alignment has the potential to introduce confusion in data collection, misalign incentives, and/or introduce conflicting interpretations of performance outcomes in the QIP (and potentially PQRS, ESCOs, and Network-led initiatives). Moreover, aligning technical specifications is merely an initial step: CMS should align incentives and accountability across providers and health care professionals to optimally enhance outcomes and improve care coordination. In the area of encouraging permanent vascular access, for example, accountability must extend beyond facilities and nephrologists to primary care physicians, surgeons, and hospitals.

With respect to alignment between PQRS and MoC, two physician-centered programs, physician professional organizations and boards must lead harmonization, but CMS should contribute given the crossover to federal programs. Similarly, other measure developers may need to participate since their measures may be involved, as well.

Including AV Grafts in the QIP

Vascular access-related complications are a major cause of excessive morbidity, mortality, and health care costs in the ESRD population. AV fistulas have superior longevity, fewer complications (e.g., stenosis and infection), and are associated with lower mortality in hemodialysis patients,^{25,26,27,28,29} but an increasing body of evidence suggests the focus should be on permanent access (AV fistulas or AV grafts), not just AV fistulas.^{30,31,32} In other words, rather than fistula first, the mantra should be hemodialysis catheters last.

Excluding grafts from the QIP has been characterized by CMS as a neutral position—i.e., a facility neither benefits nor is penalized for high numbers of patients with AV grafts. Neutrality is not enough, nor appropriate, given the current knowledge. A

more appropriate, evidence-based, and high-leverage opportunity would be to include AV grafts in the performance calculus. Its superior benefits compared to CVCs are well-documented, and CMS should include AV grafts as part of the QIP's vascular access measurement domain.

KCP notes that including AV grafts as a measurement area within the QIP is likely insufficient in and of itself to make significant strides in vascular access-related quality. As discussed elsewhere in this document, IQI initiatives must play an important role. Nevertheless, the exclusion of grafts in the QIP is a significant concern because patients for whom an AVF is medically inappropriate are not credited when the alternative permanent access—a graft—is used to avoid a CVC.^{33,34,35}

Deployment of ICH-CAHPS in the QIP

Measuring a patient's experience with care is at the heart of advancing the goal to improve patient experience. Today, the standardized instruments favored by CMS are the CAHPS family of surveys, including the ICH-CAHPS instrument for dialysis facilities. And while debate exists as to whether patient experience data provide valid information about the overall quality of patient care, one recent study using HCAHPS and Hospital Compare clinical data found that higher overall patient satisfaction and satisfaction with discharge planning are associated with lower 30-day risk-standardized readmission rates^{36,37}—even after controlling for hospital adherence to evidence-based practice guidelines.³⁸

Currently, the QIP uses ICH-CAHPS as a structural/reporting measure—i.e., facilities are scored on whether they have administered the survey (yes/no). Given that as of October 2012 hospitals' Medicare reimbursement is tied to outcomes measured in part by H-CAHPS, deployment of ICH-CAHPS seems likely to evolve in a similar direction.

Before CMS moves to using ICH-CAHPS as an outcome measure, however, it should consult with the community so that a very careful and thoughtful

strategy is developed on the most appropriate ICH-CAHPS domains to include as outcomes in the QIP, whether and how results should be stratified for reporting and scoring purposes, etc. Those questions or domains that provide little actionable information should not be included for the purpose of payment reductions.³⁹ Similarly, CMS should account for patient mix so that a single score across a facility's entire patient population does not inappropriately penalize facilities.

Finally, as its name denotes, the ICH-CAHPS instrument is limited to patients receiving in-center hemodialysis. CMS also should assess patient experience of care for peritoneal dialysis and home hemodialysis patients.

Internal Quality Improvement

Improving the quality of kidney care begins with quality initiatives within a facility or physician practice—i.e., IQI activities that self-assess performance, followed by interventions and re-assessment, using standardized protocols, identifying and disseminating best practices, and/or benchmarking. Such IQI activities can be highly effective drivers for improving kidney care quality, and must recognize that care for patients with ESRD involves a team of health care professionals (i.e., physicians, nurses, social workers, dietitians, and dialysis technicians).⁴⁰

Strategic Opportunities for Internal Quality Improvement

IQI-Vascular Access. Straight enumeration of the types of vascular access, as occurs in the QIP, should be supplemented by IQI activities that will provide facilities and physicians with a more refined assessment of the precise improvement points on which to focus.

IQI-Incident Patients. Improving care for patients transitioning from CKD to ESRD, from dialysis to transplant, and for patients during the first 120 days of dialysis represent a significant opportunity for IQI to address populations with the highest

mortality and highest hospitalizations. IQI specific to dialysis access and general patient education are related and important, but increased deployment of IQI programs targeted to the broader spectrum of clinical and social needs of incident patients in particular can yield significant improvements.

IQI-Modality Choice. Two factors are central to renal replacement therapy modality choice and selection and should be the focus of IQI activities. First, physicians must be knowledgeable about and comfortable with discussing the full range of modality options. Second, patients with kidney disease must be educated and involved in shared decisionmaking so they can make informed choices about modality options.

IQI-Fluid Management. Fluid management has the potential to have a significant impact on mortality, hospitalizations, and quality of life. While additional research would be useful, IQI based on current knowledge—such as extracellular volume (ECV) monitoring and intensified dialysis regimens—can reduce hospitalizations and mortality, and best practices from IQI should be widely disseminated and deployment accelerated.

IQI-Nutrition Management. Protein-energy wasting (malnutrition) occurs frequently in patients with renal failure and is associated with increased morbidity and mortality. Nutrition-related concerns include maintaining acceptable weight and serum proteins (e.g., albumin), minimizing renal bone mineral disease, and reducing cardiovascular risk. IQI activities focusing on iterative nutritional status assessments, counseling and, when indicated, supplementation, can improve outcomes and quality of life.

IQI-Patient Comprehension. An IQI-only measure of patient comprehension in areas

such as vascular access, renal replacement therapy modality options, diet and nutrition, and avoiding complications should be identified so that dialysis organizations and health care professionals can evaluate their existing patient education efforts and assess the efficacy of different approaches. Including Stage 4 patients is particularly important to maximize patient education and engagement related to the foundational subdomains of dialysis access and modality options, both of which have significant impact on outcomes.

IQI-Patient Experience with Care. ICH-CAHPS falls short in providing timely feedback on actionable steps to improve patient experience with care. In contrast, IQI activities can focus on near-term approaches for all patients and should be used to assess and improve their care.

IQI-Care Coordination and Care Transitions. Care coordination and care transitions for patients with kidney disease are high-leverage opportunities for IQI approaches. Transitions could be significantly improved by the development of standardized protocols, checklists, and communication tools (e.g., on hospital admission, on discharge from a hospital to the dialysis facility or to a skilled nursing facility, related to medication reconciliation, access plan, etc.).

IQI-Infections. Systematically using the Centers for Disease Control and Prevention's (CDC) protocols, audit tools, and checklists in an IQI initiative improves patient safety by reducing healthcare-associated infections (HAI) and should be broadly adopted.

IQI-Co-Morbidities Management. IQI initiatives are well-suited as the transformation driver to address co-morbidities management, particularly

diabetes control and diabetes-related complications (e.g., feet and wound checks) through innovative care delivery, standardized protocols, checklists, worksheets, automatic reminders, and other patient engagement technologies.

IQI-Depression. Pursuing IQI activities that systematically assess depression and identify best practices for approaches to address it could markedly improve the quality of life and functional status for a significant portion of patients.

IQI-Staff Engagement. Staff engagement, professionalism, and retention closely affect patient experience with care. Providers have creative programs aimed at staff retention and preventing burnout, and sharing these as best practices could improve patient experience with care, as well as patient safety.

IQI-Medication Management. Medication errors are a critical patient safety issue and can be minimized through the establishment of a culture of safety that deploys IQI processes of care that are designed to mitigate risk and uses root cause analyses when adverse events occur. Such efforts must also ensure that patients are involved in maintaining an accurate and up-to-date medication list, including all those outside the dialysis setting, even if unrelated to kidney disease.

IQI-End-of-Life Care. Palliative and hospice services are underutilized in the ESRD population. IQI activities that increase awareness and understanding of the benefits and importance of these services would begin to overcome this deficit. As part of these efforts, health care professionals need an understanding of Medicare hospice benefits as they apply to patients with ESRD in order to make appropriate and timely referrals.

Overcoming the Barriers to Realize the Strategic Opportunities

Advancing the strategic opportunities related to IQI falls largely to dialysis facilities and the health care professional teams, but patients (and their families) must also engage for IQI activities to be successful.

Vascular Access

Achieving optimal vascular access is a complex process and requires patient involvement, as well as collaboration among nephrologists, surgeons, interventionalists, dialysis facilities, primary care practitioners, and hospital systems. In 2009, *Fistula First* assembled a team from varied backgrounds and perspectives to identify the systemic root causes as to why the AV fistula use rate in the United States is significantly lower than that in other industrialized countries. Ultimately, 139 latent root causes were identified, falling into the categories of patient, physician, and system.^{41,42}

IQI activities related to vascular access should be designed to provide greater granularity of data upon which facilities and health care professionals can act—e.g., monitoring the average time on CVCs (catheter exposure days) instead of solely focusing on the endpoint, the efficacy of using peritoneal dialysis while waiting for permanent access to mature, monitoring permanent access failure and its causes, programs to address surgeon and hospital accountability, monitoring nephrologists' referral and follow-up, benchmarking, and/or distinguishing new CVC patients from patients with previous AV fistulas or AV grafts that have failed in order to identify the patient population that needs the most attention at a particular facility. Benchmarking against similar populations will further permit facilities and physicians to not only monitor their internal progress, but also assess to some degree their progress compared to others.

Finally, best practices based on the knowledge gained through IQI initiatives for vascular access should be disseminated.

Incident Patients

Patients with ESRD and CKD Stage 4 have fragile health, but patients new to dialysis—i.e., the first 120 days—are particularly vulnerable. Individuals in this cohort have significantly higher hospitalization and mortality rates,⁴³ and have been the focus of several IQI activities that have yielded clear improvements. Early and continued collaboration of primary and specialty physicians, nurses, and other health care professionals is associated with improved renal and cardiovascular outcomes in patients with CKD and ESRD.^{44,45} Additionally, primary care practitioners should strive to ensure that patients at every CKD stage are educated and knowledgeable about the importance of controlling anemia, diabetes, hypertension, and other comorbidities to improve renal and cardiovascular outcomes; timely referral to a nephrologist is essential, in particular to explore modality options.^{46,47}

Once dialysis is initiated, IQI activities have demonstrated focused attention on incident patients significantly improves outcomes. Fresenius Medical Care's RightStart and DaVita's IMPACT (Incident Management of Patients, Actions Centered on Treatment) programs demonstrate that focus on patient education and support can dramatically improve outcomes for incident renal disease patients through intense and comprehensive early education on topics such as nutrition, anemia management, dialysis dosage, and dialysis access. RightStart patients were found to have significantly improved Mental Composite Scores and reduced hospitalization and mortality rates compared to control subjects when outcomes were tracked for 12 months.⁴⁸ Likewise, IMPACT patients had lower mortality rates, improved adequacy and nutrition markers, and higher AVF rates than patients not enrolled in the program.⁴⁹ KCP's community-based, voluntary quality improvement initiative Performance Accountability and Excellence in Kidney Care (PEAK), which focused on first-year mortality, also examined 90-day mortality and the percent of patients dying within 90 days fell by about 25%.⁵⁰

Such evidence suggests that prompt and intensive medical and educational strategies in pre-dialysis and new dialysis patients can result in decreased morbidity and mortality—decreases that persist beyond the first year.⁵¹ Continued focus on incident patients through IQI activities that promote dissemination of best practices and benchmarking should remain a priority.

Modality Choice

Survival, morbidity, and quality of life are the main factors to consider when identifying the best renal replacement therapy modality for a particular patient: transplantation (including pre-emptive transplantation), in-center or home hemodialysis, or peritoneal dialysis. Choice of therapy, including conservative management without dialysis or a transplant, however, must be analyzed for each patient, taking into consideration demographic, psychosocial, and comorbid factors.

Outcomes comparisons suggest that renal transplantation is a superior treatment option for patients with ESRD. Transplantation is associated with significantly lower mortality and risk of cardiovascular events, as well as reports of substantially improved quality of life.^{52,53,54} Availability of organs for transplantation, however, remains an issue.^{55,56,57,58}

Studies comparing patient outcomes for conventional, thrice weekly hemodialysis and peritoneal dialysis yield conflicting results with respect to survival and infection.^{59,60,61,62} Some studies find patients on peritoneal dialysis have better short-term survival rates in the six-month to two-year^{§§} timeframe.^{63,64,65,66,67,68,69,70} Most studies conclude there is similar long-term survival between the two modalities,^{71,72,73} but long-term survival can differ by modality for specific patient subpopulations—e.g., related to age, gender, comorbidities.^{74,75,76,77}

^{§§}Data from the 2013 *USRDS Annual Data Report*² find the early survival advantage associated with peritoneal dialysis can persist up to five years, but USRDS adjusts only for age, gender, race/ethnicity, and primary diagnosis at ESRD and not other confounding factors.

With respect to infections, research has indicated that, as an initial modality, hemodialysis compared to peritoneal dialysis has nearly double the risk for hospitalization and/or death due to septicemia.^{78,79,80,81,82} Two recent studies suggest that patients on peritoneal dialysis have similar⁸³ or higher rates⁸⁴ of infection-related hospitalization rates, but for peritonitis, which carries a lower risk of mortality.

The short-term advantage of peritoneal dialysis might stem from selection bias, rather than an effect of the treatment itself; patients who start dialysis emergently are at high risk for mortality and are treated almost exclusively with hemodialysis (through hemodialysis catheters). One study demonstrated that incident patients who initiate dialysis electively as outpatients—after at least four months of predialysis care—have similar mortality regardless of dialysis modality, suggesting no survival advantage to switching modalities over time.⁸⁵

Under the Conditions for Coverage, dialysis organizations are required to provide patients with information about all modalities. Information about modality choice is also part of the Kidney Disease Education benefit for Stage IV patients already enrolled in Medicare. Overall, however, two factors are central to modality choice and selection and should be the focus of IQI activities. First, physicians must be knowledgeable about and comfortable with discussing the full range of options. Second, patients with kidney disease, as well as their families or caregivers, must be educated and involved in shared decisionmaking so they can make an informed decision about dialysis modality, including the option of living organ donation and the disadvantages of maintaining dialysis with a CVC.^{86,87,88}

In the first instance, physicians themselves may not be sufficiently knowledgeable or may not provide education on the full range of modality options. Testing in 2008-2009 of KCQA's patient education measure in four nephrologists' offices revealed that no patient in the sample had received education on all modality options, transplantation, and the option of no or cessation of treatment—a result mirrored in

an American Association of Kidney Patient survey.⁸⁹ IQI activities that center on providing all treatment options could be beneficial. Additionally, early education and engagement by practitioners with CKD Stage 4 patients and early referral to nephrologists is particularly important and should be a key focus of IQI activities. And while not an IQI activity per se, adding questions on peritoneal dialysis and home dialysis to the Board examination and MoC process is likely to encourage additional study in this area and improve physician familiarity with all options.

With respect to patient factors related to modality choice and selection, few studies address how a chronic illness affects treatment option choices, generally, and dialysis modality choice, specifically. Limited research suggests that the patient's modality selection process is influenced by a multitude of factors, including physician bias, physiologic, psychological, sociocultural, developmental, and spiritual.⁹⁰ One important factor rests on the quality and timing of information about and prior placement of access; early referral allowing for sufficient physical and psychosocial preparation of the patient is crucial.⁹¹ As addressed elsewhere in this section, IQI programs related to patient comprehension about modality options would focus attention on this critical step and should ideally identify the best approaches to maximize patient choice.

Fluid Management

Second only to focusing on reducing hemodialysis catheters, improving fluid management has the most significant potential to reduce hospitalizations and improve mortality, and IQI initiatives hold much promise to do so. Despite increased emphasis on urea kinetic modeling, more permeable membranes, and improved nutrition and anemia management, cardiovascular morbidity and mortality remain significantly higher in the dialysis population compared to patients without kidney disease; cardiovascular-related mortality is 5 to 30% greater in patients on dialysis.^{92,93} Chronic volume overload is the major cause of hypertension and the vascular changes that lead to adverse cardiovascular consequences in hemodialysis patients.

Controlling extracellular volume (ECV) allows for better blood pressure control, minimizes hypertensive sequelae, and improves cardiovascular outcomes. In particular, intermittent hemodialysis is associated with fluid volume fluctuations that contribute to poor cardiovascular outcomes. Clinicians attempt to achieve "dry weight" with each treatment in order to minimize such adverse effects.⁹⁴ Assessment and achievement of dry weight is often based on a purely clinical assessment of the patient, but the relative lack of accuracy of this approach has led to the use of several technology-based methods of assessing dry weight, such as bio-impedance and Crit-Line[®] monitoring.

Research has yielded conflicting results on the effectiveness of such technology-based approaches to dry weight management. Some studies suggest that conventional clinical assessment of dry weight is superior and yields lower hospitalization and mortality rates,⁹⁵ while others indicate that Crit-Line[®] monitoring can improve ECV control and minimize adverse outcomes.⁹⁶

One recent IQI initiative jointly undertaken by Renal Ventures Management, DaVita, and Fresenius Medical Care examined if objective measurement of ECV removal and attainment of normalized ECV could reduce all-cause and ECV-related hospitalizations and found that education plus monitoring was associated with a 50% decrease in ECV hospitalizations and a 78% decrease in ECV hospital days compared to education alone.⁹⁷

Regardless of the means by which ECV is monitored, recent studies on intensified treatment schedules highlight the importance of volume control. Increasing either the length or frequency of dialysis sessions has yielded promising results with better control of volume and blood pressure, reduction of left ventricular hypertrophy, and decreased requirement for antihypertensive medications.^{98,99,100,101}

Another aspect of fluid management that merits attention through IQI activities relates to myocardial stunning with rapid ultrafiltration and the

relationship of ultrafiltration rates to high mortality;¹⁰² short daily hemodialysis and home nocturnal hemodialysis can significantly impact myocardial stunning related to rapid ultrafiltration rates.¹⁰³

Given the increasing body of knowledge, IQI activities targeted on fluid management—e.g., ECV monitoring, intensified treatment schedules, avoidance of sodium loading, and limiting ultrafiltration rates—can clearly have a positive impact and should be of high priority.

Nutrition Assessment and Management

Protein-energy wasting (malnutrition) occurs frequently in patients with renal failure and is associated with increased morbidity and mortality in this population. Maintaining acceptable weight and serum proteins, minimizing renal bone mineral disease, and reducing cardiovascular risk are the goals of nutrition management for patients with CKD and ESRD.

KDOQI guidelines recommend that nutrition counseling be intensive initially and then be provided every one to two months thereafter. Further, patients on dialysis should have periodic nutrition screening of laboratory values (e.g., albumin), comparison of initial weight with usual body weight and percent of ideal body weight, subjective global assessment, and dietary interviews with review of food diaries. The guidelines also emphasize the importance of counseling, as well as deploying dietary supplements or, if necessary, tube feeding or parenteral nutrition, to meet protein and calorie requirements.¹⁰⁴

IQI activities focusing on iterative nutritional status assessments, counseling and, when indicated, supplementation, can improve quality of life and improve survival for patients on dialysis. Two programs have demonstrated that hemodialysis patients with albumin levels ≤ 3.5 g/dL who received monitored, intradialytic oral nutritional supplements have significantly better survival than matched patient controls.^{105,106}

Assessing Patient Comprehension

Patient education, health literacy, and patient engagement impact patient adherence, which is inextricably linked to areas such as dialysis access, modality choice, nutritional status, and depression. Education can be provided at multiple times, in multiple formats, and in a culturally competent manner, but it will have little impact if health literacy and patient comprehension are not addressed. Education and concomitant comprehension for CKD Stage 4 patients also is particularly important. Robust education of CKD Stage 4 patients with a focus on informed decisionmaking delays the time to dialysis and improves survival, and is likely to result in permanent access and not a hemodialysis catheter, thereby lowering the risk of infection and access-related complications that require hospitalization.^{107,108,109} Assessing comprehension is particularly important for patients who have limited health literacy: Such patients are more likely to miss dialysis treatments, use emergency care, and be hospitalized for kidney disease-related reasons.¹¹⁰

While the Conditions for Coverage demand certain education requirements, an IQI-only measure of patient comprehension is more likely to influence the four kidney care quality goals. Patient comprehension (likely in modules) could address areas such as dialysis access, modality options, diet and nutrition, and avoiding complications. Data on patient comprehension and health literacy would permit dialysis organizations and health care professionals to evaluate their existing patient education efforts and assess the efficacy of different approaches.

No standardized patient comprehension tool currently exists, though research instruments for comprehension are available in other areas and might be adaptable; still development of a tool de novo would require time and resources. One IQI approach derived from the informed consent and safety arenas might be worth exploring to gauge its worth as an IQI initiative for comprehension for patients with ESRD: “teach-back.” Teach-back is a technique recommended to confirm patient understanding, generally. It also has been

demonstrated as being particularly effective to assess understanding among individuals with limited literacy skills.^{111,112} Research demonstrates teach-back results in improved short- and long-term retention of information.^{113,114,115} Another pilot study found that a 1-page, educational worksheet for physician-delivered education was judged feasible in practice and was associated with higher patient kidney disease knowledge; such IQI approaches should be encouraged.¹¹⁶

Research on deploying current media (e.g., text messaging, smart phone applications, etc.) to engage dialysis patients and assess patient comprehension is addressed in a later section.

Improving Patient Experience with Care

As noted previously, the ICH-CAHPS instrument is limited to patients receiving in-center hemodialysis. Moreover, the instrument itself as a driver to improve patients' experiences can be challenging and, in some cases, problematic,¹¹⁷—and at 57 questions, lengthy while not addressing short-term needs of patients and dialysis providers and health care professionals.

IQI activities could be deployed that encompass peritoneal dialysis and home hemodialysis patients, not just in-center patients, and should focus on near-term, actionable issues that would improve patients' experience with care. Computer-assisted testing also could be assessed as to whether it preserves survey validity while decreasing patient burden.

Improving Care Transitions and Care Coordination

The majority of health care delivered in the United States is fragmented, occurring in clinical and payment silos. As a result, the system can be difficult for patients to navigate, is not optimally efficient, can create safety problems when incomplete information is transferred among care settings, and can result in less than optimal outcomes.¹¹⁸ USRDS reports approximately 1.9 admissions per patient year for hemodialysis patients in 2011, and this rate is largely unchanged since 1999-2000. Women, older patients, and patients with diabetes as primary cause have the

highest rates of hospitalizations.¹¹⁹ And while not 1:1, this rate of admission approximates the rate of transition back to the dialysis unit. Suboptimal transitions between the hospital and ambulatory care settings result in an increased likelihood of readmissions, emergency room visits, and medication errors in the general population,^{120,121,122} and there is no indication that patients with ESRD differ in this regard.

The ESCOs proposed by CMS¹²³ aim to deliver care that improves efficiency, care coordination, and quality. IQI initiatives also can be effective, as well. Evidence from the safety, ICU, and infections arenas demonstrates that checklists are highly effective IQI approaches.^{124,125} Developing protocols and checklists for institution-to-institution hand-offs (or institution-to-patient/family) to ensure the appropriate information is transferred when patients with kidney disease move across care settings could significantly improve care transitions, as can ensuring inter-professional communication among care team members. Standard forms and protocols related to hospitalizations being developed by ESRD Networks to smooth transition should be widely shared. As noted in a later section, medication management represents a high-leverage opportunity.

Improving Patient Safety by Reducing Healthcare-Associated Infections

Standardized protocols have demonstrated value beyond care coordination—e.g., in reducing infections. Infections are the second most common cause of death among patients with ESRD, accounting for nearly 14% of deaths.¹²⁶ Methicillin-resistant *Staphylococcus aureus* (MRSA) infections, while declining in hospitals, continue to be problematic in other care settings, including dialysis units.¹²⁷

CDC recently published the results of an IQI initiative—the Bloodstream Infection Prevention Collaborative—which demonstrated that systematically deploying its standardized protocol, checklists, and audit tools yielded a 32% decrease in

overall bloodstream infections and a 54% decrease in vascular-access related bloodstream infections.¹²⁸

Comorbidities Management

Most patients with CKD and ESRD have one or more comorbid disease(s), and diabetes, hypertension, cardiovascular disease, congestive heart failure, anemia, and peripheral and cerebrovascular disease are all more common in patients with kidney disease than in individuals with healthy kidneys; the prevalence of these comorbidities increases as the disease progresses.^{129,130,131,132} Other, less prevalent comorbidities—bone mineral disease, depression, and sexual dysfunction—also disproportionately affect patients with renal disease, worsening their prognosis and deteriorating their quality of life.^{133,134,135}

Early and continued communication and collaboration of primary and specialty physicians, nurses, and other health care professionals is associated with improved renal and cardiovascular outcomes in patients with CKD and ESRD.^{136,137} At the same time, research indicates that several obstacles often stand in the way of effective comorbidity disease management: clinical data may not be accessible to all parties; systems are not in place for reminders, case management, and quality improvement initiatives; physicians may not have the requisite knowledge and motivation to address comorbidities; and patients may not have the motivation and willingness to change their behavior, comply with therapy, and follow up with their physicians as necessary.¹³⁸

Although additional research to understand the various disease states and their impact on renal disease would be valuable, IQI initiatives that promote a collaborative and coordinated care system could make an impact today. Such initiatives should focus on effective communication and information sharing by all providers; the proposed ESCOs could be important in this regard. As part of any IQI activities, it also is essential that patients be engaged and educated so that they adequately comprehend their comorbid diseases and how these conditions relate to and impact their renal disease.

Addressing Depression

Depression is the most common psychological disorder in patients with ESRD, with a prevalence rate as high as 20 to 25% by some contemporary estimates.¹³⁹ Several studies link depression with mortality in ESRD, making early diagnosis and treatment essential. The mechanisms linking depression with mortality are unclear, but may be related to treatment compliance, poor nutritional parameters, decreased perception of social support, and demodulation of the immune system.¹⁴⁰

In addition to clinical evaluation, recent research has validated cut-off values for some of the more common depression screening questionnaires for evaluation in ESRD hemodialysis patients. A cutoff score of 14 to 16 for the Beck Depression Inventory (BDI) is believed to have the most sensitivity and specificity at making the psychiatric diagnosis of depression in ESRD hemodialysis patients. The Hamilton Rating Scale for Depression, the 9-Question Patient Health Questionnaire, and the Center for Epidemiologic Studies Depression Scale (CES-D) are other instruments that have been used to screen for depression in patients with ESRD.¹⁴¹

State-of-the art, brief interventions have been reported as useful in improving the psychosocial and behavioral health of people on dialysis.¹⁴² IQI activities that systematically assess depression and identify best practices to address it could markedly improve the quality of life, functional status, and potentially survival, for a significant portion of patients.

Staff Engagement, Retention, and Professionalism

Patients want and need health care professionals who are compassionate and knowledgeable. For patients with ESRD, who touch the health care system on a routine basis, the opportunity for established relationships with physicians, nurses, social workers, dietitians, and other allied professionals is greater than for most other patients. Ideally, the interdisciplinary team also works together to advocate for patients' needs, to guide them in making decisions about their physical and

emotional care, and to help them through counseling or support groups when needed.¹⁴³

Given the high degree of interactions between patients with ESRD and the health care team and the need to coordinate care for this vulnerable population, an engaged and stable team is a key element to ensuring high patient satisfaction and experience with care, as well as to having an impact on quality of life through improved medication, dietary, and dialysis prescription adherence. Providers have creative programs aimed at staff retention and preventing burnout, but IQI activities aimed at sharing these as best practices and ensuring that staff are engaged in implementing other IQI could have a positive impact on patient experience and satisfaction with care, quality of life, and patient safety.

Improving Patient Safety through Medication Management

Medication errors top the list of adverse events involving dialysis.^{144,145} Since patients on dialysis are prescribed an average of 10 to 12 medications, it is not surprising that medication-related errors—e.g., medication omissions, heparin infusion mistakes, and miscommunication of medication orders—can occur in significant numbers.^{146,147} While many medication-related problems in hospitalized dialysis patients have been attributed to a failure to reconcile medications during transitions between health care settings,¹⁴⁸ problems persist within the facility setting as well. The Renal Physicians Association (RPA), Forum of ESRD Networks, and the National Patient Safety Foundation collaborated to develop an Action Plan for ESRD Patient Safety and found that 6% of all patient respondents reported that they ‘never’ discuss all of the medications they are taking with their doctor, and 40% indicated that they discuss all of their medications with their doctor only ‘sometimes.’¹⁴⁹

Risk mitigation strategies to reduce medication error rates can reduce medication-related morbidity and mortality. Medication error risk mitigation involves establishing a culture of safety that deploys IQI processes wherein medication safety practices are a

priority and root case analyses are used when adverse events occur. Such efforts must also ensure that patients are involved in maintaining an accurate and up-to-date medication list.¹⁵⁰ Of note, the RPA survey results found that discussion of medications with health care providers varied as a function of patients’ involvement in their dialysis care, illustrating the important and positive role of patient engagement in potentially reducing the occurrence medication-related adverse events.¹⁵¹

End-of-Life Care

The fact that approximately 26% of dialysis patients discontinue dialysis prior to death—coupled with the increasing age, high symptom burden, multiple comorbidities, and shortened life expectancy of the ESRD population—requires that nephrologists and other dialysis health care professionals be well-versed in hospice and palliative care issues.^{152,153,154,155,156,157,158} In the ESRD population, palliative and hospice services have been shown to reduce the number of hospitalizations initiated by end-of-life events and afford patients the option of living and dying at home.^{159,160,161} However, physicians are generally poorly trained in palliative care.^{162,163} Consequently, these important services remain underutilized in the ESRD population, and only a minority of dialysis patient nearing the end of life receive palliative or hospice services.^{164,165,166,167,168,169,170} Yet despite a reticence to broach these issues, research suggests that many patients would choose differently if all treatment options were presented in a frank and open manner. For instance, a recent Canadian survey of stage 4 and 5 CKD patients revealed that 60.7% of dialysis patients regretted their decision to start renal replacement therapy,¹⁷¹ highlighting the need to educate patients and their families on the benefits of hospice and encourage them to engage in shared decisionmaking.

The American Society of Nephrology and RPA have developed evidence-based guidelines related to shared decisionmaking, advance care planning, conflict resolution, and withholding and withdrawing from dialysis.^{172,173} RPA, in conjunction with the American Medical Association’s Physician

Consortium for Performance Improvement, also has developed physician-level performance measures related to advance directives and hospice referral for patients with CKD and ESRD. Finally, NQF also recently endorsed five palliative care measures that target, among other diagnoses, patients with advanced renal failure.¹⁷⁴

IQI initiatives that deploy these guidelines and measures could be an important step forward in improving end-of-life care for patients with ESRD. In order to make appropriate and timely referrals for services, such initiatives should also ensure that the care team has an understanding of Medicare hospice benefits as they apply to patients with ESRD.^{175,176}

Research

The systematic search for new knowledge to improve the quality of care for patients with kidney disease must be robust, and in an era of limited dollars, efficient. Research is necessary to inform how clinical practice should evolve, to identify how IQI activities should be structured, and to construct and test valid performance measures.

Myriads of important research issues can be identified for all of the (sub)domains (Table 1), but focus here is on specific knowledge gaps for which near-term research could advance understanding and make a significant improvement in survival, hospitalization, patient experience with care, and/or quality of life.

Strategic Research Opportunities

R-Bone Mineral Metabolism and the QIP.

A gap exists in both the availability of suitable measures for the QIP, as well as the underlying evidence base to even construct appropriate measures for several domains. Research that evaluates the effectiveness of interventions related to bone mineral metabolism is a noteworthy gap, given MIPPA.

R-Fluid Management. After vascular access, improving fluid management has the potential to have the second greatest

impact on mortality, hospitalizations, and quality of life. While accelerating IQI initiatives can jump-start improvement, additional research in this area, in particular identifying an accurate way to assess dry weight and determine appropriate ultrafiltration rates, innovative methods for assessing extra-cellular volume, avoidance of sodium loading, and exploring the utility of more frequent/extended hemodialysis is desirable.

R-Reducing Rehospitalizations.

Recognizing that CMS is emphasizing the need to reduce rehospitalizations, research on the underlying factors behind repeated readmissions of patients with chronic kidney disease is urgently needed.

R-Reducing Sudden Death. Research on the underlying factors that contribute to sudden death in patients with ESRD—and the impact of potentially modifiable risk factors (e.g., interdialytic weight gain; calcium, potassium, and bicarbonate levels; regional heart wall motion abnormalities; arrhythmias; dialysis schedule)—is important to reduce mortality rates.

R-Patient Communication Tools. The body of knowledge related to deploying 21st century communication tools—including text messaging, smart phone applications, social media, and interactive web tools—to improve patient education, experience with care, and engagement/activation, as well as assess patient comprehension, is rapidly expanding. Research for optimal deployment in the CKD and ESRD populations is needed.

R-Quality of Life Assessment. Although standardized assessments for quality of life (QOL) and functional status exist (KDQOL, SF-36), they lack the granularity to make judgments on a non-risk adjusted population basis and so are inappropriate for the QIP. Current surveys are useful for longitudinal assessment of an individual,

but are still not optimal to assess facility-wide quality. Additional research and development would be useful.

R-Patient Engagement. An important and related aspect of assessing a patient's experience with care—and ultimately patient outcomes—is patient engagement and shared decisionmaking, also referred to as patient activation. Because of an underdeveloped evidence base for patients with ESRD, even assessing patient engagement for IQI purposes is difficult. Additional research on the factors related to, and mechanisms to improve, the engagement of patients with ESRD and their families and caregivers should be pursued.

Overcoming the Barriers to Realize the Strategic Opportunities

The strategic opportunities for research require the efforts of multiple stakeholders: dialysis providers, health care professional organizations, manufacturers, public and non-profit funders. Additionally, funders and research should coordinate with all stakeholders—e.g., health care professionals, caregivers and patients—to avoid duplication of effort and ensure that scarce dollars are optimally spent.

Bone Mineral Metabolism and the QIP

Metabolic bone disease is a common complication in patients with CKD and ESRD and is part of a broad spectrum of disorders that occurs in these populations. CKD-mineral and bone disorder (CKD-MBD) can be manifested by any one or a combination of the following:¹⁷⁷ abnormalities of calcium, phosphorus, parathyroid hormone (PTH), and vitamin D metabolism; abnormalities of bone turnover, mineralization, volume, linear growth, and strength; and vascular or soft tissue calcification. Untreated, significant consequences arise on both the bone itself and at extraskeletal sites. For instance, disorders of mineral metabolism have been linked to arterial calcification and diminished vascular compliance, and are thought to contribute to myocardial ischemia, heart failure, and sudden death.^{178,179}

Research over the past few decades has shed light on many of the CKD-MBD pathogenic mechanisms, and effective therapeutic strategies are now available. Therapy is generally focused on correcting biochemical abnormalities of calcium, phosphorus, PTH, and vitamin D using phosphate binders, calcitriol, and vitamin D analogs or calcimimetics.^{180,181} The balance of calcium, phosphorus, vitamin D, and PTH is complex and interrelated. Moreover, patients must adhere to strict dietary restrictions, dialysis therapies, and complicated medication regimens to control of CKD-MBD and its sequelae.

MIPPA requires that the QIP include bone mineral measures to the extent feasible. To date, however, only a process measure for phosphorus and a hypercalcemia measure have been included for payment year 2016. The chief barrier has been the lack of professional consensus on outcome measures, and especially the lack of NQF endorsement. In particular, outcome measures for calcium and phosphorus have failed because of sentiments that proposed interventions do not directly link to improved survival and/or that too many factors outside the control of the health care professional and dialysis provider (e.g., diet, medication adherence) also affect performance for any given metric.^{182,183}

Given the significant adverse health consequences of CKD-MBD and clear consumer and congressional interest in including bone mineral measures in the QIP, research that would address the evidence base and drive consensus on the development of performance measures for bone mineral metabolism is a significant gap and should be a priority.

Research Related to Fluid Management

Despite increased emphasis on urea kinetic modeling, more permeable membranes, and improved nutrition and anemia management, cardiovascular morbidity and mortality remain unacceptably high in the dialysis population. Chronic volume overload is the major cause of hypertension and other cardiovascular morbidity in dialysis

patients. The aim of the nephrologist is to efficiently correct extracellular fluid overload to obtain near euvolemia or “dry body weight,” with the goal of maintaining or normalizing blood pressure and improving the high contribution of cardiovascular issues to hospitalization and mortality rates among dialysis patients.^{184,185}

In clinical practice, however, the discontinuous nature of conventional hemodialysis can cause saw-tooth volume fluctuations, making exact estimation of this crucial component of dialysis adequacy a major challenge. While assessment and achievement of dry-weight is clinically feasible, clinical examination is not effective in detecting latent increases in dry-weight, and its relative lack of accuracy has led to several nonclinical methods (e.g., relative plasma volume monitoring, body impedance analysis, Crit-Line[®] monitoring) intended to improve the assessment of fluid status in dialysis patients.¹⁸⁶

Fluid management is one of the most important goals for physicians and other health care professionals managing patients with chronic kidney disease,¹⁸⁷ yet understanding of the volume-cardiovascular relationship is still rudimentary. Given its contribution to morbidity and mortality in patients with kidney disease, additional research in fluid management should be pursued—in particular identifying an accurate way to assess dry weight and determine appropriate ultrafiltration rates, identifying innovative methods to measure ECV, examining the appropriateness of sodium modeling, and examining the impact of more short daily and nocturnal hemodialysis.

Understanding Rehospitalizations

Reducing rehospitalization is a high priority for the federal government.¹⁸⁸ For example, since October 1, 2012, CMS reduces payments to hospitals with excess readmissions related to heart failure, pneumonia, and acute myocardial infarction—and proposes to expand this list in the near future. CMS sought comment in March 2013 of a proposed rehospitalization measure under development. CMS reports its analysis of 2009 Medicare claims data found that 30% of patients with ESRD discharged

from the hospital have an unplanned readmission within 30 days.¹⁸⁹ Extrapolating from clinical studies in the non-ESRD population,¹⁹⁰ CMS speculates that a “sizable” portion of these rehospitalizations are preventable.¹⁹¹

Currently, performance measurement for readmissions of dialysis patients focuses on the number of readmissions, their associated costs, and when they occur after discharge. To truly improve quality and significantly impact these rates, research on the underlying factors (both clinical and social/environmental) behind repeated readmissions of patients with chronic kidney disease is urgently needed. Moreover, because research from non-ESRD readmissions demonstrates that they often result from poor care transitions,¹⁹² research on a measure similar to the general 3- and 15-item Care Transition Measure (CTM) validated for hospitals could be undertaken; for general populations, the CTM intervention population had lower rehospitalization rates at 30 days (8.3 vs. 11.9) and 90 days (16.7 vs. 22.5) as compared to control.¹⁹³

Identifying Causes Underlying Sudden Death

All-cause mortality and first-year mortality rates for people on dialysis are high. Specifically, the rate is ten times greater in this population as compared to Medicare patients of similar age without kidney disease. Mortality is twice as high for dialysis patients 65 years and older as for same-age patients who have diabetes, cancer, congestive heart failure, stroke/transient ischemic attack, or acute myocardial infarction. And while mortality rates have declined 19% since 2000, only 51% of dialysis patients survive three years after starting renal replacement therapy.¹⁹⁴

Cardiovascular disease accounts for approximately 40% of ESRD deaths, and sudden cardiac death (SCD) is a significant portion.^{195,196} SCD rates have decreased for the prevalent population, but a similar reduction has not been achieved for patients in their first 90 days.¹⁹⁷ Research on the underlying factors that contribute to sudden death in patients with ESRD—and the impact of potentially modifiable factors (e.g., interdialytic weight gain; calcium,

potassium, and bicarbonate levels; regional heart wall motion abnormalities; arrhythmias; dialysis schedule) to reduce the risk of SCD—is important to improve survival and to begin closing the gap in rates between patients with ESRD and other conditions.

State-of-the Art Tools for Patient Education, Comprehension, and Engagement

As noted repeatedly in this Blueprint, patient education, comprehension, and engagement are central to improving outcomes, quality of life, and patient satisfaction and experience with care—not just for patients with kidney disease, but all patients. Health care has been slow to integrate HIT to facilitate information exchange.

While many sectors have deployed (and in some cases perhaps over deployed) text messaging, smart phone applications, mHealth, social media, and interactive web tools to engage consumers, it is generally acknowledged that using state-of-the art tools in health care for provider-patient education, assessment of comprehension, and patient engagement has lagged—yet will become increasingly important.¹⁹⁸ Still, the body of research related to the use of 21st century communication tools in different areas of health care for different purposes is growing.^{199,200,201,202,203,204} However, targeted research for optimal deployment in the CKD and ESRD populations is needed.

Quality of Life/Functional Status Instruments for Population Use

Patients with chronic renal disease face many challenges related to their diagnosis: CKD and ESRD patients are more frequently afflicted with fatigue and depression than their healthy counterparts; body image may be affected by the presence of a fistula, graft, catheter, or peritoneal dialysis catheter for dialysis access; lifestyle is disrupted by the need for frequent and time consuming dialysis treatments and unplanned hospital admissions for complications; finances can be affected by high medical costs; and personal relationships and independence might also be threatened.^{205,206,207}

Recent studies reveal an association between perceived QOL and morbidity and mortality in ESRD

patients and, along with survival and other types of clinical outcomes, patient QOL can be an important indicator of the effectiveness and quality of the medical care patients receive.^{208,209,210} To date, no conclusive data demonstrate differences in QOL between hemodialysis and peritoneal dialysis patients.²¹¹

Poor physical and mental functioning are correlated with an increased risk for hospitalization and mortality.²¹² Other factors such as age, ethnic or national background, stage of CKD, modality of dialytic therapy, exercise interventions, sleep disturbances, pain, erectile dysfunction, patient satisfaction with care, depressive affect, symptom burden, and perception of intrusiveness of illness also may be associated with differential perception of QOL.²¹³

Functional status is an important aspect of the quality of life, a strong predictor of survival, and a determinant of the health care systems costs.²¹⁴ Functional status assessment is important in the ESRD population. Independent of perceived quality of life, it is a strong risk factor for mortality in dialysis patients.²¹⁵ Studies indicate that the prognosis of older adult patients who exhibit functional decline is poor, and nursing home placement and death are not uncommon outcomes. Various risk factors for functional decline in the chronically ill elderly patient have been identified, including pressure ulcer, pre-existing functional impairment, cognitive impairment, and low social activity.²¹⁶

QOL and functional status are readily measured for individual patients through standardized instruments such as the Kidney Disease Quality of Life Survey [KDQOL] or the Short Form Health Survey [SF-36]. Moreover, the Conditions for Coverage and implementing guidance require an assessment of QOL. Nevertheless, while these surveys are useful for longitudinal assessment of an individual, they lack the granularity to make judgments on a non-risk adjusted population basis so are inappropriate for the QIP. Additional research must be undertaken for any application broader than the patient level. Moreover, while the KDQOL is useful as a tool to

assess individual patients, it does not adequately identify patients' underlying goals and values that would permit a truly patient-centered approach to improving QOL; additional research and development in this area could improve care plans, QOL, and patient satisfaction and experience with care.

Understanding and Assessing Patient Engagement

Increasingly, health care professionals, providers, and researchers recognize that a high degree of self-reported patient satisfaction or positive experience with care is an insufficient parameter in and of itself as a patient-centered driver to improve outcomes: Satisfied patients may not indicate better value and improved outcomes. One study of nearly 52,000 patients found higher patient satisfaction was associated with less emergency department use, but greater in-patient use, higher overall expenditures, and higher mortality.²¹⁷

Instead of patient experience and patient satisfaction, high patient engagement/patient activation—a patient's ability to be a true partner in managing his or her health and health care—is increasingly viewed as the important aspect to achieve. Higher activation is associated with lower levels of unmet needs and support from health care professionals and providers for self-management of chronic conditions.^{218,219} Engaged patients are more likely to adhere to treatment regimens and behaviors known to be beneficial overall to improved health, better experience with care, and better outcomes.^{220,221} Importantly, activation can be increased by interventions.²²² Research on educational interventions with an emphasis on empowerment report improvements in depression, medication and treatment attendance, and choice of vascular access;^{223,224} patients who take a lead in choosing their treatment modality are much more likely to choose home dialysis modalities, get a transplant, and survive than patients who assume a passive role in their care.²²⁵

A validated 13-item patient activation measure (PAM) assesses the individual's "knowledge, skill, and confidence in managing their

health."^{226,227,228,229,230} Additional systematic research with a standardized instrument to assess interventions to increase patient engagement has been undertaken in other areas with variable success,^{231,232,233} and research understanding patient engagement and activation for dialysis patients could yield important benefits.

System Innovation

Innovation here refers to potential system delivery changes, technological advances, or policy changes that are explored through smaller-scale projects or testing²³⁴ because they might be promising—based on the existing knowledge base—to address one of the Blueprint's four goals, but for which widespread adoption might be premature.

Strategic Opportunities for System Innovation

SI-Integrated Care. As with other care sectors, decreasing health care delivery fragmentation and increasing care coordination through integrated care models or other proposals should be a high-priority.

SI-Alternative Dialysis Strategies. The thrice weekly, 3- to 4-hour dialysis treatment is a paradigm that, for the most part, has been largely unchanged for 40 years. Multiple factors contribute to maintaining this status quo, but growing evidence suggests that federal agencies should pursue projects that examine patient, health care professional, provider, and system factors, as well as economic issues.

Overcoming the Barriers to Realize the Strategic Opportunities

Realizing the proposed strategic opportunities ultimately require CMS to act, but the importance and breadth of each means the Agency should closely work with the kidney care community.

Integrated Care Models

For the most part, health care services in the United States are still provided in clinical and payment silos. As a result, the system can be difficult for patients to

navigate, is not optimally efficient, can create safety problems when incomplete information is transferred among care settings, and can result in poorer outcomes.²³⁵ As evidenced by the CMS Disease Management Demonstration (2006-2010), a more coordinated approach can result in improved first-year survival, fewer hospitalizations, more placement of permanent access, higher immunization rates, improved care for patients with diabetes, and better medication adherence. Beyond improved clinical outcomes and as important, patients reported a high degree of satisfaction.^{236,237}

Until recently, integrated care models to address the unique needs of patients with ESRD, among the most vulnerable clinical populations, has not been a high priority. With enactment of the Affordable Care Act, advancing integrated care initially centered on Accountable Care Organizations (ACOs). Rather than enrolling patients with ESRD in general ACOs, a more renal-focused entity was viewed as more appropriate.^{238,239} Moreover, the degree to which a formal ACO can serve patients with ESRD and accrue meaningful savings was questioned.²⁴⁰

In February 2013, the Center for Medicare and Medicaid Innovation (CMMI) announced a new Initiative: ESRD Seamless Care Organizations (ESCOs) to “test and evaluate a new model of payment and care delivery specific to Medicare beneficiaries with ESRD.” CMS should place a high priority on ensuring a robust set of ESCOs, and should be particularly thoughtful in its evaluation and seek community consensus on the quality measures it uses for the program.

Examining the ESRD Care Delivery Paradigm

The vast majority of patients with ESRD receive thrice weekly in-center hemodialysis for three or four hours—a paradigm that has existed for 40 years for multiple reasons. Recent research, however, suggests that more time spent on dialysis through increased frequency and/or duration of dialysis sessions reduces morbidity and mortality rates and improves QOL.²⁴¹ Specifically, increased frequency of dialysis sessions and longer duration are associated with a 13 to 45% reduction in mortality in

four studies,^{242,243,244,245} as well as lower weight, blood pressure, and blood phosphorous levels.^{246, 247} Finally, USRDS reports that mortality is highest on the day following the “long” interdialytic interval—i.e., the 2-day period since the last session.²⁴⁸

Shifting the care paradigm is a multifaceted issue: Research indicates that when given the choice, 44% of patients declined to switch from conventional hemodialysis to short-daily hemodialysis, despite being informed of the expected health benefits.²⁴⁹ Additionally, no randomized controlled trials have yet demonstrated the clinical advantage of these strategies over the standard hemodialysis protocol. Further, Kt/V remains the main tool for determining dialysis adequacy—despite evidence that the formula does not take into account important factors such as control of extracellular fluid volume or phosphate balance. If these parameters are inadequate despite sufficient dialysis dose in terms of small molecule clearance, dialysis time and frequency are the only tools that can be used to improve the situation.²⁵⁰ Another issue relevant to greater adoption of alternative strategies is these regimens can disrupt the organization of dialysis units and/or impose considerable staffing and economic burdens on the units. Finally, current reimbursement does not address a shift from the traditional dialysis archetype, although some economic evaluations have found that home-based hemodialysis and peritoneal dialysis are less costly than in-center hemodialysis.^{251,252} Overall, however, the economic issues of alternative strategies have not yet been clearly analyzed by either the scientific community or health care authorities.²⁵³

Although the issues just articulated are complex, they exist against the backdrop of a growing body of research that finds reducing interdialytic time and/or increasing frequency improves outcomes. The multifactorial nature of shifting the care paradigm logically suggests that federal agencies should pursue projects on intensified and/or alternative regimens that examine the full range of patient concerns, health care professional, provider, and system factors, quality considerations, and economic issues.

Policy

Federal policies affect care delivery and are a key driver for health care quality in general. For kidney care quality, the impact is enormous, since Medicare is the primary payer for most patients. Obviously, payment policies ultimately intertwine and impact quality. KCP's specific views on payment issues and the ESRD Prospective Payment System (PPS) are available elsewhere.²⁵⁴ The Blueprint addresses other federal policies that could be reasonably eliminated or modified in order to improve kidney care quality in the near-term.

Strategic Policy Opportunities

P-Advancing Quality. Federal policies should support the advancement of quality in the delivery of care to patients with kidney disease.

P-Incentive Payments. Other federal government's value-based purchasing programs—e.g., for hospitals and physicians—provide for incentive, or bonus payments, but the QIP focuses only on payment penalties. CMS should adopt consistency across programs and provide incentive payments under the QIP.

P-Health Information Exchange and Health Information Technology. Current federal policy to promote health information exchange (HIE) should be examined to encourage the adoption and utilization of effective health information technology (HIT) for dialysis care.

P-New Technology. Under its authority to add new adjusters to the ESRD PPS, CMS should establish a new technology adjustment that is not budget neutral.

P-Patient Education. Congress should enact legislation that permits dialysis facilities to be reimbursed for providing education sessions for pre-ESRD patients in the Medicare program.

Overcoming the Barriers to Realize the Strategic Opportunities

Advancing each of the strategic opportunities that center on policy changes centers on HHS and CMS. As appropriate, Congress also can drive progress through its oversight and legislative authorities.

Advancing Quality

In 2011, more than 615,000 people received ESRD treatment,²⁵⁵ with the vast majority covered by Medicare.²⁵⁶ Thus, while federal health care policies affect all sectors, their impact on patients with ESRD—along with the providers and professionals who treat them—are disproportionate by comparison.

We have previously noted recommendations specific to the QIP, but here KCP emphasizes that federal policies should support the advancement of quality in the delivery of care to patients with kidney disease. Dialysis facilities have been subject to a 2% payment cut under the new bundled payment system. In addition, Congress recently enacted reductions in Medicare payments, such as the decrease in Medicare bad debt payments and the 2% sequestration adjustment, that affect dialysis facilities. Similarly, annual administrative changes that are considered as part of rulemaking can distress economics in a way that can cascade to infrastructure disruptions that negatively impact quality (e.g., CMS put forth a Final Rule in November 2013 that would cut reimbursement for dialysis treatments significantly over time).

Federal policy should recognize that untenable cuts will undermine the advances in quality documented by the KCP's PEAK Campaign²⁵⁷ and by MedPAC.²⁵⁸

Incentive Payments Under the QIP

KCP appreciates that MIPPA requires CMS to include payment reductions in the QIP, but also believes establishing incentive bonus payments for exceeding performance standards is an important component that is missing from the program—yet is present, for example, in federal quality programs for hospitals and physicians. As KCP has documented elsewhere,²⁵⁹ even though MIPPA does not expressly

authorize incentive reward payments, it does not expressly prohibit them either. KCP posits that CMS can use the funds resulting from the reductions by providing incentive payments to high-performing entities because MIPPA does not require CMS to use the funds collected through the penalty in a specific manner. Such payments would increase the incentives to attain performance standards and improve quality, while ensuring that there is adequate funding to the program as a whole.

Implementing an incentive reward payment also would be consistent with the views of MedPAC²⁶⁰ and the Institute of Medicine (IOM),²⁶¹ which have explicitly stated that quality programs linking payment to performance should not be used to obtain program savings.

Health Information Exchange and Health Information Technology

HIT (e.g., electronic health records [EHRs] and computerized provider order entry, decision support) and the ability to share data through HIE are considered fundamental to improving health care quality, in particular the coordination of care.^{262,263,264} Numerous studies have documented that HIT improves quality and efficiency.²⁶⁵ One estimate models that fully standardized HIE and interoperability could yield a net value of \$77.8 billion per year if fully implemented.²⁶⁶

Failure to effectively coordinate care has been identified as a major cause of morbidity, rehospitalizations, and mortality in the ESRD population. Problems with coordination initiate with infrastructure failures in both the HIE and HIT policy and technology components. Still, EHR systems remain largely disjointed and incompatible among physician practices, dialysis organizations, and acute care facilities.

Of note, the Health Information Technology for Economic and Clinical Health (HITECH) Act (Public Law 111-5) and the Affordable Care Act (Public Law 111-148) established federal programs to improve health care quality, safety, and efficiency through the promotion of HIT. HITECH, in particular, permits

eligible health care professionals and hospitals to qualify for incentive payments if they adopt certified EHRs and use them to achieve specific objectives set forth by HHS. HITECH, however, was not intended to address the unique needs of coordinating dialysis care among nephrologists, dialysis organizations, and hospitals.²⁶⁷ Still, significant opportunity exists to improve communication between these parties to improve the continuity of care for patients with ESRD. To realize the potential of HIE for renal disease, current federal policy should reward improved continuity and coordination of care within the structure of today's dialysis care delivery infrastructure. The National Renal Administrators Association recently identified several principles necessary for HIT to support ESRD program requirements, which noted that dialysis facilities, nephrologists, and the ESRD program have a number of unique needs that should be examined so that HIE can be optimized among the multiple settings that care for patients with ESRD.²⁶⁸

New Technology

New technology is central to improving quality in all health care, including the care of patients with kidney disease. New technologies can lead to better diagnoses, better treatment options, and ultimately better outcomes for patients. Historically, however, there have been few technology improvements in dialysis treatment given the limited reimbursement rates under Medicare's (then) composite payment. Without an adjuster in the ESRD PPS that recognizes the additional cost associated with adopting new technology, those who develop new items and procedures might not find sufficient incentive to move forward with such work.

A new technology adjuster for the ESRD PPS would incentivize research, development, and implementation. The adjuster should apply to items and services (i.e., drugs, devices, other items, and procedures or services), and should be limited to only truly "new" items or services that have been approved by the Food and Drug Administration or the appropriate specialty society and are innovative. The add-on should *not* be budget neutral. It should allow for new money to be incorporated into the

program so that it incentivizes innovation to improve the quality of care for this vulnerable population.²⁶⁹

Predialysis Patient Education

As noted earlier, patient education and engagement programs for incident patients significantly improves outcomes.^{270,271} Similarly, education programs for CKD patients have been shown to delay the time to dialysis and even improve survival.^{272,273,274} Research also indicates that patients with greater knowledge about dialysis at initiation are more likely to use an AV fistula or graft than a catheter.²⁷⁵

Given the importance of patient education of CKD-4 patients to improved outcomes, Congress should enact legislation that reimburses dialysis organizations for this purpose.

SUMMARY AND NEXT STEPS

2012 marked the 40th anniversary of Public Law 92-603, which authorized the Medicare ESRD program to provide dialysis care for all in the United States regardless of age (and subject to a few other requirements). Since the program's launch on July 1, 1973, hundreds of thousands of lives have been extended and the quality of care provided has improved through advances in care, research, and technology. Much more can be done, however, to

ensure that individuals living with kidney failure are able to live Life to the Fullest.²⁷⁶

This strategic Blueprint sets forth KCP's recommendations for near-term opportunities that can improve survival, decrease hospitalizations, improve quality of life, and improve patient experience with care. KCP sees the Blueprint as serving as a guidepost for public and private sector stakeholders to expand upon and/or identify their own priorities. The report is intended to be accessible to the full range of interested parties, including: patient groups; physician, nursing, and other health care professionals; dialysis providers, manufacturers, policymakers, CMS, the ESRD Networks, and research funders. As noted earlier, it is not a tactical document that identifies or recommends that specific entities take specific actions, except in a few cases related directly to federal policy.

For KCP, completion of the Blueprint is a first step, and during the coming months, we will use it to thoughtfully examine our organization's priorities. We also look forward to partnering with CMS and others in driving progress to achieve the highest quality of life and quality of care for patients with kidney disease.

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APPENDIX A: KCP MEMBERS SUPPORTING THE BLUEPRINT

Kidney Care Partners was founded in May 2003, as a coalition of patient advocates, dialysis professionals, care providers, and manufacturers dedicated to working together to improve quality of care for individuals with chronic kidney disease. A *Strategic Blueprint for Advancing Kidney Care Quality* was approved and supported by all KCP members as of February 12, 2014:

[AbbVie](#)[Hospira](#)[Akebia Therapeutics, Inc.](#)[Keryx Biopharmaceuticals, Inc.](#)[American Kidney Fund](#)[Kidney Care Council](#)[American Nephrology Nurses' Association](#)[Mitsubishi Tanabe Pharma America](#)[American Renal Associates, Inc.](#)[National Kidney Foundation](#)[American Society of Nephrology](#)[National Renal Administrators Association](#)[American Society of Pediatric Nephrology](#)[Nephrology Nursing Certification Commission](#)[Amgen](#)[Northwest Kidney Centers](#)[Baxter Healthcare Corporation](#)[NxStage Medical](#)[Board of Nephrology Examiners and Technology](#)[Renal Physicians Association](#)[Centers for Dialysis Care](#)[Renal Support Network](#)[DaVita Healthcare Partners, Inc.](#)[Renal Ventures Management, LLC](#)[Dialysis Patient Citizens](#)[Rogosin Institute](#)[Dialysis Clinic, Inc.](#)[Sanofi](#)[Fresenius Medical Care North America](#)[Satellite Healthcare](#)[Fresenius Medical Care Renal Therapies Group](#)[U.S. Renal Care](#)[Greenfield Health Systems](#)

APPENDIX B: KCP BLUEPRINT STEERING COMMITTEE

A Strategic Blueprint for Advancing Kidney Care Quality represents the many contributions of KCP members through interviews, an in-person meeting, and review (Appendix C). This work was overseen through the significant time and efforts of the KCP Blueprint Steering Committee.

Akhtar Ashfaq, MD – Amgen

Donna Bednarski, RN, MSN – American Nephrology Nurses Association

Dolph Chianchiano, JD – National Kidney Foundation

Edward Jones, MD – Renal Physicians Association

Chris Lovell, RN, MSN – Dialysis Clinics, Inc.

Franklin Maddux, MD – Fresenius Medical Corporation, North America

Allen Nissenson, MD – DaVita HealthCare Partners

Gail Wick, MHSA, RN – American Kidney Fund

APPENDIX C: PARTICIPANTS, KCP BLUEPRINT SUMMIT

Following an informal prioritization process and semi-structured interviews of KCP members, KCP convened a Blueprint Summit on March 28, 2013, in Washington, DC. The thoughtful discussions at the Summit provided critical input into the Blueprint, and KCP is grateful for the participation of the following representatives from its member organizations.

AbbVie Laboratories

Michael Heifets MD

American Kidney Fund

Susan McDonough
Gail Wick

American Nephrology Nurses' Association

Donna Bednarski

American Renal Associates, Inc.

Richard Cronin, MD
Sue Rottura

American Society of Nephrology

Rachel Nell Shaffer
Dan Weiner, MD

American Society of Pediatric Nephrology

Barbara Fivush, MD
Katie Schubert

Amgen

Serena Anderson
Akhtar Ashfaq, MD

Baxter Healthcare Corporation

Jim Sloand, MD

Centers for Dialysis Care

Diane Wish

DaVita Healthcare Partners, Inc.

Allen R. Nissenson, MD

Dialysis Patient Citizens

Tony Barkey
Hrant Jamgochian

Dialysis Clinic, Inc.

Chris Lovell
Klemens B. Meyer, MD

Fresenius Medical Care North America

Franklin Maddux, MD
Eduardo Lacson, Jr., MD, MPH

Kidney Care Council

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Mitsubishi Tanabe Pharma America

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National Kidney Foundation

Dolph Chianchiano
Tonya Saffer

National Renal Administrators Association

Katrina Russell

Nephrology Nursing Certification Commission

Nancy Gallagher

Northwest Kidney Centers

Connie Anderson

NxStage Medical

Leslie Spry, MD
Linda Upchurch

Renal Physicians Association

Edward Jones, MD

Renal Ventures Management, LLC

Tom Parker, MD

Sanofi

Sara Froelich

U.S. Renal Care

Stan Lindenfeld, MD
Thomas L. Weinberg

APPENDIX D: KCP MEMBER INTERVIEWSEES

In preparation for the Blueprint Summit convened on March 28, 2013, in Washington, DC, KCP conducted semi-structured interviews to gather members' perspectives and help prioritize the focus for discussions at the Summit. KCP is grateful to the following individuals for providing critical input to the project.

AbbVie Laboratories

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American Kidney Fund

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American Nephrology Nurses' Association

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Glenda Payne, MS, RN

American Renal Associates, Inc.

Ginny Grogan, RN, MHA
Shari Cousins, RN
Sue Rottura

American Society of Nephrology

Dan Weiner, MD, MS

American Society of Pediatric Nephrology

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Joseph Flynn, MD, MS

Amgen

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Nephrology Nursing Certification Commission

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Northwest Kidney Centers

Suhail Ahmad, MD
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Joyce Jackson

NxStage Medical

Leslie Spry, MD
Michael Kraus, MD

Renal Physicians Association

Dale Singer, MHA

Renal Support Network

Lori Hartwell

Renal Ventures Management

Thomas Parker, MD
Ellen Davis, CPA

Sanofi

Jose Menoyo, MD
Sara Froelich

Satellite Healthcare

Heather Dauler

Takeda Pharmaceuticals USA

Deb Walter
Ali Hariri, MD

U.S. Renal Care

Stan Lindenfeld, MD
Thomas L. Weinberg, JD

APPENDIX E: EXTERNAL REVIEWERS

The KCP Blueprint was reviewed in draft form by individuals chosen by the Steering Committee for their expertise and diverse perspectives. The external reviewers provided many constructive comments and suggestions, but they did not see the final Blueprint—which represents the views of KCP members (Appendix A) and not the reviewers—prior to its release. We gratefully acknowledge the efforts of the following external reviewers:

Louis Diamond, MBChB – QHC Advisory Group

Debra Hain, DNS, APRN – Florida Atlantic University

Rajnish Mehrotra, MD, MS – University of Washington/Harborview Medical Center

Barry Straube, MD – Marwood Group

Beth Ulrich, EdD, RN – Innovative Health Resources

Thomas Valuck, MD, JD – Discern Health