

NC IOM TASK FORCE ON CHRONIC KIDNEY DISEASE

March 29, 2007
NC Hospital Association
10:00-3:00

ATTENDEES

Task Force/Steering Committee: Tammie Bell, Paul Bolin, Joel Bruce, Jennifer Cockerham, Sam Cykert, Annette DuBard, Thomas DuBose, Laura Edwards, James Fleming, Linda Gross, Deidra Hall, Donna Harward, Jeffrey Hoggard, Cynda Johnson, Jim Keene, Chip Killian, Jenna Krisher, Ann Lefebvre, Mark Massing, Marilyn Pearson, Barbara Pullen-Smith, Janet Reaves, Leanne Skipper, John Smith, Linda Upchurch

Interested Persons/Staff: Alice Connelly, Amy Cook, Bill Hoskins, Bill Isley, Abhijit Kshirsagar, Jim Martin, Billena Richardson, Leighann Sauls, Suma Vupputuri, Kimberly Alexander-Bratcher, Kristen Dubay, Thalia Fuller, Mark Holmes, Kiernan McGorty, Pam Silberman

WELCOME AND INTRODUCTIONS

Leanne Skipper

Co-Chair

Chief Executive Officer

National Kidney Foundation of North Carolina

Ms. Skipper introduced herself and asked the Task Force members and guests to introduce themselves and the organizations they represent. Dr. Pam Silberman introduced herself and the North Carolina Institute of Medicine. The members introduced themselves, their organizations, and their passion for chronic kidney disease (CKD) prevention.

Dr. Silberman gave an overview of the work of the Task Force on Chronic Kidney Disease thus far. There were several new members and presenters for whom this was the first meeting. Dr. Silberman explained that a Research Assistant conducted a literature review and organized it by parts of the Task Force charge. It was included in the handouts given to members and guests.

In summary of the system of care for chronic kidney disease, Dr. Silberman gave an overview including the general public (public education), people in stages 1-3 of CKD (case management & primary care), and people in stages 3-5 of CKD (specialty care & dialysis). She explained that Task Force members are experts in the field, but as a lay person, she wanted to see the big picture.

SCREENING FOR CHRONIC KIDNEY DISEASE

Abhijit V. Kshirsagar, MD, MPH

Department of Medicine

Division of Nephrology and Hypertension

University of North Carolina School of Medicine

Dr. Kshirsagar introduced himself and the UNC Kidney Center. He described the prevalence of CKD as 1 in 9 adults in the US. Most of those people have stages 1-3 while the minority has advanced CKD in stages 4-5. Over the last 15 years, both the prevalence and incidence of the disease has grown. It is a profound life event for patients and their families. Providing care for these patients is very expensive; about .5% of the population uses 10% of the Medicare budget. There are simple tests that are very inexpensive like serum creatinine concentration, but most individuals with known risk factors are not routinely tested. When the glomerular filtration rate (GFR) is reduced, most patients are asymptomatic. Because physicians are dealing with so many issues during a patient visit, they might not think to screen for CKD.

A recent LabCorp study showed that only 20% of people with diabetes and 30% of people with hypertension have serum creatinine levels checked. When they compared these results to other chronic disease states and testing for common risk factors, they found lower rates for CKD. Many chronic conditions have systematic methods to predict risk score including cardiovascular disease (Framingham), cancer recurrence, and stroke recurrence. The UNC researchers wanted to apply the same type of methodology to CKD. The important prerequisites were that the scale be easy to use and cumulatively predict the effect of concurrent risk factors.

The UNC researchers developed their scoring system - SCreening for Occult Renal Disease (SCORED) - through cross sectional analysis of a nationally representative population based survey, the National Health and Nutrition Examination Surveys (NHANES). Data from NHANES 1999-2000, 2001-2002, and a literature review were used to determine the predictor variables. The outcome variable selected was GFR calculated from the equation used in the Modified Diet in Renal Disease (MDRD) study. Individuals with missing variables were excluded from the study. Dr. Kshirsagar explained the methods of the study in detail using the following risk factors as predictors: age, female gender, anemia, hypertension, diabetes, history of cardiovascular disease, peripheral vascular disease, and proteinuria. The questionnaire used the predictive risk factors, could be performed in less than one minute, and recommended seeking care for CKD with a score of four or more. The results showed the model to be a good fit that meets the original prerequisites and has a variety of foreseen uses through mass screening, public education initiatives, medical emergency departments, web-based medical information sites, and public and private clinics.

There are several limitations of the SCORED study. The questionnaire is weighted towards common risk factors, family history information is not included, and proteinuria is not specific for CKD. The risk is predictive of prevalent, not incident, CKD and the

age related decline in GFR is not accounted for in the weighting system. Future directions for the SCORED study include refining the tool, adding the latest NHANES data, comparing it with other screening guidelines, testing real world performance, and predicting incident kidney disease.

Comments/Questions: The discussion that followed focused on suggestions for improvement of the SCORED tool. Some members noted that family history of CKD and length of time with diabetes should be added to the questionnaire while gender may be an artifact of the calculation. Others suggested using the SCORED tool with secondary data like large HMOs or other screening programs like the NKF Kidney Early Education Program. A participant noted because the likelihood ratio for scores of three and four were almost identical three should be used as the cut off, while another explained that everyone over age sixty would need follow up for CKD with three as the cut off. That would make Medicare an important stakeholder. The lack of national screening guidelines including frequency of screenings was also discussed.

LAB CORP: SCREENING TESTS FOR KIDNEY DISEASE

James K. Fleming, PhD

Vice President and Director

Department of Science and Technology

Laboratory Corporation of America

Dr. Fleming introduced himself and LabCorp. He is a member of the Laboratory Working Group of the National Institutes of Health National Kidney Disease Education Program, which began following release of the K-DOQI guidelines. In using eGFR, they realized that creatinine values varied from one lab to the next. Solving that problem was the focus of his presentation.

Dr. Fleming provided an overview of the problem of chronic kidney disease. Thirty percent more Americans die from diabetes than their European counterparts and American diabetics have four times more kidney disease than European diabetics. When comparing U.S. deaths from kidney failure to those from various types of cancer, only lung cancer causes more deaths than kidney disease. Both prevalence and incidence of kidney failure are greatly increased, but the risk is not uniform across racial groups. African-Americans have almost four times the risk of kidney failure compared to Caucasians. The cost of care for kidney failure is greater than the total National Institutes of Health budget.

Research shows that chronic kidney disease is not recognized nor treated as often as recommended. Most practices screen less than 20% of their Medicare patients with diabetes for chronic kidney disease. Many patients, especially African-American men, with chronic kidney disease are referred to a nephrologist late in the disease progression. Less than one third of those with chronic kidney disease are prescribed ACE inhibitors. Regular testing is recommended for people with the following risk factors: diabetes,

obesity, hypertension, relative with kidney failure, cardiovascular disease, elderly, and chronic NSAID use. Treatment is recommended for individuals based on microalbumin/creatinine ratio and eGFR.

Dr. Fleming summarized the National Kidney Disease Education Program's (NKDEP) rationale for using and reporting eGFR. Glomerular filtration rate (GFR) and creatinine clearance (CrCx) are poorly inferred from serum creatinine alone. Creatinine is more often measured than urine albumin and measurement of renal function is essential once albuminuria is discovered. The MDRD equation is the most validated and superior of the methods of eGFR calculation. It also does not require the use of 24 hour urine collection or weight and height variables. Both NKDEP and the National Kidney Foundation (NKF) are bringing awareness to the physician community about eGFR as a screening tool and checking for microalbumin if eGFR is less than 90.

The KDOQI guidelines describe five stages of CKD based on eGFR values. They include basic descriptions, screening, and follow up for each of the stages. Detection of CKD depends on the person's previous medical history. Diabetics should be tested using the "spot" urine albumin/creatinine ratio once yearly. Other people at risk should have creatinine tested to estimate GFR using a "spot" urine albumin/creatinine ratio or albumin dipstick.

Dr. Fleming discussed several of the analytical considerations of the MDRD equation. There are two separate formulas to use depending on whether the worldwide standardization method, Isotope Dilution Mass Spectrometry (IDMS), is used. Advantages of the MDRD study equation are its accuracy and inclusion of only four parameters including race listed as African American or non-African American. One limitation of the study is the equation is based on an adult CKD population so healthy people and children are not accounted for. The equation has not been validated and underestimates eGFR in normal healthy people. If the value is less than 60, a whole number should not be reported but rather the range. Urine creatinine clearance should be used if the patient has an unusual diet, strict vegetarian or creatinine supplements, or abnormal creatinine production as in the morbidly obese, severely malnourished, amputees, paraplegics, or those with other muscle wasting diseases.

Dr. Fleming also made several recommendations for laboratories and manufacturers of laboratory equipment to consider. Because of the variability in creatinine measurement, performance criteria should be established regarding accuracy and precision. Manufacturers should calibrate equipment using the international standard IDMS and specify the method for creatinine measurement. Collaboration between reference material from CAP, NKDEP, and the National Institute of Standards and Technology (NIST) is also important. Laboratories may encounter complications with pharmacy dosing, children, and creatinine clearance measurement. Laboratories should report specific eGFR values only for those above 60, not report eGFR for children, and be aware of limitations and specifications of the MDRD equation.

Dr. Fleming concluded with information on other states' eGFR legislation and other measures of kidney function. Several states have pending eGFR legislation including Colorado, Connecticut, New Jersey, North Carolina, Pennsylvania, South Carolina, and Virginia. Other tests for renal function include cystatin C and cysteine C. Cystatin C solves creatinine limitations related to muscle mass, gender, diet, and inflammation and is an independent risk factor for coronary heart disease. There are currently no clinical practice guidelines to suggest its best use.

Comments/Questions: The discussion that followed focused on limitations and legislation around eGFR. A participant noted that many hospitals order eGFR automatically, but cancelled automation when using whole numbers. Another suggested that education should focus on patients, primary care providers, and widespread laboratories. The suggestion was made that all patient groups should have eGFR calculated, not just Medicaid or Medicare patients.

KIDNEY DISEASE OUTCOMES QUALITY INITIATIVE CLINICAL PRACTICE GUIDELINES FOR PRIMARY CARE PROVIDERS

Cynda Ann Johnson, MD, MBA
Senior Associate Vice Chancellor for
Clinical and Translational Research
Division of Research and Graduate Studies
East Carolina University

Dr. Johnson introduced herself explaining her transition from family medicine and delivering babies to a focus on kidney disease. At her previous post in Iowa, she was introduced to kidney disease by a colleague. In preparation for writing the guidelines, NKF began with the Dialysis Outcomes Quality Initiative (DOQI) guidelines from 1997 and then transitioned to the Kidney Disease Outcomes Quality Initiative (K-DOQI) guidelines. The CKD Work Group was charged with guideline preparation and literature abstraction. There is quite a lot of subjectivity, and it was important to compare and contrast the literature. The value of the anecdote and experience is important to include in evidence-based practice.

The first K-DOQI guideline lays out the definition and stages of CKD. For clarity, the guidelines used the word kidney rather than renal or nephrology. Many complications are evident when GFR is greater than 60, so the definition includes both symptoms and laboratory tests. The most critical reason for the staging was to create a common language to communicate about the disease. The system was designed to make intuitive sense and be fairly simple. The new National Health and Nutrition Examination Survey (NHANES) data show an increased incidence of CKD. Care for CKD patients must be a collaborative effort. The work group was able to change ICD-9-CM codes to read CKD instead of chronic renal failure. There are now seven separate codes including five for the stages, one for ESRD, and one for unspecified CKD. The NKF website provides detailed information on the stages.

The second KDOQI guideline is evaluation and treatment of CKD. This guideline adds a clinical action plan to the stages. Rather than an action for each stage, the action plan is cumulative. The most important part of the action plan is risk factor management. The goals of risk factor management are blood pressure less than 130/80, low density lipoprotein (LDL) less than 100mg/dl, and the use of angiotensin converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARB) to slow the progression of protein in the urine.

The third guideline focuses on risk factors for CKD. Diabetes, hypertension, and family history of CKD are some of the most common clinical risk factors. Older age and U.S. ethnic minority status are two of the sociodemographic risk factors for CKD. All of the previously listed risk factors have been targeted in screening for CKD.

The fourth KDOQI guideline is estimation of GFR. The stages are based on estimates of GFR. Creatinine should not be used alone as a measure of kidney function because it is inaccurate, and GFR declines to 50% before creatinine rises above normal. The distribution of creatinine for males and females is bimodal and not easily understood without GFR. Using the MDRD equation to calculate GFR restores the bell curve shape for both males and females. Help calculating eGFR can be found on the National Kidney Foundation website and nephron.com as well as other sources. New Jersey was the first state to mandate laboratories to calculate GFR. The group discussed compelling reasons to require laboratories to calculate GFR, including the example of prothrombin time and international normalized ratio (PT/INR) as measures of coagulation. Once the PT/INR was widely available on laboratory reports, physicians became accustomed to using the measures correctly.

The fifth guideline is assessment of proteinuria. Untimed spot urine samples should be used to assess the level of protein in the urine. The first morning urine sample is preferred, but random samples are acceptable. The 24 hour urine sample is not accurate. Further evaluation depends on risk to the patient, cost, and availability of tests.

Dr. Johnson did not discuss KDOQI guidelines six and seven. The eighth guideline discusses the association between GFR level and anemia. The kidneys of CKD patients produce less erythropoietin, and there is shortened red blood cell survival in the uremic state. Anemia contributes to other chronic diseases like congestive heart failure and increased mortality in CKD. The prevalence of anemia does not have a clear cut off in CKD. Hemoglobin should be tested annually in patients with eGFR values below 60. The target range for hemoglobin is 11-12/mg/dl in CKD patients.

The last guideline Dr. Johnson discussed was the tenth, which covers bone disease and disorders of calcium and phosphorus metabolism. As kidney function declines, there is an increase in abnormal values of both calcium and phosphorus and an increase in the incidence of bone diseases. In all CKD patients with eGFR values less than 60, calcium, phosphorus, and intact parathyroid hormone should be monitored.

In 2006, the Kidney Disease Improving Global Outcomes (KDIGO) international group held a conference focused on controversies in kidney disease. The international markers are slightly different than the US guidelines. The topics of focus were CKD classification, screening and surveillance, public policy, and chronic diseases in conjunction with CKD. Some of the KDIGO recommendations include keeping the current classification, targeting screening and surveillance in each country, improving public health policies for CKD, testing CKD patients for HIV and hepatitis C, vaccinating stage 5 patients against influenza, hepatitis B, and pneumococcus, and screening CKD patients for cancer.

Dr. Johnson concluded with a brief summary of the take home message and available resources for patients, providers, and others with an interest in CKD.

Comments/Questions: The discussion that followed focused on resources, coordination between guidelines and providers, and testing. A participant asked why KDOQI guidelines have not been incorporated into other guidelines. Dr. Johnson believes collaboration and time will help. Another participant commented that new paradigms of care are needed between nephrologists, primary care providers, and mid-level providers. It was suggested that the SCORED tool would help with screening, determining whether people are at risk during their evaluation for proteinuria. Normal, healthy patients can use a regular dipstick, but those already at risk should use protein-specific dipsticks.

IMPROVING PERFORMANCE IN PRACTICE (IPIP)

Samuel Cykert, MD

Associate Director

Medical Education and Quality Improvement

North Carolina Area Health Education Program

Dr. Cykert introduced himself and the need to lessen the burden on primary care providers. The sentinel article on quality of care was written by McGlynn et al. He created quality indicator lists according to type of care and function. Barriers to care include systems of care, reimbursement, visit length, and competing concerns/patient acuity. Systems of care include computers and their use. Many providers have no disease registries or quality data collection instruments. Doran et al. described a pay for performance (P4P) quality initiative in family practices in the United Kingdom. They created a quality indicator list similar to McGlynn et al. Doran et al.'s list has similar barriers to perfect care but emphasizes the impact of systems of care.

Ten years ago in the National Cancer Institute study "Making Prevention Work," one practice sent computerized reminders to their patients and attained 90% compliance. According to the New England Journal of Medicine, P4P has great success in the UK. Compliance rates are 80-100%. Primary care provider salary increased from the equivalent of \$130,000 to \$170,000. It is important to note that providers paid for the system themselves, and patient satisfaction is listed as a quality indicator. The Stark law, which is designed to prevent conflict of interest in health care settings, has been revised to allow hospitals to pay for practice computers.

Improving Performance in Practice (IPIP) is a quality improvement initiative funded by the Robert Wood Johnson Foundation and the American Board of Medical Specialists. North Carolina was one of the first states to pilot the project focusing on chronic diseases. Initially eastern and western parts of North Carolina had pilots targeting diabetes and asthma. Community Care of North Carolina (CCNC), Area Health Education Centers (AHEC), and the Division of Public Health (DPH) were the involved parties. Using a quality improvement coach in the practice, baseline data was collected. The project involves a disease registry, electronic records, point of service reminders, and data feedback. Many practices do not know how to create registries and collect data on quality indicators. The system analysis will follow the acronym PDSA (plan, do, study, and act). Current quality measures for diabetes follow the American Diabetes Association diabetes measures.

The Statewide Quality Initiative is a consortium of health care, provider, insurance, and state organizations. It will spread IPIP methodology throughout the state. In addition to asthma and diabetes, this initiative also will include congestive heart failure, hypertension, and post-myocardial infarction care. North Carolina is the only state with this type of initiative. It is physician led and supported by the stakeholders.

With regard to CKD, reasonable expectations of primary care providers include screening using creatinine clearance, medication in the form of ACE and ARBs, chronic disease management for diabetes and hypertension, and attempted nephrology referral. The same system deficiencies for other chronic diseases are limitations in the care of CKD. Other limitations are education, patient ownership, and patient and provider understanding. The large majority of CKD patients suffer from other chronic diseases. These patients need coordination of their medical care. Screening them for CKD without providing care is not ethical; they must have a unifying system of care. The ideal system would include regional chronic care centers like electronic ICUs, a formal attachment of patient and physician, and information connectivity and hierarchical care. That system has not yet been achieved. A plan to move in that direction is possible using the assets of quality improvement.

GROUP DISCUSSION

Dr. Silberman asked the task force members to look at the February minutes to determine if there were new ideas that needed to be added to the list of topics for discussion. Suggestions included a non-physician health care professional to titrate and suggest revision of care between primary care provider visits with strong protocols and guidance. A participant stated that the primary care workforce is overworked and this work may increase screening for a disease the system is not yet able to handle. Someone commented that diabetes educators are a great model, but they are not yet accessible to everyone. They are currently in the process of review, but have shortfalls in reimbursement, availability, and training. Another suggested reimbursement to pay the intermediary professional that already exists in Medicaid but not in the private payer system. Cross training of educators for chronic diseases including CKD, diabetes, and

hypertension was a recommended solution. The connection and partnership with the North Carolina Community College system is a great resource to train those professionals. The Stanford model is a chronic disease self management program that is training professionals and lay people with chronic diseases. A trainer at the UNC School of Nursing is using the African American population for a study on the model.

In the area of legislation, the issue of mandated eGFR reporting was raised. The General Assembly process is two years if not in long session and that will be too long to wait. There are examples of other tests that were incorporated into standard practice without legislation like the PT/INR, which was previously discussed. Another participant suggested support for legislation mandating labs to calculate GFR. The need for updates with current standards is a barrier to legislation. A participant responded that the eGFR value can be derived even if other methods of calculation are used. It will be important to have information for and outreach to primary care providers so they will be aware that GFR values will be reported. There has been successful local implementation. Someone else suggested using the Commission for Health Services regulation rather than a statute.

Other topics for discussion were the UNC KEOP providing follow up in the same rural communities where it performed screening, how to demonstrate long term cost savings by screening for CKD, and insurance qualification differences for CKD, ESRD, and disabilities.

Dr. Silberman announced the primary care and disease management work group meeting April 23 at the NC IOM and invited the interested Task Force meetings.