KEEP 2009

Tenth anniversary of the National Kidney Foundation's Kidney Early Evaluation Program (KEEP)

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Introduction

This year, 2010, the National Kidney Foundation's (NKF) Kidney Early Evaluation Program (KEEP) will celebrate its tenth anniversary and screen its 150,000th participant. KEEP has served as the most comprehensive and sustained multicenter, community-based chronic kidney disease (CKD) screening program in the United States (Figure 1). Moreover, KEEP represents the largest organized effort to screen for any chronic disease in the country. While focused on CKD, KEEP also functions as a unique means of identifying people at risk for diabetes, hypertension, and cardiovascular disease. KEEP's data capabilities, longitudinal tracking, and feedback to clinicians have made the program a valuable part of a "community of awareness" with respect to CKD and its relationships to common medical problems.

Background

Since KEEP's national launch in August 2000, the NKF and its local offices have been screening high-risk individuals for CKD. KEEP targets people aged 18 years and older who have a history of diabetes or hypertension, or who have a family history of these conditions or of kidney disease. The NKF had pilot tested the program, screening 889 high-risk people in 21 cities from April through October 1997. KEEP was an adaptation of a screening program developed by the NKF of Indiana in 1991, called the Computerized Assessment of Risk and Education (CARE). This program, which targeted relatives of dialysis patients, was provided in collaboration with the Diabetes Research and Training Center, and was multidisciplinary, using health professionals and social workers. KEEP's first steering committee was led by Wendy W. Brown, MD, MPH, FACP, FAHA, and a nucleus of nephrologists who recruited cardiologists, endocrinologists, internists, and epidemiologists over time. The current KEEP steering committee is chaired by George Bakris, MD, FACP, FASN, and co-chaired by Peter McCullough, MD, MPH.

In its present form, KEEP is a free, community-based, health screening program designed to identify and educate individuals at increased risk of kidney disease. KEEP targets risk factors for kidney disease,[1,2] and raises awareness early, when appropriate intervention may delay or prevent disease progression and related health complications. KEEP helps inform and educate, allowing people to more actively participate in their medical care. KEEP is implemented locally through the NKF's network of divisions and affiliates across the country. Local multimedia promotional efforts target people at risk, and the screenings are held in non-medical, non-institutional locations such as churches, community-based settings, and social centers. The screening consists of a series of six stations, staffed by local volunteer clinicians and physicians. Particpants provide informed consent for the screening and for de-identified health information data merge for research purposes, then complete a comprehensive health questionnaire. Measurements include height, weight, blood pressure, waist circumference, and body mass index. A diagnostic panel of urine and blood tests is used to assess evidence and risk-factor control of diabetes, dyslipidemia, CKD, anemia, CKD mineral and bone disorder, and kidney damage.[3] The following tests are also performed:

- Urine albumin-creatinine ratio (UACR; mg/g)
- Fasting blood glucose (mg/dL)
- Serum creatinine (mg/dL)
- Estimated glomerular filtration rate (eGFR), as assessed by the 4-variable Modification of Diet in Renal Disease Study equation (mL/min/1.73 m^2)
- Hemoglobin (g/dL)
- Lipid profile: total cholesterol, triglycerides, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol (mg/dL)
- Hemoglobin A1c, for participants with self-reported diabetes or onsite blood glucose test results indicative of diabetes (%)

Additional tests are performed for participants with eGFR below 60 mL/min/1.73 m^2:

- Intact parathyroid hormone (ng/L)
- Calcium (mg/dL)
- Phosphorus (mg/dL)

All participants consult with a physician, physician assistant, or nurse practitioner to review risk factors and onsite test results, including an initial diagnosis of hypertension, diabetes, or CKD.[4] Lab results are reviewed within 72 hours for critical values by NKF medical personnel. Participants with abnormal test results are contacted directly by NKF Call Center staff. Lab reports with comprehensive review of all screening results, including physical measurements, and lay explanations are mailed to participants after the screening. If participants consent, their physicians also receive the same results with a detailed clinical action plan based on NKF Clinical Practice Guidelines. For participants with CKD, additional information regarding complications, including anemia and CKD mineral and bone disorder, is sent to their clinicians.

Through the NKF KEEP Call Center, staffed by trained clinical personnel, participants receive counseling and support, and are encouraged to have any abnormal results further reviewed by their health care providers. Call Center staff members engage participants by phone to confirm receipt of screening data and to review results. Participants and their clinicians also have access to printed and online NKF resources. This post-screening follow-up is intended to increase awareness of CKD and to share clinical findings with participants and their physicians.

Recently, a longitudinal component was added to KEEP. Participants are invited back annually so their results can be tracked over time.[5] From the KEEP database, an electronic trigger signals KEEP staff to send targeted invitations to prior participants, asking them to return for repeat examination. Return participants are identified upon arrival, and are asked to complete a questionnaire developed to assess interval changes in CKD risk factors and other medical events.

KEEP Data Coordinating Center

The KEEP Data Coordinating Center is a centralized data center, established in 2002 at the Minneapolis Medical Research Foundation, Minneapolis, Minnesota, for managing data collection processes, maintaining data consistency and quality, and conducting epidemiological research on the high-CKD-risk KEEP populations. The Data Coordinating Center:

- Develops Windows-based database systems and Optical Character Recognition applications to facilitate online data entry and survey form scanning.
- Manages data and database systems for maintaining data integrity and participant confidentiality.
- Implements management tools for performing data quality assurance and control.
- Assists and collaborates with KEEP investigators in conducting biostatistical analyses for peer-reviewed manuscripts and abstracts.
- Generates slides and posters for national meetings, and produces the KEEP Annual Data Report to highlight the unique social and demographic characteristics of the KEEP populations and their associated risk for CKD and other major chronic diseases.

The KEEP Annual Data Report is published annually as a supplement to the American Journal of Kidney Diseases, to coincide with NKF Spring Clinical Meetings and World Kidney Day. It is also available on CD and on the NKF web site, http://www.kidney.org/news/keep/index.cfm.

Data Highlights, Accomplishments, and Visibility

KEEP has developed a unique cohort of volunteers, enabling the NKF to uncover some fascinating observations in a population with or at increased risk for CKD. Since its inception, KEEP has collected rich data on CKD and other risk factors in order to:

- Examine population trends to determine a public health agenda;
- Promote communication, education, and follow-up with KEEP participants and their doctors;
- Improve patient outcomes and track changes over time;
- Increase the number of KEEP-related presentations an publications available to the medical community;
- Advocate change by sharing findings with government, policymakers, payers, and providers.

Publications

In addition to the KEEP Annual Data Report, more than 30 articles highlighting KEEP data have been published in peer reviewed journals, and more than 100 poster and oral presentations have been featured at national and international meetings. Articles featuring KEEP have appeared in premier nephrology journals such as the American Journal of Kidney Diseases and Kidney International, and in journals outside the field of nephrology, including Archives of Internal Medicine, the American Journal of Medicine, and the American Heart Journal. The KEEP Publications Committee plans to launch an online data request service in 2010 to increase visibility through research publications. This service will allow researchers to request and access KEEP data online, providing an opportunity for investigators who are not members of the KEEP Steering Committee or Publications Committee to participate in manuscript development and submission.

Findings

Over its first ten years, KEEP data findings have been consistent:

- Approximately 26% of KEEP participants have CKD, but only 2% were aware that they may have the disease.
- More than 30% of participants have diabetes.
- At the time of screening, 30% of participants with diabetes do not meet target blood sugar levels.
- Approximately 70% of participants have hypertension.
- At the time of screening, 74% of participants with hypertension do not meet target blood pressure levels.
- Nearly 32% of participants with CKD report a history of cardiovascular disease.
- Participants with cardiovascular disease have high short-term mortality.[6]
- Only 20% of participants without CKD report a history of cardiovascular disease, yet 86% of KEEP participants have a cardiovascular disease risk factor.

One or more laboratory values is outside the normal range for more than 90% of KEEP participants. Prevalence of CKD and its comorbid conditions is higher in the KEEP population than in the National Health and Nutrition Examination Survey (NHANES).

KEEP participants by race/ethnicity:

- 32% are African American (three times the African American population in NHANES)
- 47% are white
- 5% are Asian/Pacific Islander
- 3.6% are American Indian/Alaska Native (about twice US census prevalence; these data are not collected in NHANES)
- 13% with Hispanic ethnicity

As CKD involves many well-documented ethnic and racial disparities, the ability to reach these vulnerable populations is significant.[7] For example, hypertensive kidney failure and CKD anemia are both more prevalent in African Americans than in other races. KEEP participants provide an "enriched" population for risk conditions. KEEP's data set is based on a convenience sample, but has been shown in peer-reviewed publications to be similar to the random NHANES sample with regard to diabetes and hypertension.[8] The CKD yield from KEEP is high (26% using UACR and eGFR), approximately twice that of NHANES. Compared with the general population, the KEEP cohort includes a high percentage of women and minorities. Participants are generally older, and most report having a secondary education. KEEP participants report being well insured and having primary care physicians whom they visit; they also have higher prevalence of diabetes, hypertension, obesity, anemia, and cardiovascular disease, and are more likely to have evidence of kidney damage.[9] While 85% of KEEP participants report having seen a doctor in the past 12 months, 60% learn of a new condition, of which they were previously unaware, during screening. KEEP data demonstrate that knowledge of CKD improved medication adherence and blood pressure control.[10]

KEEP clearly demonstrates that targeted screening for kidney disease has a high yield for identifying people in the community at elevated risk, and for detecting people whose kidney function may already be decreased. The versatility of the KEEP database enables the NKF to correlate data and to identify individuals and groups with specific abnormal laboratory parameters. From this information, the NKF can identify need for future educational programs and match content with needs of target audiences.

KEEP's goal is not just to measure illness parameters, but also to increase awareness of kidney disease risk and complications among physicians and patients to optimally influence care measures and clinical outcomes.

KEEP and the Centers for Disease Control and Prevention

KEEP's success has affected federal and state government initiatives. In a cooperative agreement for state-based kidney disease screening, the Centers for Disease Control and Prevention (CDC) selected KEEP as the model for implementation in four states in a demonstration project. The group used the KEEP and NHANES datasets to determine that diabetes, hypertension, or age older than 50 years were the risk conditions. The CDC's recognition of KEEP is critical, as the CDC is one of the most respected public health agencies worldwide. A CDC web site (http://www.cdc.gov/diabetes/projects/kidney.htm) details kidney disease efforts. The CDC wields tremendous influence though implementation and funding of state health departments.

KEEP is recognized by the CDC as a model of "Best Practice" in chronic disease screening. Recognized around the world for its effectiveness in identifying at-risk patients, KEEP is being replicated in countries in Europe, Asia, Latin America, and South America. In the United States, KEEP has enabled the NKF to identify and help address health disparities at the community level. Free to participants and conducted in English and Spanish, KEEP successfully reaches people most at risk, provides timely reporting of their clinical status, and offers access to health care for those most in need.

The CDC established its own CKD program, calling for establishment of a CKD surveillance system in the US to track all CKD manifestations in the general population, which completed its first phase of pilot testing in 2009.[11]

Another initiative focuses on generating knowledge to translate into standardized prevention and control programs that all states can employ. Both initiatives reviewed KEEP data and examined KEEP's model. The KEEP infrastructure will be able to test CDC protocols and help implement them in the future.

KEEP and State Health Departments

State health departments recognize KEEP's value in their efforts to establish education campaigns and to direct access to health care services, focusing on people without health insurance and those who experience disparities of health care services. Currently, the NKF is working with the Department of Health in the District of Columbia to pilot test CKD screening initiatives and interventions based on KEEP, designed to reach out to minority and under served high-risk populations, particularly the Medicaid Managed Care Organizations managed by the Department.

KEEP and Medicare

Every state and three US territories have Quality Improvement Organizations (QIO). Each QIO has a three-year contract or scope of work directed at specific tasks, such as influenza vaccination for Medicare beneficiaries. For the first time in the history of the Medicare QIO program, CKD is being addressed in 10 states, with goals of improving UACR screening of people with diabetes, enhancing angiotensin-converting enzyme inhibitor and angiotensin receptor blocker use for people with diabetes and hypertension, and increasing arteriovenous fistula use for patients who initiate therapy with hemodialysis. Each of the states has inquired about use of KEEP data and processes to meet its goals, and has requested NKF educational materials. Several states recommend targeting poor-performing regions for KEEP screenings. Despite budgetary constraints, KEEP could contribute to national implementation of a Medicare QIO CKD project that would attract the attention of primary care and other physicians.

Global KEEP

KEEP has influenced the medical community and other kidney-related organizations worldwide, as exemplified by a request from the World Kidney Day committee to present an overview of the world epidemic of hypertension and kidney disease showcasing KEEP as an example of efforts to curtail this epidemic.[12] A global CKD screening movement has begun, and the Kidney Disease Prevention Network has been established in Japan, Australia, Mexico, and other countries. At the first meeting, held in September 2009, representatives from numerous countries currently conducting CKD detection programs convened. The mutual goal set was to collectively work on developing best practices for CKD detection, including data collection and analysis, patient and professional follow up, government collaboration, and cost effectiveness. Representatives from the World Health Organization and the Pan American Health Organization participated.

Future Directions

KEEP's primary intent is to provide comprehensive screenings. The reach continues to expand, and KEEP screenings are entering new geographic regions, focusing on areas with large at-risk populations and high disease incidence. By engaging high-risk people and the broad clinical community that treats them, KEEP's impact on patient awareness and clinical intervention will continue to effect change and improve care. Each time a KEEP program is advertised, the message that CKD is important resonates throughout the community.

Strategies to encourage previous KEEP participants to return annually for repeat screenings will continue in 2010. To maintain the initial cohort of repeat participants over successive years, and to further increase repeat participation rates, outreach with individuals will be expanded. KEEP will continue to work closely with local NKF divisions and affiliates to determine how and where screenings can be offered to increase accessibility for previous participants; the NKF will also work to extend KEEP's scope and reach to additional communities and populations. As part of ongoing activities designed to maintain and increase the cohort of longitudinal participants, the NKF will continue to distribute KEEP event calendars, conduct mail and phone follow-up surveys, send annual appointment reminders, and call participants directly with courtesy reminders. This will enable participants to select the most convenient screening event and increase the likelihood of their ongoing participation.

Further analysis of the longitudinal data will be conducted, enabling KEEP to determine successful interventions and whether modifications or interventions need to be implemented. Metrics of success include increased awareness, improved CKD risk factors, slowed CKD progression, reduced complications (anemia and mineral and bone disorders), and ultimately reduced end-stage renal disease, cardiovascular events, and mortality.[13]

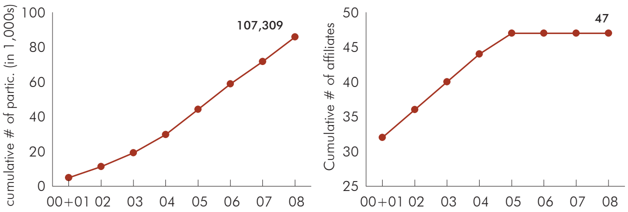
Summary

As KEEP celebrates its tenth anniversary, supplementary activities will be planned throughout the year in addition to the core KEEP functions, to generate greater visibility and recognition of KEEP in the medical community and for the public. KEEP has been effective in identifying individuals with reduced kidney function and in raising awareness among people at increased risk for kidney disease due to poor risk-factor control and undetected conditions such hypertension and diabetes. KEEP's ongoing involvement in developing educational strategies targeted at health care professionals and at people at increased risk is increasingly important, so improvements will be apparent in treatment, management, and overall health outcomes affecting this population over the next 10 years and beyond. Importantly, we believe KEEP can be a sustainable model for other societies to follow for chronic disease and risk factor screening, including cancer, diabetes, and musculoskeletal, heart, and lung diseases.

Sponsor Information

KEEP sponsors include Amgen, Abbott Laboratories, Siemens, Fresenius Medical Care, Genentech, Genzyme, Nephroceuticals, LifeScan, Pfizer, Abbott Suplena, and Takeda.

Figure 1: Cumulative number of KEEP participants and affiliates, by year.



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