

**National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
Workshop on Translating Chronic Kidney Disease Research
into Improved Clinical Outcomes**

**October 18-19, 2010
Hyatt Regency Bethesda
Bethesda, Maryland**

Meeting Summary

I. Opening Remarks

Welcome and Objectives of the Workshop

Robert Star, MD, NIDDK

Dr. Star welcomed participants and thanked them for taking part in the meeting. He noted that the meeting, which is focused on translating chronic kidney disease (CKD) research into improved clinical outcomes, marked a new direction for NIDDK. There are many effective treatments available for CKD, and it is known what comprises good care, but this care is not reaching patients. Research results are not fully translated into practice and the community. NIDDK seeks to improve efforts in this area.

The workshop focused on Type 2 translational research (T2) for CKD. The goal of T2 research is to identify factors that lead to the adoption, maintenance, and sustainability of science-based interventions at the practice level. The objectives of the workshop were to:

1. Identify possible T2 research questions for CKD.
2. Share lessons learned from T2 research in other diseases.
3. Identify opportunities to collaborate across various disciplines and settings.

Dr. Star noted that T2 research constitutes an important opportunity and that NIDDK likely will be funding more research in this area.

Background – Chronic Kidney Disease and Translating CKD Research into Improved Clinical Outcomes (T2)

Andrew Narva, MD, NIDDK

Dr. Narva thanked the planning committee and NIDDK staff for organizing the meeting.

In CKD, delivering optimal care is the major challenge. There is broad consensus of how people should be treated; various guidelines, from around the world, outline similar protocols. Despite these guidelines, patients with CKD, as well as patients with other chronic diseases, are not receiving the recommended care, even when there is early referral. This lack of appropriate care results in poorer health outcomes and higher mortality.

In addressing these challenges, it is important to keep in mind that there are tremendous health disparities in terms of CKD. It is also important to look for opportunities that will facilitate efforts to address CKD, such as focusing on diabetic kidney disease.

In response to these challenges, NIDDK is funding an initiative to translate scientific evidence into measures that will reduce the burden of CKD. The purpose is to link interventions to routine clinical practice. This workshop and a recently released RFA are the first steps in this initiative.

Keynote Speaker – Science of T2 Translation

Russell Glasgow, PhD, National Cancer Institute (NCI)

Dr. Glasgow focused on the gap between research and practice, what is known about dissemination and implementation, and future directions in these areas. The science of dissemination and implementation is relatively new, and there are lessons to be learned from previous efforts. There are many challenges to dissemination and implementation:

- Underperforming health care system;
- Cost of health care;
- Siloed approach to care; and
- Health disparities.

When promoting the uptake of innovations, it is necessary to focus on the audience. For CKD, this includes both specialists and primary care providers. The capacity of these providers to incorporate new information is also a consideration—primary care providers have significant demands on their time.

Roger’s Diffusion Principles provide insight into how to promote the successful uptake of an innovation.

There are six characteristics of diffusion: comparative advantage; “trialability” (i.e., easy to try/test); complexity of intervention; cost; observability (i.e., can see quickly if it makes a difference); and compatibility with the setting.

The challenge is to put the critical elements of an innovation into practice—it is not necessary to implement the whole innovation. Keys to success are whether the innovation fits into the culture of the organization and fostering partnerships between researchers and practitioners.

There needs to be a greater focus on the delivery of innovations. Currently, much of the focus is on development—over 98 percent of NIH resources are dedicated to T1 research. Many people

Terminology in the United States

Implementation research: The scientific study of methods to promote the systematic uptake of clinical research findings and other evidence-based practices into routine practice, and hence to improve the quality and effectiveness of health care.

Diffusion: The passive or “naturalistic” spread of innovation across settings and time.

Dissemination: The active process through which information needs (pull) of target groups working in specific contexts (capacity) are accessed; information is tailored to increase awareness, acceptance, and use of lessons learned from science. (Kerner 2007)

Dissemination research: The study of processes and variables that determine and/or influence the adoption of knowledge, interventions, or practices by various stakeholders. (Lomas)

consider T2 research to be too difficult. There are many opportunities in T2 research since so little effort has been devoted to it.

To fully integrate scientific findings into the delivery of care it is necessary to go beyond T2 research. A more realistic description of the research process includes the following steps:

- T1: Discovery to application;
- T2: Getting the innovation to patients/practice;
- T3: Clinic/community (bringing innovation to large-scale settings); and
- T4: Dissemination across all settings (community, population, policy change).

New models for dissemination and implementation research should include the following characteristics:

- Contextual (take into consideration the setting);
- Complexity;
- Multi-component programs and policies;
- Non-linear;
- Transdisciplinary; and
- Multi-level.

A significant challenge is taking an intervention that was developed under ideal conditions and applying it to complex problems in diverse settings. This is how guidelines are used in practice. Another challenge is the cascading effect in implementation—only a certain number of clinics will implement an innovation, only a certain number of providers in each clinic will implement it, and not all patients will accept it.

The following areas represent research opportunities:

- T3 and T4 research;
- Comparative effectiveness research;
- Scale up and sustainability;
- Cost effectiveness/cost savings; and
- Training.

Discussion Points

- Study sections should be educated about T2, T3, and T4 research so that they are better able to evaluate applications that propose this type of research.
- Practice-Based Research Networks are true collaborations across HHS agencies. More funding should be available for this type of research.
- Examples of successful T2 and T3 research include smoking cessation, the diabetes prevention model, and the chronic care model.

II. Collaborating in T2 Translation in CKD

Eduardo Ortiz, MD, MPH, National Heart, Lung, and Blood Institute (NHLBI)
Moderator

Collaboration with VA QUERI

David Atkins, MD, MPH, Veterans Administration

Dr. Atkins provided an overview of the Veterans Health Administration's (VHA) efforts to navigate the gulf between researchers (and their findings) and clinicians in the field. The VHA is a centralized system, which facilitates the translation of research findings. While the VHA system has unique elements, others can learn from its experiences.

Effective research/practice partnerships require time, effort, and flexibility. There are multiple challenges: combining both top-down and bottom-up efforts; balancing centralized and locally driven approaches; and meeting the needs of a heterogeneous mix of clinicians. In response to these challenges, the VHA developed the Quality Enhancement Research Initiative (QUERI) program. The program, initiated in 1998, was designed to speed the uptake and spread of evidence-based care throughout the VHA by understanding and overcoming barriers to adoption of new or best practices. Nine QUERI Coordinating Centers were established.

An incremental implementation process is used:

- *Single site demonstration* to study feasibility and understand barriers.
- *Small scale multi-site implementation* to test effectiveness and do “formative evaluation” to refine model.
- *Regional roll out* to test large-scale adoption, refine tools and support.
- *National roll out.*

QUERI Steps

- Identify priority opportunities for improvement.
- Identify effective practices for improving outcomes.
- Examine variations in practices, their sources, and their relation to health outcomes.
- Identify and test interventions to improve the delivery of best practices.
- Evaluate the feasibility, adoption, and impact of coordinated improvement programs.
- Evaluate the effects of improvement programs on veterans' health outcomes.

Various tools are needed to support the implementation process. These include training manuals, fidelity tools, IT instructions, curricula, “train the trainer” tools, and tracking systems. Plans also need to support sustainability.

A significant challenge is generating pull—getting clinicians to support the implementation. Anything that adds even slightly to a clinician's workload is a barrier, so it is essential to *make the right thing the easy thing to do*. Ways to generate pull include aligning research with high priorities in the health system, combining centralized and locally driven approaches, involving clinicians in the research process, and allowing flexibility in the adoption process.

The following are lessons learned from the QUERI program.

- Change is not a linear process driven by the research community; it is not a pipeline.
- A single uniform approach may not work, even in an integrated system like VHA.
- There is not enough emphasis on the capacity and priorities of health system partners (solutions that aren't aligned with clinician needs and/or health system context aren't sustained).
- There must be a commitment of leadership in support of the proposed changes.
- Most changes require active facilitation (local champions, tools, training).
- Barriers differ with specific context (leadership, resources, IT, inertia).

Future opportunities were identified:

- Patient-centered medical home (integrated nurse-based care management);
- Patient self-management support (peer led, technology supported);
- Pharmacy-based medication support; and
- Enhanced patient-centered performance measures (better performance measures).

Collaboration with Community Health Centers

David Stevens, MD, National Association of Community Health Centers (NACHC)

Dr. Stevens described quality improvement (QI) efforts related to CKD that have been conducted in community health centers (CHCs). There are approximately 1,200 CHCs with 6,000 sites in the United States, and the number of CHCs is expected to double in five years. Currently, CHCs serve almost 19 million patients.

For over a decade, QI has been a priority for CHCs. In pursuing QI activities, key elements include leadership, national- and state-level infrastructure to support transformation of practice, use of models (e.g., PDSA, IHI), and partnerships. In addition, it is necessary to generate enthusiasm for the activities, as participation can constitute an additional burden for staff. Cost effectiveness (i.e., making the business case) must also be a consideration.

CHCs have also participated in T2 research. The following are key considerations:

- Relevance/generalization;
- Target population;
- Setting;
- When and whether to adopt (leaders and champions);
- Benefits: staff morale, outcomes;
- System changes: necessary to adopt; and
- Patient preferences.

Health care reform presents opportunities for T2 research. The focus on medical homes, accountable care organizations (ACOs), team-based care, care management, early treatment, and the use of electronic health records (EHRs) can facilitate this research. It also provides opportunities for comparative effectiveness research.

In particular, “meaningful use” could serve as a driver of innovations. The following are measures of meaningful use:

- Improving quality, safety, efficiency, and reducing health disparities;
- Engaging patients and their families in their health care;
- Improving care coordination;
- Improving population and public health; and
- Ensuring adequate privacy and security protections for personal health information.

CHCs are participating in the HRSA-funded Patient-Centered Outcomes Research (PCOR) initiative. The Community Health Applied Research Network (CHARN) is a three-year cooperative agreement with four research nodes. Three of these nodes focus on delivery of primary care; the fourth focuses on care and treatment of individuals with HIV/AIDS. The Central Data Management Coordinating center is based at the Kaiser Foundation Hospitals’ Center for Health Research in Portland.

The following CKD translational research opportunities were identified:

- Expanding insurance coverage and the number of CHCs to reach greater numbers of high-risk CKD populations for prevention and treatment.
- CHC capacity to transform practices guided by evidence base.
- Policy and reimbursement changes to support comprehensive primary care and integrated health systems focused on quality and efficiency in managing the health of a population.
- Health information technology (HIT) investments to support health system transformation.
- Comparative effectiveness research.

Collaboration with CDC

Sharon Saydah, PhD, MHS, Centers for Disease Control and Prevention (CDC)

Dr. Saydah described the CDC’s efforts in the area of CKD. Congress recognized that CKD was a growing public health threat and in 2005-2006 passed legislation to provide CDC with support to develop a CKD public health program. The focus of the initiative is to design, develop, and implement public health strategies for promoting kidney health. The initiative includes the following activities:

- Prevent and reduce progression of CKD;
- Raise awareness of CKD and its risk factors;
- Promote early diagnosis; and
- Improve outcomes and quality of life for those living with CKD.

CDC’s focus is surveillance activities. In addition, a screening demonstration project is being conducted in collaboration with the National Kidney Foundation. The demonstration project is being carried out at eight sites.

Cost-effectiveness studies being conducted as part of the initiative are exploring:

- Disease progression through CKD stages (cohort of simulated patients aged 30 until age 90 or death);
- Control scenarios; and
- Intervention scenarios.

These studies have yielded the following findings:

- Screening and early treatment in high-risk groups was most cost effective when screening was initiated at age 50;
- Annual screening and early treatment was highly cost effective for persons with diabetes in all age groups (30-80 years); but
- Annual universal screening was not cost effective.

Discussion Points

- Frontline clinicians must be involved in research design.
- Patients must be involved in research design, especially for behavioral interventions. Patient self-management must be an intentional part of models.
- Social determinants of health in the community are an important consideration, as are co-occurring health issues (e.g., homelessness, access to services, etc.).
- Practice re-design is critical to uptake, but funding is not available to support this.
- Changes in health care delivery, such as medical homes and care managers, present opportunities. NIDDK should develop tools specific to the management of CKD that can be used by care managers.
- More focus is needed on how to train T2 researchers. VHA has developed some materials (e.g., an implementation-science training curriculum, a webinar series). Mentors can also play a role.
- Researchers must demonstrate that they have the support of practitioners in their proposals (i.e., the endorsement of end users).
- More study of sustainability is necessary (e.g., best practices, natural experiments, natural variation).
- Research needs to be integrated into medical training, with a focus on increasing the receptiveness of clinicians to research.
- Qualitative research has a role in T2.

III. Challenges in T2 Translation Research

Ann Bullock, MD, Indian Health Service (IHS)

Moderator

Multidisciplinary Team-Based Chronic Care

Barry Carter, PharmD, University of Iowa

Team-based care has been carried out since the 1960s, when it was employed primarily in the management of hypertension. Much of the research related to team-based care is lacking. This

is due in part to insufficient funding to correctly carry out the studies. Dr. Carter reviewed two studies focusing on team-based care. These included: a study on the effect of clinical pharmacy services on patients with essential hypertension, and a randomized, controlled effectiveness trial of physician/pharmacist collaboration to improve blood pressure control.

The medical home model is based on a team approach. The following are key aspects of this model:

- Facilitated access to care;
- Patient engagement in care;
- Clinical information system;
- Care continuum;
- Patient feedback; and
- Publicly available information.

A barrier to increasing research in this area is that study sections focus on a single element, whereas medical homes and team-based care address a broad range of patient issues. It is a challenge to develop a scientifically sound study that is acceptable to study sections.

Research opportunities for models of care delivery for chronic conditions are listed below:

- Lay person or medical assistant to help patient with access, self-management and “navigation” of the health care system;
- Nurses for chronic care management, especially lifestyle and behavioral approaches;
- Clinical pharmacists for chronic care management, especially medication management, complicated regimens, poor adherence, those who have difficulty achieving control; and
- Social workers, dietitians, and others.

In considering these models, it is important to acknowledge the limited capacity on the part of providers. It is necessary to balance the volume of patients with the expertise of providers. Providers such as social workers and dietitians can assume some responsibilities. The challenge is who should be on the team, the roles of the members, and how the team should interact.

Reducing Medication Discrepancies during Transitional Care

Cindy Corbett, PhD, RN, Washington State University

Transitional care is a set of actions designed to ensure the coordination and continuity of health care as patients transfer between different locations or different levels of care within the same location. Medication discrepancies—differences between a medication list and the medications a patient reports routinely using—commonly occur during transitions. Dr. Corbett discussed a study focusing on the use of pharmacists to reconcile medications. The study focused on reducing medication discrepancies as patients transitioned from hospital to home with referral to home care services. Included were patients with polypharmacy and multiple co-morbid conditions. Pharmacists conducted a home visit to work with patients to resolve medication discrepancies.

After 30 days, pharmacists reviewed medical records to see if medication discrepancies had been resolved. The findings indicated that most discrepancies were resolved in the intervention group and that there were fewer hospitalizations. While the study did show that discrepancies were reduced, the intervention was expensive since it involved pharmacists making home visits.

A second study explored the use of trained nurses to resolve discrepancies. Nurses were involved in the design of the study. The identification of discrepancies did not improve as a result of the intervention—in the earlier study, the pharmacist identified two times as many discrepancies. There was a change in Centers for Medicare and Medicaid Services (CMS) policy halfway through the study but it had no impact on the results. The researchers concluded that this is a complex problem and there are many factors involved. More analysis is planned.

The researchers identified the following challenges:

- Development of a common vision;
- Ambiguity (there are many factors);
- Need right combination of staff on team;
- Researcher vs. clinician roles;
- Development of partnerships;
- Monitoring fidelity;
- Adapting to different settings;
- Obtaining patient input;
- Protecting human subjects;
- Attrition;
- Training procedures, longitudinal monitoring; and
- Incorporating qualitative research.

Health Literacy

Kerri Cavanaugh, MD, MHS, Vanderbilt University Hospital

Dr. Cavanaugh explained that there are many different definitions of health literacy. The one that she uses in her research is: *The degree to which individuals can obtain, process, understand and communicate about health-related information needed to make informed health decisions.*

There are also many components of health literacy. These include cultural and conceptual, listening, speaking, writing, reading, and numeracy. Research indicates that 45 percent of people in the United States have basic or below basic literacy skills; 55 percent have basic or below basic numeracy skills.

Measures of health literacy include the Test of Functional Health Literacy in Adults (TOFHLA) and the Rapid Estimate of Adult Literacy in Medicine (REALM). Both are easy to administer. It is important to note that assessments can make patients feel uncomfortable, as there is significant stigma attached to limited reading skills.

There is a large body of literature on health literacy and CKD. Studies explore health literacy and mortality—those with low literacy skills predicted mortality. Low literacy individuals are less likely to be listed for a kidney transplant. People with low literacy did not view themselves as at risk for kidney disease. Low numeracy is also related to being less likely to be listed for a kidney transplant

Questions relating to health literacy can be incorporated in CKD research in the following ways:

- Primary hypothesis/study question;
- Literacy as a moderating factor; and
- As a mediating factor/potential confounder.

Health literacy can also play a role in the design of T2 research, as consent forms and intervention materials must be accessible and communication between providers and patients clear. The following are key elements of clear communication:

- Assess patients' baseline understanding;
- Use plain language, avoiding medical jargon;
- Emphasize one to three key points and repeat them; and
- Encourage patients to ask questions.

It is also important to ensure that health literacy is addressed at the organizational level. Organizations can take the following steps:

- Promote productive interactions;
- Improve providers' communication skills;
- Develop communication technology platforms;
- Prioritize patient-centered care;
- Streamline, simplify, standardize; and
- Use incentives and reinforcements for quality.

Discussion Points

- Patients have different learning styles and their ability to process information varies. Interventions must be tailored.
- Move away from a physician-centric model to patient self-management.
- Ensure that the use of technology incorporates strategies to involve all populations.
- Promote the use of patient navigators.
- There must be multiple messages and interventions over time. The layering of messages is critical.
- It is necessary to facilitate the use of new technology. Approaches include: addressing issues of confidentiality (e.g., HIPAA); system-wide payment systems (to demonstrate cost effectiveness); getting electronic health record (EHR) systems to talk to each other.
- Strategies are necessary to support sustainability. Approaches include:
 - Frequent follow up;
 - Use of other clinicians to assist patients (besides nurses and physicians);

- Making it easy to continue with the intervention;
- High utility and value; and
- Rewards for patients, providers, the system, and the public.

IV. T2 Translation as a Means to Reduce Disparities

Ebony Boulware, MD, MPH, Johns Hopkins School of Medicine and Johns Hopkins Bloomberg School of Public Health

Dr. Boulware described disparities in health and health care, reviewed studies exploring potential determinants of race disparities in health and health care for patients with CKD, and discussed the role of T2 research to address disparities.

There are many factors related to health disparities. Systems, legal/regulatory issues, institutional policies, payers, discrimination, bias, and social norms play a role. Providers' skill, communication, bias, beliefs, and cultural competency can also be factors.

Much of the research relating to disparities has focused on describing the problem and understanding the mechanisms. It is necessary to move to designing interventions and understanding outcomes.

Definitions

Health disparity: Differences in health that occur by gender, race or ethnicity, income or education, disability, living in a rural locality, or sexual orientation.

Health disparity population: A population in which there is a significant disparity in the overall rate of disease incidence, prevalence, morbidity, mortality, or survival rates as compared to the general population.

Disparities in health care: Differences in care that emerge from discriminatory processes within the health care system or from bias and prejudice, stereotyping, and uncertainty in communication and clinical decision making on the part of providers.

There are disparities in health outcomes for CKD. End-stage renal disease (ESRD) incidence is up to four times greater in minorities. African Americans are at increased risk of all stages of CKD as well as death. They are also less likely to be on the waiting list for transplantation.

There have been many studies relating to CKD and disparities, covering the following topics:

- Knowledge of transplant (before starting dialysis);
- Race differences in knowledge of renal replacement therapies;
- Awareness of CKD;
- Health literacy and transplant referral;
- Socioeconomic status and progressive CKD;
- Lifestyle factors and excess risk of CKD;
- Rates of uncontrolled hypertension in Stage 3-4 CKD;
- Blood pressure control among African Americans with early and late CKD;
- Low perception of risk about CKD, utilization of CKD among African Americans;
- African American and family discussion with physician about live kidney transplant; and
- African American and late referrals for pre-ESRD care.

Successful T2 research seeking to explore disparities will need to incorporate many key elements. It must be multidisciplinary, incorporating such disciplines as clinical epidemiology, behavioral science, communication theory, informatics, and organizational theory. Multiple research methodologies will be required including observational methods (qualitative and quantitative), effectiveness trials, community-based participatory research, system redesign, and quality improvement. The research steps are listed below:

- Identify modifiable key determinants (at patient, provider, and system level);
- Develop novel, “customized” strategies to modify key determinants (explore concepts of culture, cultural sensitivity, and cultural competence); and
- Study strategies’ effectiveness.

Key Strategies in T2 Research to Address Race Disparities

- Identifying modifiable targets
- Addressing issues of “culture,” “cultural sensitivity,” and “cultural competence”
- Use of rigorous study designs
- Dissemination of sustainable interventions into clinical practice

Discussion Points

- Disparities are often in the delivery of care—it is necessary to look at the regimens to see if patients are receiving the care and making informed decisions about it.
- Racial/ethnic minorities are underrepresented among health care providers. Having providers that “look like” the population they serve is important.
- Provider/patient communication is a key area for research

V. Presentations by Breakout Groups

Katherine Tuttle, MD, University of Washington School of Medicine
Moderator

On the afternoon of October 18, meeting participants were assigned to six breakout groups, each of which was tasked with exploring a series of questions and reporting their findings back to the larger group on the morning of October 19. The spokesperson for each breakout group was asked to identify the top research priority associated with the topic they were asked to explore.

Designing Interventions to Reach High-Risk Populations

William McClellan, MD, MPH, Emory University

How can high-risk populations (besides racial/ethnic groups) in the U.S. and territories be identified?

- Need metric and identifiers for “high risk”
- Use outcomes
- Use attributes of disparities (e.g., literacy groups, geospatial groups, etc.) to define high-risk groups
- Underserved populations (e.g., homeless, undocumented)

The group also discussed which data sources could be used to document that these high-risk groups are receiving disparate care. Those identified included the “usual sources” of data (e.g., EHRs, population databases) as well as qualitative data collection. There is also a need to identify an appropriate metric for disparate care.

How should medical care teams approach each of these populations?

- Interventional study designs

What communication tools could be utilized to increase awareness and knowledge of chronic disease?

- Need to be population specific
- Need to be evidence based (literature is available)
- Sequential application of the intervention (staging intervention so that comparison group also receives intervention)
- Identify components of behavior change strategies that are uniform across groups—they are multi-factorial, involve feedback (face-to-face interaction), emphasize evidence-based interventions
- Use of mass communication (social networks, telephone interventions, peer providers)

Who on the care team should bear the most responsibility for the intervention?

- The care team should include nephrologists, primary care providers, allied health providers, patients, patient’s family, patient’s social network.

Are physicians a part of the problem in carrying out such interventions?

- Problems related to physicians need to be addressed. These include a lack of awareness of the problems related to CKD care, time demands, and practice organization (systems).

How should we measure the success/failure of these interventions?

- Measure change in degree of the disparity
- Translational trials strongly recommend measuring of intermediate steps
- Group randomized designs

Priority Research Question: How to promote evidence-based, sustainable, and generalizable interventions?

Nephrology/Primary Provider Collaboration

Katherine Tuttle, MD, University of Washington School of Medicine

Ann Bullock, MD, IHS

How should nephrologists approach primary care practitioners (MDs, NPs, etc.) to decrease barriers related to concerns about subspecialists “stealing” patients from PCPs?

The group identified the major challenge as effective communication between PCPs and nephrologists, not competition for patients. As nephrologists and PCPs engage in discussions, mutual respect is essential (i.e., specialists should not “look down” on PCPs). When to refer a patient to a nephrologist is the most significant question.

PCPs must be engaged in discussion of these issues. Interest on the part of PCPs will depend on the number of patients they see with CKD. In managing patients with CKD, PCPs appreciate access to nephrologists for consultation. PCPs also can serve as a bridge between patients and nephrologists, as nephrologists can be viewed as “scary” by patients.

Specific issues to be raised with PCPs:

- Issues of workload and lack of reimbursement
- CKD 4-5 is scope for nephrologists
- Specifics about medicine, care, evaluation, delegation of duties
- Understanding of role (e.g., when to refer—early versus late)
- Communication between professionals and patients
- Adaptable and simple systems
- Awareness is low among professionals and the public
- How to increase recognition and actions
- Interest of PCPs in CKD may depend on scope of practice (e.g., frequency of diabetes and hypertension in practice)
- Increase advocacy

Should communities move toward a “medical home” concept in caring for patients with chronic disease?

- Domain of primary care
- Role of nephrology (and other specialties)
 - Available and helpful consultants
 - Specialist as possible “medical home” at advanced CKD stages
- Patient interactions
 - Individualizing care
 - Group visits
- Reimbursement issues require attention

What is the role of government in establishing guidelines for referral?

- The Federal government is already involved in this area. The challenge is how to provide a framework for discussions about referral. Nephrologists need to come to consensus on what is reasonable (no mixed messages), and PCPs must be included in the development of referral recommendations.

Guidelines should be:

- Carefully crafted
 - eGFR <30mL/min/1.73m² confirmed
- Define reasons for exclusion from referral
 - Advanced cancer or other severe illness

- Define reasons for earlier referral
 - Systemic or kidney disease with specific treatment implications

What research will have the greatest impact?

- Implementation of medical home
 - Does it improve processes of care and relevant clinical outcomes?
- Primary care/nephrology interactions
 - Best practice for referrals and communications
 - Include provider and patient satisfaction as outcomes
- How to use available tools most effectively
 - Consider group visits
- Target high-risk groups and regions
 - Race/ethnicity vs. common experience
 - Urban, suburban, rural

Priority Research Question: What interventions best foster communication between PCPs and nephrologists?

Where Does CKD Fit in Chronic Disease Management?

Thomas Sequist, MD, MPH, Harvard Medical School

Major Observations:

- Setting up a CKD management program is unnecessary, but recognition needs to improve among clinicians.
- More efforts to increase awareness are necessary. Public awareness campaigns (general), stressing difference between dialysis-ready kidney disease and chronic kidney disease.
- Improve collaborative care to reduce resource issues. Utilize existing health professionals (e.g., diabetes educators) to start or continue the conversation.
- Medication safety—e.g., provider, pharmacist (e.g., GFR-based tools), and patient interventions and other tools such as medication review.
- Role of multidisciplinary team in diagnosis (e.g., can serve to allay fears).
- Capacity of PCPs is limited. What roles can other team members (e.g., health educators, dietitians, nurses, pharmacists) play?

Research Priorities:

- How to improve provider awareness and recognition?
- How to improve patient awareness?
- What are the communication strategies for delivering the diagnosis properly and accurately? (i.e., How do you tell the patient they have CKD without scaring them?)
- How to improve provider management of CKD (e.g., demonstration projects)?

Other Considerations:

- Focus on patient-centered disease management. Start with the point of view of the patient, not the point of view of the disease.
- Should CKD be managed as a stand-alone disease or approached as part of diabetes/hypertension care? CKD is different than diabetes and hypertension because it is under-recognized.
- Providers may be less likely to discuss CKD because patients reactive negatively to it (e.g., fear of dialysis). This needs to change.
- Education needs to be less specific (e.g., health educator instead of a diabetes educator).
- How to develop a management program for patients who don't know about a disease? Look at models such as Kaiser Permanente's screening program.
- More public awareness campaigns (e.g., PSAs). Need to send message that CKD doesn't mean dialysis—it is preventable, manageable, and is not a death sentence.
- PCPs need tools to help them deliver CKD diagnosis to patients (e.g., National Kidney Foundation KEEP screening exit interview).
- Focus on value of treatment/prevention (i.e., the fix is not a big fix).
- The variability in the numbers is significant enough that a “Know Your Numbers” program would not make sense.
- Nutrition recommendations will change over time (i.e., nutrition recommendations for people managing hypertension and diabetes will change when/if the patient progresses to kidney disease).

Priority Research Question: How best to engage PCPs in CKD care?

Designing Multidisciplinary Team Interventions

Barry Carter, PharmD, University of Iowa

This breakout group focused on team design, with the specific goal of developing research evaluations of team performance to prevent kidney disease and/or to improve the care of patients with kidney disease. The group developed recommendations in response to the questions.

Who should be included on a multidisciplinary team?

- Recommendation 1: We should consider the terms “interdisciplinary” or “trans-disciplinary” instead of “multidisciplinary.”
- Recommendation 2: Evaluations should be conducted to determine training needs for teams in order to achieve optimal performance.
- Recommendation 3: Patients should be included as members of the team, able to obtain their records via the Web or flash drives, and be empowered to manage their own care.

Who should lead the team?

- Recommendation 4: Ideally, teams caring for patients with kidney disease should include physicians, nurses, pharmacists, social workers, and dietitians, among others. However, the makeup of a given team or research protocol may differ depending on the setting and whether the team is caring for a patient with kidney disease versus promoting prevention.
- Recommendation 5: NIDDK should encourage applications that evaluate the outcomes of specific teams, as well as applications with strong methodologies.
- Recommendation 6: Applications should be encouraged that evaluate the interaction with PCPs who care for the majority of patients with CKD and the “renal team.”
- Recommendation 7: Applications should be encouraged that examine outcomes of team-based care within primary care to prevent CKD (or progression) as well as manage CKD.
- Recommendation 8: Applications should evaluate the barriers and facilitators to team-based care and patient outcomes within dialysis centers, including financial incentives and other rewards.
- Recommendation 9: Applications should be encouraged in which investigators partner with companies offering dialysis to evaluate different team-based strategies to caring for patients with ESRD.

How should reluctant physicians be approached to participate?

- Recommendation 10: Financial incentives, authorship, showing them how teams can improve not only patient care but also physician satisfaction by “making their lives easier.” Investigators need to define how participating physicians (and other team members) will be recognized and/or rewarded.

Will electronic health records assist with team management?

- Recommendation 11: EHRs must be developed that “talk to one another” so that better registries can be developed for CKD and ESRD.
- Recommendation 12: EHRs must be developed so that they can assist with medication reconciliation and assist the team to achieve optimal performance. (Grant applications should be encouraged to test the integration of technology into team performance).

How does the government promote interdisciplinary teams?

- Recommendation 13: NIH Institutes (including NIDDK, NHLBI, and others) should partner with CMS to obtain waivers to pay team members (who are not being paid for their services) when studies are being conducted to evaluate the outcomes of team performance.
- Recommendation 14: When considering grant applications on team care, NIDDK should convene special-emphasis study section panels with strong representation of individuals with expertise in implementation science and quality improvement research.

How can we measure a team’s efficacy or performance?

- Recommendation 15: Need interventions that can determine cost vs. benefit while hopefully determining which components were most effective—and at the same time determining how overall team performance is influenced by these components, organizational structure, and communication links.

- Recommendation 16: Research proposals must include strong formative evaluations that identify the critical organizational links within the team that led to the best outcomes.
- Recommendation 17: Include strong cost-effectiveness analyses of team care that is relevant to stakeholders who will pay for future services.
- Recommendation 18: NIDDK (with help from CMS?) should: 1) encourage companies that provide dialysis to become more involved in developing registries, developing computer databases that can be linked to one another; and, 2) encourage them to evaluate team-based care interventions.
- Recommendation 19: Research applications must evaluate patient-centered outcomes, including conducting formative evaluations of the intervention and collecting data in the following areas:
 - Quality of life;
 - Patient satisfaction;
 - Adverse reactions;
 - Patient empowerment and inclusion as a member of the team-based care;
 - Patient knowledge and understanding; and
 - Patients' perception of their care.
- Recommendation 20: Research should be encouraged that evaluates patient safety regarding polypharmacy, which is prevalent in patients with CKD and ESRD.
- Recommendation 21: Applications should be encouraged that evaluate team-based care and its use of group patient teaching, support groups, lay leaders from the group who can support peer learning, etc.

<p>Priority Research Question: How to constitute an interdisciplinary team?</p>
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Literacy/Numeracy

Kerri Cavanaugh, MD, MHS, Vanderbilt University Hospital

The breakout group emphasized that more qualitative research is necessary and that information about research and implementation actions needs to be made available.

How do we increase attention given to kidney disease?

- Reinforce existing efforts to raise national awareness
- Further define the core concepts/messages of CKD (kidney disease is complicated)

For providers:

- Define the participants and roles of the multidisciplinary team
- Give special attention to partnership between primary care/nephrology; identify who should be the point person (define role)

For patients:

- Relevance to heterogeneous populations

How to engage the community to maintain sustainability?

- Reassurance that there is a long-term plan—once engaged, the focus will remain

How to develop methodology for a simple, but valid/reliable, measure of health literacy for use in translational research?

- Consider including health literacy as a component of the medical record

What tools are needed to bridge knowledge/skill gaps?

- For providers: algorithms, checklists
- For patients: games, written materials, video
- Tools must be appropriate for the target audience (e.g., consider density of information, culture)

What other related concepts must be considered?

- Self-efficacy, self-care behaviors
- Quality of life
- Concept of health literacy/numeracy (potential applications in T2 research/kidney care)
- More qualitative research
- Need for a simple tool for measurement
- Not all available materials are targeted to specific populations
- There is growing awareness of kidney disease in various populations, but it remains less than desired
- Attitudes about risk/treatment
- Health literacy of providers
- How to elevate the importance of CKD
- Ways to reach communities (e.g., billboards, TV/newspaper, building personal relationship/local champions)
- Strategies for sustainability (e.g., lay health advisors)
- Further define the roles of the multidisciplinary team in CKD care

Priority Research Question: How to identify strategies for effective, relevant, and sustainable methods to enhance communication between systems and participants?

Performance Measures and Tracking

Puneet Sahni, MD, CSI Solutions/Health Resource Services Administration

Sharon Wyatt, PhD, University of Mississippi

Indicators of a Good Measure:

- Simple (few, well-defined)
- Obtainable and retrievable (can be obtained and retrieved across a wide variety of systems—e.g., academic settings, CHCs)
- Has meaning (acknowledges context, alignment between participants and providers)
- Reproducible (all measures have error)

Uses for Performance Measures:

- Accountability (for individual provider/patient; linked to risk/benefit, notion of harm—all measures must do no harm)
- Quality improvement (illuminate system redesign needs)
- Population (macro indicators not ready for individual performance implementation)

Barriers to Obtaining Data and Tracking:

- Complexity
- People (multiple issues)
- Communication (people and systems don't talk, interoperability limits, feedback, goal analysis of both patients and providers)

Data Capture/Analyses Modalities:

- Definition of variables needed regardless of electronic system (outcome and process indicators, mediators, moderators) and data capture system
- Multilevel to capture key outcomes indicators within complex context of health care system and patient/societal determinants of health
- Multilevel and hierarchical analyses (qualitative)

<p>Priority Research Question: What are the key simple metrics that can be accommodated across systems?</p>
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Discussion Points on Breakout Sessions

- Study sections need a better understanding of qualitative research.
- Qualitative research could be used to explore referral to appointments and peer-to-peer interaction.

VI. Response: What NHS Has Done

Donal O'Donoghue, BSc, MBChB, National Health Service, UK

Dr. O'Donoghue described the National Health Service's (NHS) approach to CKD. The health care system in the United Kingdom is based on primary care, not specialists. In the treatment of CKD, other chronic disease models are being used as a guide—NHS is looking at where kidney disease best fits. An objective of this approach is building relationships and respect between primary and secondary care givers.

NHS Framework Standards relating to CKD were adopted in 2004. The standards address the following areas:

- Prevention and detection of early CKD;
- Patient-centered service that supports the person in managing their condition to achieve the best possible quality of life;

- Minimizing the consequences of CKD;
- Prompt identification of acute kidney injury;
- Preparation and choice for renal replacement therapy;
- Timely evaluation of prognosis and information about choices and end of life care based on agreed palliative care plan;
- Those likely to benefit to be transplant listed;
- Timely surgery for access; and
- Dialysis designed around individual needs.

The NHS quality and outcome framework is based on the following principles:

- Indicators should, wherever possible, be based on the best available evidence.
- The number of indicators for each clinical condition should be kept to the minimum compatible with an accurate assessment of care.
- Data should not be collected purely for audit purposes.
- Only data useful in patient care should be collected.
- Data should not be collected twice.

Quality is the only organizing principle of the NHS. Care should be:

- Safe
- Timely
- Equitable
- Patient centered
- Effective
- Efficient
- Sustainable

In 2006, CKD was added as a domain within the quality and outcome framework. Initially, there were four outcomes; now there are six. NHS has been tracking outcomes: referrals to secondary care (stage 4 and 5) have increased, while late presentations have decreased.

The NHS is looking at ways to increase transplantation rates, especially live donor programs.

VII. Closing

Andrew Narva, MD, NIDDK

Dr. Narva thanked the presenters, facilitators, and participants.