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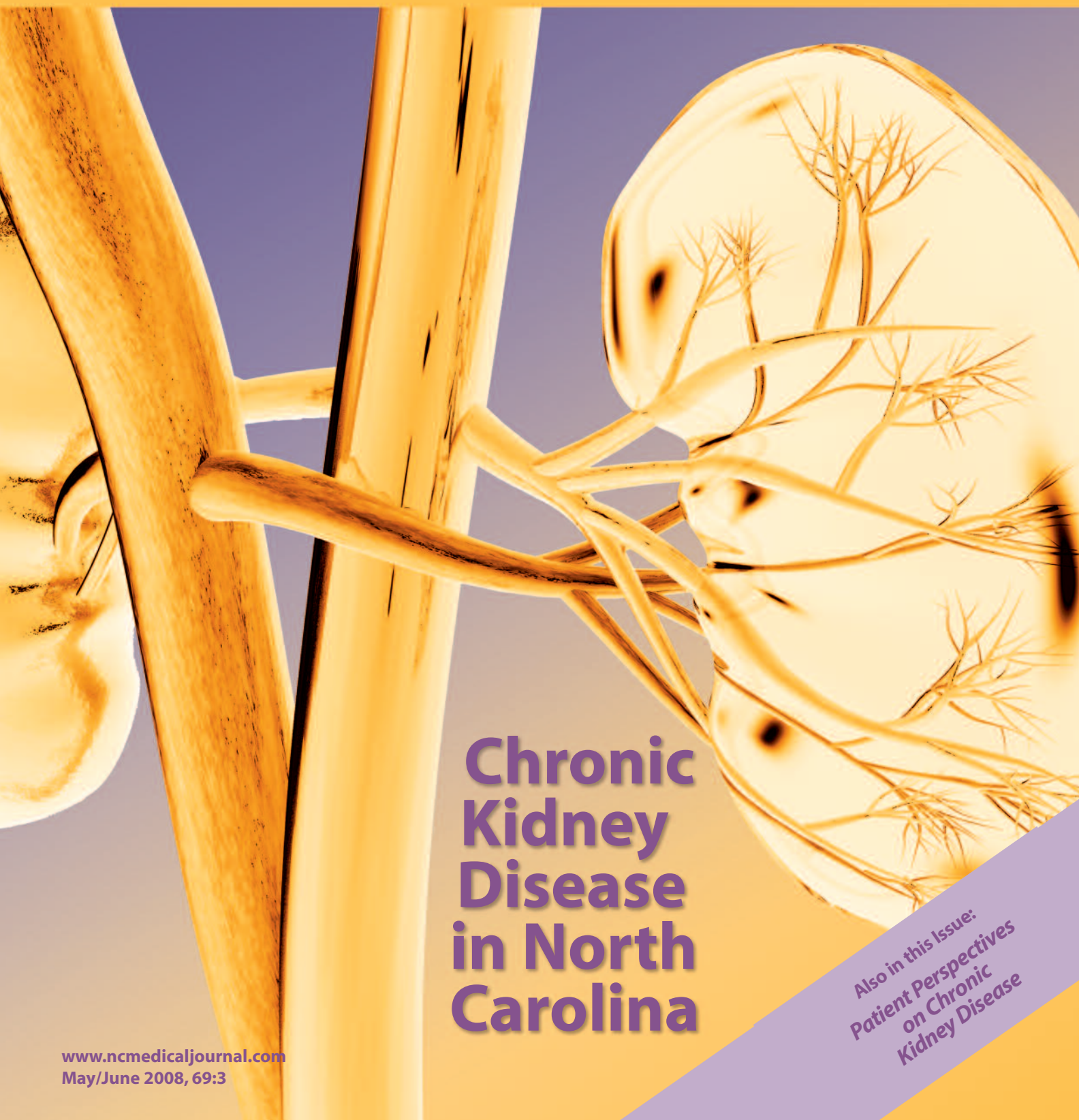

Chronic Kidney Disease in North Carolina

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Tarheel Footprints in Health Care

Recognizing unusual and often unsung contributions of individual citizens who have made health care for North Carolinians more accessible and of higher quality

Ann Bullock, MD
Medical Director, Health and Medical Division, Eastern Band of Cherokee Indians
Recognizing the Commitment of a Community

The Eastern Band of the Cherokee Indians possesses a history rich with tradition. In addition, tribe members share similar health backgrounds and an unfortunate predisposition to higher rates of diabetes and chronic kidney disease (CKD). More than 15% of the Cherokee population has been diagnosed with type 2 diabetes. For 18 years, Dr Ann Bullock has been passionate about increasing diabetes awareness and prevention among the Eastern Band of the Cherokee Indians while honoring the tribal traditions and history.

Ann Bullock is a board-certified family physician who has worked with the Eastern Band of the Cherokee Indians since 1990. In 2000, she became the medical director for the tribe's Health and Medical Division. Dr Bullock oversees the Cherokee Diabetes Clinic and Cherokee Choices, a diabetes prevention program which has received national recognition.

Under Dr Bullock's leadership, the Cherokee Choices program has worked to increase diabetes awareness through elementary school mentoring, worksite wellness for adults, and church-based health promotion. Diabetes had touched so many Cherokee families that prior to the project there was a general acceptance among members that diabetes was a way of life. Accordingly, one of the first capital projects for the tribe was the construction of the Cherokee Dialysis Center to treat many diabetic tribe members who had developed end-stage renal failure.

Although much of Dr Bullock's time is now spent in a management role, she continues to serve the local population as a primary care physician. Patients regularly comment on her genuine compassion and her interest in their well-being. Vickie Bradley, director of Health Operations, says "Ann has demonstrated an extraordinary commitment to health promotion and disease prevention services. Her contributions to the Cherokee community have been tremendous."

The Eastern Band of the Cherokees has received national awards for their ongoing diabetes prevention efforts. Keen awareness of the link between diabetes and chronic kidney disease has also led the tribe to become a corporate partner with the National Kidney Foundation of North Carolina for the new Kidneyville Cruiser set to unveil in October. "Slowing the progression of CKD among Native Americans is especially important to the Eastern Band of the Cherokee Nation. We recognize the importance of early detection in the fight against CKD and have gotten involved to help not only our tribe members but residents across North Carolina," says Michell Hicks, Principal Chief of the tribe.

For Dr Bullock, medicine is about more than prescribing the right pills. In her quest to treat the whole person, not just the disease, Dr Bullock has been an advocate for alternative medical therapies. She is a firm believer in the power of the mind. Dr Bullock was inspired to create a meditation garden located at the tribe's diabetes clinic. The garden provides a sanctum for the local community and incorporates indigenous medicinal plants traditionally used by the Cherokee. Dr Bullock was recently nationally recognized when she was named chief clinical consultant for Family Medicine in the Indian Health Service of the US Department of Health and Human Services. She has also been described as a pioneer in connecting stress and trauma to physical disorders.

Dr Ann Bullock has combined medical knowledge, cultural understanding, and a profound sense of humanity into all of her work. For her extensive work in diabetes prevention and the treatment of chronic kidney disease, the *North Carolina Medical Journal* is pleased to recognize Ann Bullock, MD.

Kristen Reed is the vice president of Marketing and Communications at the National Kidney Foundation of North Carolina. She can be reached at kreed (at) nkfnc.org or 704.479.3302.

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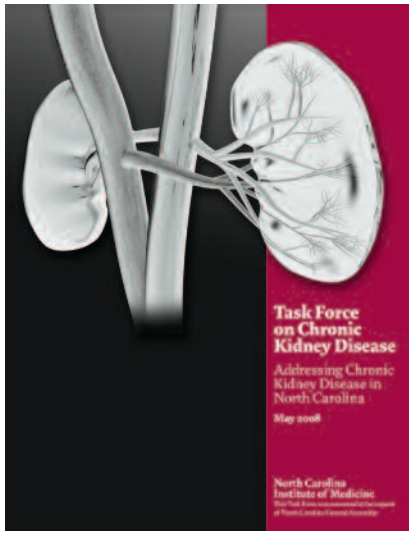
SCIENTIFIC ARTICLES

POLICY FORUM

Chronic Kidney Disease in North Carolina

COMMENTARIES

DEPARTMENTS



North Carolina Institute of Medicine Task Force on Chronic Kidney Disease Report: Addressing Chronic Kidney Disease in North Carolina

Disparities in Motor Vehicle Crash Fatalities of Young Drivers in North Carolina

Satomi Imai, PhD; Christopher J. Mansfield, PhD

Abstract

Background: *Motor vehicle crashes (MVCs) are the leading cause of death for young people, but rates based on the general population do not account for differences in risk across groups as proportions of people driving vary. We examine disparities in MVC death rates for various demographic groups based on numbers of drivers in each group.*

Methods: *North Carolina driver license holders 16 through 24 years of age are determined. Fatality rates per population and per licensed driver are calculated and compared by age, gender, race/ethnicity, and region.*

Results: *Proportions of individuals holding a license vary substantially by age, race/ethnicity, and region. Eighty-three percent of young Whites hold licenses compared to 68% of Hispanics, 55% of African Americans, and 52% of Native Americans. Substantial disparities in fatality by race/ethnicity and age exist using a rate per licensed driver. In younger age groups, fatality rates per licensed drivers are much greater than rates per population: 300%, 200%, 50%, and 25% greater for 16, 17, 18, and 19-year-olds, respectively. African Americans have the lowest fatality rate per population, but their rate per driver is equal to that of Whites. The rate for Native Americans is 2.2 times greater than Whites; for Hispanics, 1.5 times greater. Disparities are 20%-60% greater when rates per driver are used.*

Limitations: *Potential misspecification of race and ethnicity in records, inability to count unlicensed drivers, and exclusion of those with learner's permits may unequally bias rates across subgroups.*

Conclusions: *Significant disparities are revealed using a rate based on number of drivers. Policy makers and physicians should tailor prevention efforts accordingly.*

Keywords: *Disparities; mortality; motor vehicle crash; traffic fatalities; adolescent; risk factors*

"Is it curse or culture?… One year, one high school, three fatal wrecks, six dead teenagers…." (*Raleigh News and Observer*, January 21, 2007).[1] The 6 high school students were among 300 to 400 young North Carolinians who die each year in motor vehicle crashes (MVCs). MVCs are the leading cause of death for teens and young adults in North Carolina[2] and the United States.[3] MVC death rates per population are observed to start high for the youngest drivers, peak at age 19, and decrease significantly only after age 24.

In North Carolina in 2004, 385 teens and young adults aged 16 to 24 years were killed as drivers or passengers in motor vehicle crashes. This death rate of 36.5 per 100 000 is higher than the diabetes mortality rate (27.0 per 100 000, age-adjusted) in the general population.[4] The loss of so many years of potential life and the heartbreak of parents, friends, and loved ones is tragic, particularly because fatal crashes are preventable. The problem is widely recognized and perceived to disproportionately take the lives of young White males, but disparities by race/ethnicity and region have not been adequately examined. Significant disparities are reported here using deaths per licensed drivers rather than the number of people in the age group as the measure of fatality rate.

Reducing deaths from MVCs is a goal of the state's Healthy Carolinians 2010 Health Objectives, but the plan has no data or objectives for teens or specific population groups.[5] Existing reports, statistics, and news coverage lead to the perception that MVC deaths are primarily a young, White, male phenomenon, but this may be because more individuals of this group are behind the wheel and obtaining drivers licenses at an earlier age than youth from other groups. The risk of MVC death should be described in relation to the number of people driving and miles driven and should ideally be adjusted for road and driving

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Christopher J. Mansfield, PhD, is a professor of family medicine and director of the Center for Health Services Research and Development at East Carolina University.

conditions (day or night, wet or dry), type of vehicle, and access to emergency medical and trauma surgery services. The proportion of people obtaining licenses and having a car to drive varies across race, age, and income.[6,7] We know from national surveys that teenagers drive fewer miles than other age groups,[8] yet their fatal MVC involvement rates are the highest per miles driven.[9] We also know from national surveys that minorities and persons with low income travel fewer miles than Whites or persons with high income.[6,7] Data on the number of miles driven, however, are not available at the state or local level, and data from national surveys are neither representative of nor generalizable to state or local populations.

We use an alternative measure of risk, deaths per licensed drivers by demographic groupings, to examine trends and disparities in MVC deaths for teens and young adults across race/ethnicity, gender, and regions in North Carolina. We examine data on motor vehicle crash fatalities of young drivers aged 16 through 24 years for the years 2000 to 2004. Fatality rates per licensed driver are computed and compared to those computed per population.

METHODS

North Carolina death certificate (death file) data were obtained from the H. W. Odum Institute for Research in Social Science.[10] Population by age, race/ethnicity, gender, and county were obtained from the National Center for Health Statistics.[11] Data on the number of licensed drivers by age, race/ethnicity, gender, and county, as of December 31 for each year, were obtained by request through the University of North Carolina Highway Safety Research Center.

Data on license holders were analyzed to determine numbers and differences by age, race/ethnicity, gender, and region of residency. *Driver* was defined as an individual with a North Carolina driver's license other than a Level 1 Limited Provisional License (Learner's Permit).[12] Race or ethnicity was missing or unspecified for less than 1% of MVC deaths and 2.2% of licenses.

We define young drivers as 16 through 24 years of age to analyze MVC fatality rates for this age group as well as discrete ages within it. Teen drivers were defined as those 16 through 19 years of age. We observed fatalities occurring in North Carolina to young drivers of cars, pickup trucks, vans, off-road vehicles, and other vehicles recorded in ICD-10 codes as the underlying cause of death in North Carolina death files.[a] Passengers and occupants for whom place in car was not determined were excluded.

MVC fatality rates were calculated for drivers 16 through 24 years of age and analyzed by discrete age, age group, race/ethnicity, gender, and region for the 5-year period 2000-2004. The rates were calculated in 2 ways: deaths per population in the age group and deaths per licensed drivers in the age group. Geographic analysis examined the state as a whole, and also examined 3 distinct regions in the state, including the piedmont region, the western region, and the eastern region. The latter is the state's most rural and ethnically and racially diverse region. MVC fatality victims were classified as non-Hispanic White (White), non-Hispanic African American (African American), non-Hispanic Native American (Native American), or Hispanic (Hispanic). Others (N=5) were excluded for analyses by race/ethnicity.

RESULTS

Proportions of Licensed Drivers

The proportion of young people in North Carolina holding drivers' licenses was found to vary substantially across age, race/ethnicity, and region, reflecting differences in exposure to motor vehicle crash risks. While only a third of 16 year-olds held drivers licenses; over half (53%) of 17 year-olds had obtained licenses. Almost all members of the group obtained a license by age 24. There is little difference by gender in the proportion of 16 to 24 year-olds holding licenses (75% male, 74% female), but the proportions licensed vary substantially by race and ethnicity: 83% of young Whites, 68% of young Hispanics, 55% of young African Americans, and 52% of young Native Americans. Statewide, 75% of 16 to 24 year-olds held licenses compared to 68% in the eastern North Carolina region.

Motor Vehicle Crash Fatality Rates

During the 5-year period examined, 6012 people of all ages died from injuries sustained as occupants in motor vehicle crashes. Young people (1726) between the ages of 16 and 24 were almost a third (29%) of the 6012 killed. As this age group comprises only 12% of the total North Carolina population, its motor vehicle death rate is greatly disproportionate. Of the 1726 young people killed in MVCs, 985 (57%) were determined to be drivers; of these, 672 were White, 175 were African American, 112 were Hispanic, 21 were Native American, and 5 were Asian or other race. In 18% of deaths (309), it could not be determined that the person was the driver. These deaths were excluded from the analyses. The 5-year fatality rate for 16 to 24 year-olds was 25.4 per 100 000 licensed drivers in the age

a The International Classification of Diseases, Tenth Revision (ICD-10), by the World Health Organization specifies codes for underlying causes of death. In our analyses, we included deaths from unintentional motor vehicle injuries, including those involving motorcycle drivers (V20-V29), drivers of three-wheeled motor vehicles (V30-V39), drivers of cars (V40-V49), drivers of pick-up trucks or vans (V50-V59), and drivers of other vehicles including special vehicles (V60-69), industrial, construction, or off-road vehicles (V84-V86). Whether the death occurred to a driver or to a passenger was specified in subcategories as in .0 or .5 for cars or .0 or .4 for motorcycles.
As classified in ICD-10 coding, the majority of fatalities by MVC of 16-24 year-old drivers in North Carolina from 2000-2004 involved cars (76%) followed by pickup trucks or vans (13%) and motorcycles (9%). Off-road and heavy vehicles comprise small portions (1.7% and .6% respectively). Among MVC deaths for 16-24 year-old drivers in North Carolina from 2000-2004, 985 (57%) were drivers while 432 (25%) were passengers and 309 (18%) were unspecified/unknown.

group, one-third (33.7%) higher than the rate per population (19.0 per 100 000). Rates have generally increased in recent years in North Carolina regardless of the metric used.

Figure 1 illustrates the differences in driver fatality in North Carolina at specific ages from 16-24 years using rates per number of licensed drivers compared to rates per population. Rates and patterns vary substantially depending on the measure used.

The fatality rate per population is lower for 16 year-olds than for other age groups through age 23. The rate increases from 15.1 per 100 000 at age 16 to 24.7 per 100 000 at age 19 and then gradually declines. Measuring by deaths per drivers by age, the fatality rate is highest for 16 year-old drivers: 3 times greater than the rate based on population. The youngest drivers face the highest risk. The MVC fatality rate of 16 year-olds per licensed 16 year-old driver (45.7 per 100 000) is 1.4 times that of 17 year-old drivers and 3.6 times higher than 24 year-old drivers. The use of population as the denominator for fatality rate greatly understates the vulnerability of teen drivers. The licensed driver fatality rates for 16, 17, 18, and 19 year-olds are approximately 300%, 200%, 50%, and 25% greater than population-based rates for 16, 17, 18, and 19 year-olds, respectively. The measure-to-measure differences in MVC fatality rates for young adults continue to narrow but do not approximate equivalence until age 24.

Racial/Ethnic Disparity in Young Driver Fatality

Figure 2 illustrates the differences in fatality for young drivers among racial/ethnic groups using both metrics.

There is a substantial difference in fatality rate patterns between White, Native American, and Hispanic drivers using the per driver rate compared to the rate per population. The fatality rate per driver for African Americans is essentially equivalent to that of Whites. In contrast, using the population-based rate, young African American drivers appear to have the lowest fatality rate (13.6 per 100 000 population). Using number of drivers as the denominator, a greater disparity is revealed in fatality of young Native Americans and Hispanics compared to that of Whites and African Americans. The rate for Native Americans is 2.2 times greater than the rate for Whites; the rate for Hispanics is almost 1.5 times greater than the rate for Whites.

Racial/Ethnic Disparities in Young Driver Fatality by Age

The MVC fatality rates of young drivers differ markedly across race/ethnicity by age, revealing very different risks of death depending on the metric used. Using the rate per population, 16 year-old African American drivers appear to be the least likely to die in a motor vehicle crash (a fatality rate of 6.1 versus 19.9 per 100 000 population for Whites). However, using the rate per number of drivers (see Figure 3), White 16 year-olds are the least likely to be killed in MVCs among the racial/ethnic groups with a rate of 44.0 per 100 000 drivers versus 59.5 for African Americans, 155.0 for Hispanics, and 81.6 for Native Americans.

The greatest racial/ethnic disparities in MVC fatality rates for young drivers are among 17 year-olds. Comparing minorities to Whites in this age group, the relative risk (rate ratio) is 5.5 to 1 for Hispanics; 4.1 to 1 for Native Americans; and, 1.3 to 1 for African Americans.

Figure 1.
Motor Vehicle Fatality Rates of Young Drivers by Age in NC, 2000-2004 (per Population and per Number of Drivers)

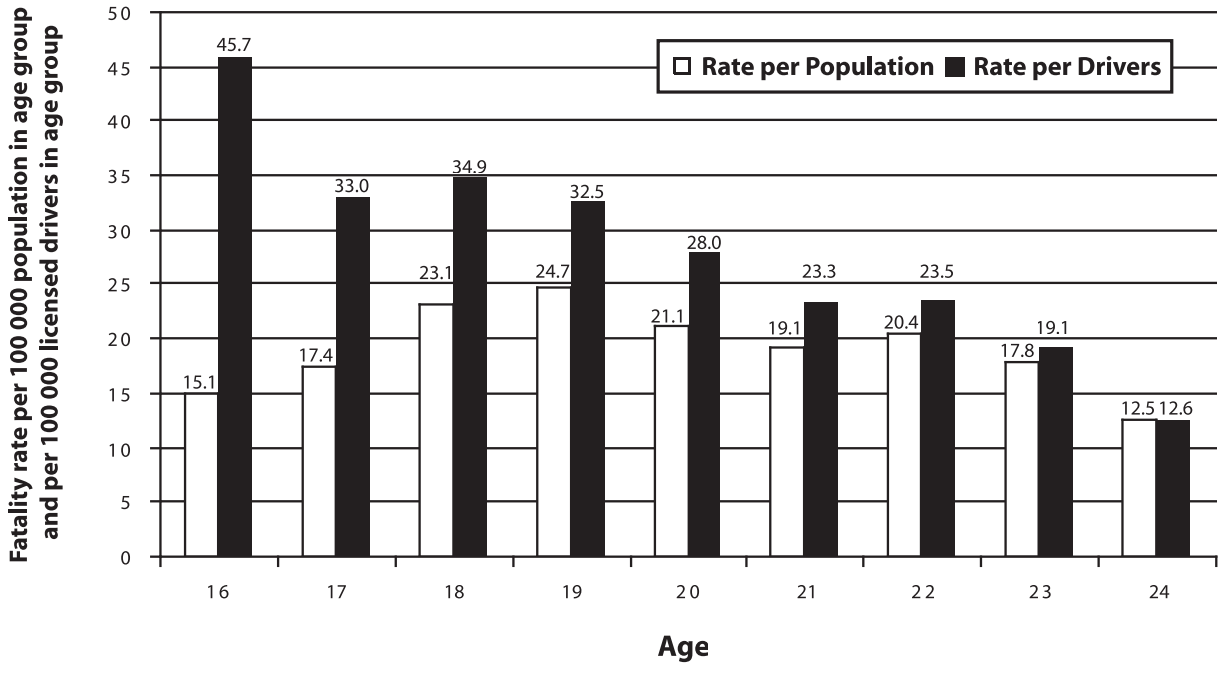
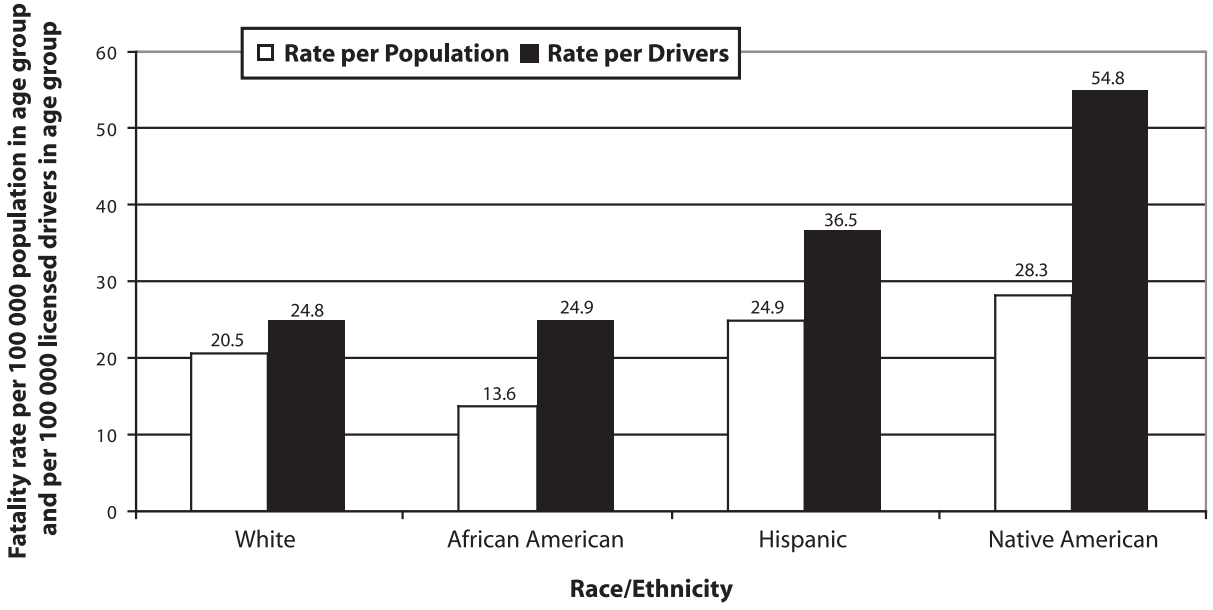


Figure 2.
Disparities in Fatality Rates of Drivers by Race/Ethnicity, Ages 16-24, in NC, 2000-2004 (per Population and per Number of Drivers)



Gender Disparity

Over the 5-year period, 745 young male drivers and 240 young female drivers died of MVCs. As there is little gender difference in the proportion of 16 to 24 year-olds holding licenses, choice of rate does not affect the magnitude of gender disparity in fatality rates. The relative risk of males compared to females is 2.8 to 1 regardless of metric. For young males the fatality rates were 36.6 per 100 000 drivers and 27.5 per 100 000 population; for young females, the comparable fatality rates were 13.1 and 9.7, respectively. Looking at a trend based on the per licensed driver rate, the rates increased over the 5-year period for both males and females from 29.3 in 2000 to 39.0 in 2004 for males and from 10.2 to 16.8 for females.

Disparities Among Regions

The eastern North Carolina region has a higher fatality rate for 16 to 24 year-old drivers than the state as a whole and than the piedmont or western regions of the state regardless of metric. The population-based rate for eastern North Carolina was 37% higher than the rest of the state but the per licensed driver rate was 58% higher. Using drivers as the denominator, the 5-year fatality rate for eastern North Carolina was 33.4 compared to 22.2 and 22.1 for the piedmont and western North Carolina, respectively.

Trend in Teen Motor Vehicle Crash Mortality

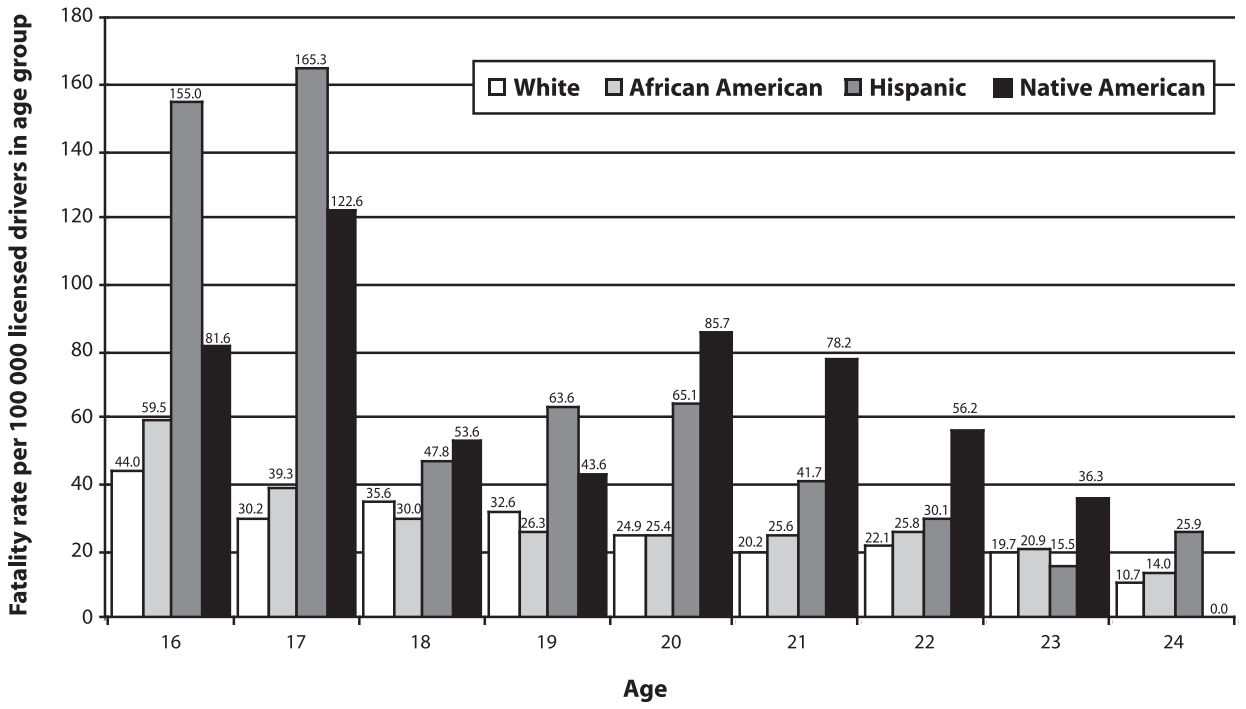
MVC deaths for the youngest drivers in North Carolina have increased over the 5-year period regardless of measure used. The MVC fatality rate for teen (16 to 19 year-old) drivers from 2000 to 2004 increased from 24.3 to 43.7 per 100 000 drivers.

DISCUSSION

The loss of so many young lives in motor vehicle wrecks is a continuing tragedy in spite of improvements in vehicle safety features and enactment of a graduated licensing law for the youngest drivers. The tragedy can be described for young people collectively by either the per population or per licensed drivers rate. While a per population rate is commonly used for descriptive epidemiology and policy, these rates do not accurately reflect risk across subpopulations if the subpopulations are not equally exposed to the basic risk of injury—operating a motor vehicle. More young White drivers are killed because there are more of them in the population. We have shown that a rate per licensed driver reveals disparities by specific age, race/ethnicity, and region of residence. Because teens and young adults do not start driving at the same age, the rate per number of licensed drivers should be used to examine variation in MVC fatalities across groups. Data on the number of drivers' licenses issued are systematically collected in North Carolina and include information on specific age, race/ethnicity, gender, and county of residence. These data are not readily available but can be obtained to describe young North Carolinians granted licenses to drive and to calculate rates based on number of drivers for specific groups.

Using a fatality rate based on the number of licensed drivers within population subgroups enables a focus on those exposed to motor vehicle crash risk and reveals not only risk within groups of young drivers but also disparities among groups. For 16 to 24 year-old drivers, unfavorable disparities in relation to the fatality rate of Whites are much greater for Hispanics and Native Americans than previously published and perceived.

Figure 3.
Motor Vehicle Fatality Rates of Young Drivers per Licensed Driver by Age and Race/Ethnicity in NC, 2000-2004



Conversely, African Americans do not have the advantage over Whites suggested by the per population rate; their risks are equivalent. A disparity for Hispanics has previously been of concern, but the Hispanic disparity increases from 21% greater than Whites to 47% greater when the per driver rate is used. Similarly, the Native American disparity goes from 38% greater to 121% greater. These racial/ethnic disparities are evident for the whole age group but greatest among 17 year-olds followed by 16 year-olds. As teen boys and girls get licenses in about the same proportion, either rate may be used for gender comparisons. MVC fatality rates have increased for both young male and female drivers, and this trend should be monitored.

There are substantial differences across the state's 3 regions. These differences are likely the result of differences in demographic characteristics, race/ethnicity, and wealth in particular, and perhaps road conditions and access to emergency medical services and trauma centers as well.

This study has limitations. Race and ethnicity are poorly defined concepts and subject to specification errors, problems inherent in all such studies. Using a per population rate in North Carolina, we must be skeptical of the accuracy of the denominator for virtually anything we would measure in regard to Hispanics; their number is difficult to establish. Using either the rate per population or per drivers, we must be skeptical of the numerator. There is potential to underreport Hispanic ethnicity on death certificates particularly when decisions are based on surname.

We may also have undercounted the number of licensed 16 year-old drivers. We included only drivers aged 16-24 years with Level 2 or higher licenses. While 16 year-olds who held Level 1 licenses would be driving legally only with a supervisor, excluding them may have inflated the per driver rate for 16 year-olds. We also had to exclude 18% of MVC deaths not specified as driver or passenger. We do not know how much bias this might cause across racial and ethnic groups.

There is also the problem of people driving without a valid license. Hispanics are more likely than other racial/ethnic groups to be driving without a valid license, which would bias their per driver rate upwards,[13] but we do not know if those drivers without valid licenses have higher risks for MVCs than those with valid licenses. Lastly, because the number of deaths of Hispanics and Native Americans are small, rates for single years and ages are unstable and should be used with caution.

The basic data for this study in North Carolina are reliable and have high validity. They are derived from the population of licensed, young drivers. Death certificate data are accurate, and we believe the license data are as well. Only about 2% of license data lacked specification of race or ethnicity. The findings cannot be generalized to other states, but we suspect that similar disparities based on drivers instead of population would be found elsewhere. Obtaining comparable data in other states may be a problem. Valid licensure data are not consistently available in many states or reliable at the national level. This is an important issue that has been brought to the attention of the Federal Highway Administration.[14-16]

Our results illuminate a greater risk for teens and young

minority drivers in North Carolina than previously thought. In the context of strategies to address deaths from motor vehicle crashes, community leaders, policy makers, injury control specialists, and public health professionals should think about how resources for interventions are targeted to specific groups and crafted to be culturally appropriate and effective. The graduated license law was an important step, and initial evaluation of its impact on 16 year-old drivers by Foss et al (2001) provides evidence that it reduced their crash rate, particularly after 9:00 pm as intended.[17] If the policy goal is reduction of fatality rates for all young drivers, we should be concerned about improvement across subpopulations. The data presented here show that for the larger 16-24 age group, neither the population-based nor driver-based fatality rates have declined during the 5 years examined here. We suggest the driver-based rate be used in evaluating success of the initiatives aimed at reducing driver death as well as in defining disparities and tracking efforts to eliminate them.

Regardless of number or rate employed, statistics in reports like this are merely sterile descriptions of tragedies. What can we do to reduce the number of young drivers killed in car crashes? Policy to tie expanding the privilege of driving with a longer graduated period of learning is a step in the right direction. Policy makers and physicians should be aware of the disparities and consider targeting messages to young African Americans, Hispanics, and Native Americans as well as young Whites. Do we need to increase the public health messages about drinking and driving for this age group, especially, for young male drivers? The 2005 Youth Risk Behavior Survey reveals that 11.8% of 11th graders and 14.2% of 12th graders drove when they had been drinking. Twenty-five percent reported that in the last 30 days they had ridden in a car with a driver who had been drinking, and 9.6% never or rarely wore a seat belt.[18] Safe driving messages about seat belts, drinking and driving, and cell phone use can come from or be reinforced by physicians. These behaviors could be included in a life-course preventive history for adolescents. Driving a motor vehicle is a serious threat to life for all young patients. **NCMJ**

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Do the Obese Know They Are Obese?

Kimberly P. Truesdale, PhD; June Stevens, MS, PhD

Abstract

Objectives: *To determine whether adults accurately perceived their weight status category and could report how much they would need to weigh in order to be classified as underweight, normal weight, overweight, or obese.*

Research Methods and Procedures: *Height and weight were measured on 104 White and African American men and women 45 to 64 years of age living in North Carolina. Body mass index (BMI) was calculated for each participant, and participants were classified as underweight (<18.5), normal weight (≥18.5 to <25.0), overweight (≥25.0 to <30.0), or obese (≥30.0). Participants self-reported their weight status category and how much they would have to weigh to be classified in each weight status category.*

Results: *Only 22.2% of obese women and 6.7% of obese men correctly classified themselves as obese (weighted kappa: 0.45 in women and 0.31 in men). On average, normal weight women and men were reasonably accurate in their assessment of how much they would need to weigh to be classified as obese; however, obese women and men overestimated the amount. Normal weight women thought they would be obese with a BMI of 28.9 kg/m^2, while obese women thought they would be obese with a BMI of 38.2 kg/m^2. The estimates were 30.2 kg/m^2 and 34.5 kg/m^2 for normal weight and obese men, respectively.*

Limitations: *The sample size was small and was not selected to be representative of North Carolina residents.*

Discussion: *Obese adults' inability to correctly classify themselves as obese may result in ignoring health messages about obesity and lack of motivation to reduce weight.*

Keywords: *Body mass index; body image; body size; awareness; perception*

The World Health Organization[1] and the National Institutes of Health[2] have set clinical guidelines using body mass index (BMI) to categorize adult weight status as underweight (<18.5 kg/m^2), normal weight (≥18.5 to <25.0 kg/m^2), overweight (≥25.0 to <30.0 kg/m^2), and obese (≥30.0 kg/m^2). While these weight status categories are widely used by researchers and clinicians, little is known about whether laypersons can accurately place themselves within these categories. Researchers have shown that adults can self-report their height and weight with reasonable accuracy,[3-5] although overweight and obese adults tend to underestimate their body weight while normal weight adults tend to overestimate their body weight. Given the growing obesity epidemic[6] and the consequences of obesity,[1,7,8] it is important to know how well obesity can be identified in order to design interventions that will reduce the numbers of people who are overweight. If people do not perceive themselves to be overweight or obese, they may not try to lose weight and may not believe that public health messages about obesity apply to them. The objectives of this study were to examine the ability of women and men to accurately (1) self-report their height and weight, (2) perceive their weight status category, and (3) recognize how much they would need to weigh in order to be classified in each weight status category.

METHODS

Study Participants and Recruitment

We recruited a purposive sample of 104 White and African American men and women (26 per race-gender group) 45 to 64 years of age selected to represent a predefined range of BMI levels. Participants were recruited via an email announcement to faculty, staff, and students at the University of North Carolina at Chapel Hill and via flyers distributed in the Raleigh-Durham-Chapel Hill area of North Carolina. Participants were asked to participate in a study to help improve our understanding of waist measurements and weight

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maintenance. Exclusion criteria were underweight (<18.5 kg/m^2), self-reported poor health, inability to read and write in English, lack of transportation to the General Clinical Research Center at the University of North Carolina at Chapel Hill, and health problems that would cause pain, discomfort, or skin irritation when having waist and hip circumferences or tricep and subscapular skinfolds measured. This study was approved by the University of North Carolina at Chapel Hill Public Health Institutional Review Board as research involving human subjects.

Anthropometrics

Body weight was measured without shoes on a standard physician's balance beam scale and was recorded to the nearest pound (1 lb=0.454 kg). Height without shoes was measured to the nearest centimeter (1 cm=0.394 in) using a metal rule attached to a wall and a standard triangular headboard using a vertical ruler. BMI was calculated as weight in kilograms (kg) divided by height in meters squared (m^2). Based on participants' measured BMI (kg/m^2), they were classified as normal weight, overweight, or obese.

Self-Administered Questionnaire

Prior to the anthropometric measurements, participants completed a brief self-administered questionnaire. Self-reported BMI and weight status categories were based on the participant's self-reported height (feet and inches) and weight (pounds). Participants were asked, "Would you consider yourself now [underweight, normal weight, overweight, or obese]?" (hereafter described as *perceived weight status*). They were also asked, "How much would you have to weigh to classify yourself as [underweight, normal weight, overweight, obese]?" (4 separate questions). Since height varied across participants, the reported weights were converted to BMI using the participant's measured height (hereafter reported as *BMI cutpoint for underweight, normal weight, overweight, and obesity*).

Statistical Analysis

Differences between self-reported and measured height, weight, and BMI were calculated such that negative values indicated that participants underestimated their actual height, weight, or BMI. Linear regression models (using the PROC GENMOD procedure) were used to estimate (1) the mean difference between self-reported and measured height, weight, and BMI, and (2) the mean reported BMI cutpoint for each weight status category. All models were stratified by gender and adjusted for age and race. The LSMEANS option was used to determine whether the adjusted means differed by measured weight status category. Frequency distribution and corresponding unweighted and weighted kappa statistics were calculated to assess the percent agreement between measured and perceived weight status categories. All analysis was done using SAS version 9.1 (SAS Institute, Cary, North Carolina).

RESULTS

Table 1 shows demographics characteristics in women and men by measured weight status. Normal weight women and men were slightly younger than those women and men who were overweight and obese. Normal weight women and men were predominately White (80.0% and 68.8%, respectively), whereas a substantially lower percentage of obese women and men were White (27.8% and 13.3%, respectively).

Self-Reported Versus Measured Weight and Height

Overall, the correlation between self-reported weight, height, and BMI and the measured values were 0.99, 0.91, and 0.99 in women and 0.99, 0.95, and 0.98 in men, respectively. In general, participants tended to slightly underestimate their weight (-0.5 lbs in women and -0.2 lbs in men) and overestimate their height (0.8 cm in women and 1.0 cm in men) resulting in underestimation of BMI (-0.4 kg/m^2 in women and men).

Table 1.
Demographic Characteristics by Measured Weight Status Categories†

	Measured Weight Status Categories					
	Women			Men		
	Normal Weight (n=15)	Overweight (n=19)	Obese (n=18)	Normal Weight (n=16)	Overweight (n=21)	Obese (n=15)
Age: years (SD‡)	50.9 (4.6)	53.0 (5.4)	52.5 (4.5)	51.5 (5.6)	55.2 (4.4)	52.4 (5.9)
Race: % White	80.0	47.4	27.8	68.8	61.9	13.3
Measured Anthropometrics						
Weight: lbs (SD)	131.2 (14.7)	164.1 (13.9)	209.6 (32.3)	166.2 (18.2)	194.9 (18.0)	236.2 (39.0)
Height: in (SD)	64.6 (2.1)	64.8 (1.9)	64.2 (2.1)	70.5 (3.3)	70.2 (2.8)	70.3 (2.4)
BMI: kg/m^2 (SD)	22.1 (1.8)	27.4 (1.5)	35.7 (4.6)	23.5 (1.0)	27.8 (1.6)	33.5 (4.7)

† Measured weight status categories were based on participants' measured height and weight.
‡ Standard deviation

Percent Agreement Between Perceived and Measured Weight Status Categories

The percent agreements between perceived and measured weight status categories for women and men are shown in Table 2. We found that 66.7% of normal weight women and 89.5% of overweight women correctly perceived their weight status category. However, 33.3% of normal weight women considered themselves to be overweight (overreported) and 10.5% of overweight women considered themselves to be normal weight (underreported). In contrast, only 22.2% of obese women considered themselves to be obese. Seventy-two percent of obese women considered themselves to be overweight and 5.6% perceived themselves as normal weight. In normal weight men, 75.0% correctly identified themselves as normal weight, 12.5% underreported, and another 12.5% overreported their weight status. However, 42.9% of overweight men considered themselves to be normal weight, and 57.1% correctly perceived themselves as overweight. Only 6.7% of the obese men considered themselves to be obese. Similar to women, the majority (73.3%) classified themselves as overweight, and 20% considered themselves to be normal weight.

Table 2.
Percent Agreement Between Perceived† and Measured‡ Weight Status Categories

	Measured Weight Status Categories					
	Women			Men		
Perceived Weight Status Categories	Normal Weight (n=15)	Overweight (n=19)	Obese (n=18)	Normal Weight (n=16)	Overweight (n=21)	Obese (n=15)
Underweight	0.0	0.0	0.0	12.5	0.0	0.0
Normal Weight	66.7	10.5	5.6	75.0	42.9	20.0
Overweight	33.3	89.5	72.2	12.5	57.1	73.3
Obese	0.0	0.0	22.2	0.0	0.0	6.7
	(kappa=0.38; weighted kappa=0.45)			(kappa=0.21; weighted kappa=0.31)		

† Perceived weight status categories were based on participants' response to the question, "Would you consider yourself now [underweight, normal weight, overweight or obese]?"

‡ Measured weight status categories were based on participants' measured height and weight.

Reported BMI Cutpoints for Underweight, Normal Weight, Overweight, and Obesity

The reported BMI cutpoint for underweight was similar across measured weight status categories. (See Figure 1.) Overweight and obese women's reported BMI cutpoints for normal weight (23.2 kg/m^2 and 24.6 kg/m^2) were within the normal weight definition but were significantly higher than BMI cutpoints reported by normal weight women (21.2 kg/m^2). The magnitude of the differences reported by normal weight and overweight women compared to obese women increased when examining the BMI cutpoints for overweight and obesity.

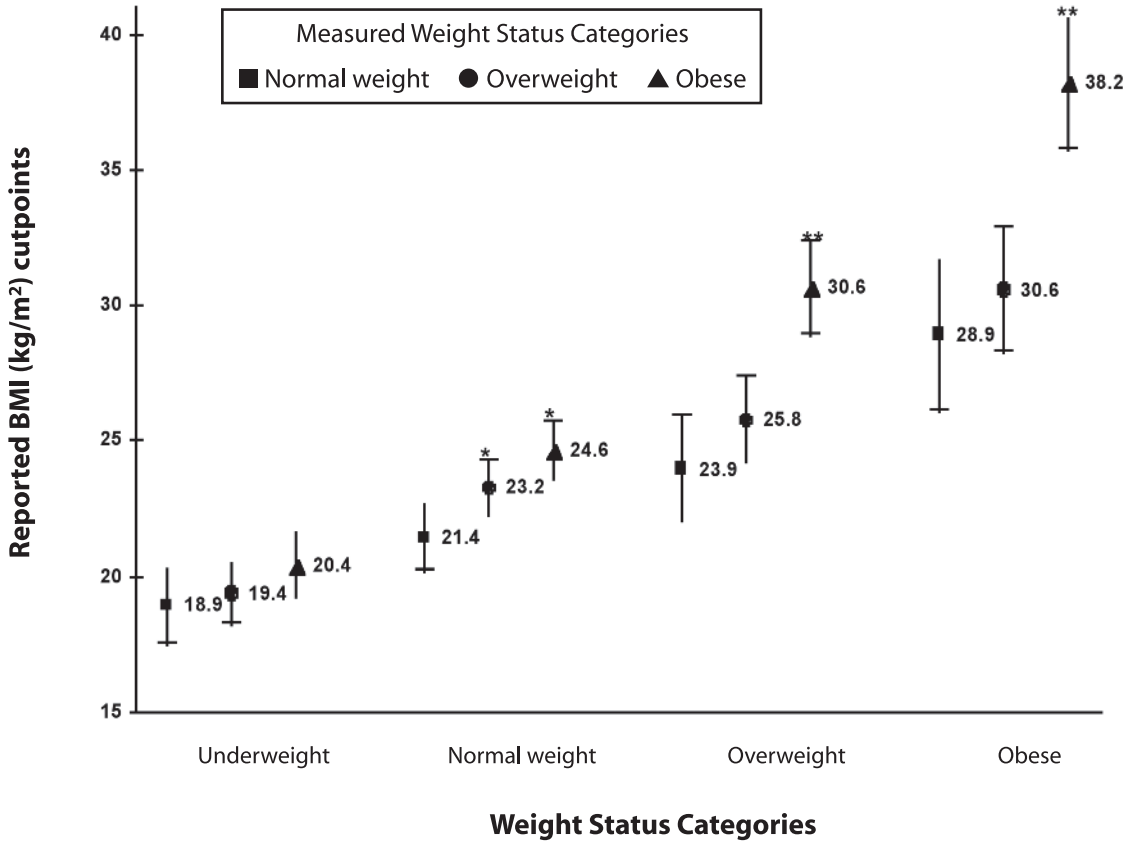
The discrepancies in the reported BMI cutpoints for underweight, normal weight, overweight, and obesity across measured weight status categories appeared smaller in men (see Figure 2) than in women. Reported BMI cutpoints for underweight and normal weight among obese men (23.9 and 26.7 kg/m^2) were significantly larger than for normal weight (20.9 and 23.5 kg/m^2) and overweight (22.3 and 25.5 kg/m^2) men. In addition, obese men's reporting of BMI cutpoints for overweight and obesity differed significantly from that of normal weight men.

DISCUSSION

The current study examined the accuracy of self-reported height and weight, perceived weight status category (underweight, normal weight, overweight or obese), and ability to recognize how much one would need to weigh in order to be classified in each weight status category. Our results showed that in general women and men tended to slightly underreport their weight and overreport their height, thus causing BMI to be slightly underreported. These findings are consistent with other studies.[3-5,9] Using self-reported weight and height, the majority of subjects would have been categorized into the correct weight status category. In general, the magnitude of underreporting for obesity was greater among women than men (3.9 versus 1.9 percentage points). Similar patterns were found using data from the third National Health and Nutrition Examination Surveys (NHANES III), where the prevalence of obesity was underreported by 4.5 and 6.1 percentage points in White and African American women and 3.2 and 2.3 percentage points in White and African American men[10] when they were categorized using BMI from self-reported height and weight.

We saw less accuracy when participants classified themselves into the weight status categories, and 40.4% of women and 51.9% of men misclassified their weight status category. Researchers wanting to classify adults into weight categories should ask participants to report their weight and height and use these data to construct weight status categories rather than asking participants to classify themselves into a category.

Figure 1.
Reported BMI Cutpoints for Underweight, Normal Weight, Overweight, and Obese in Women by Measured Weight Status Category (Models were Adjusted for Age and Race.)



* Significantly different (p<0.05) than normal weight women.

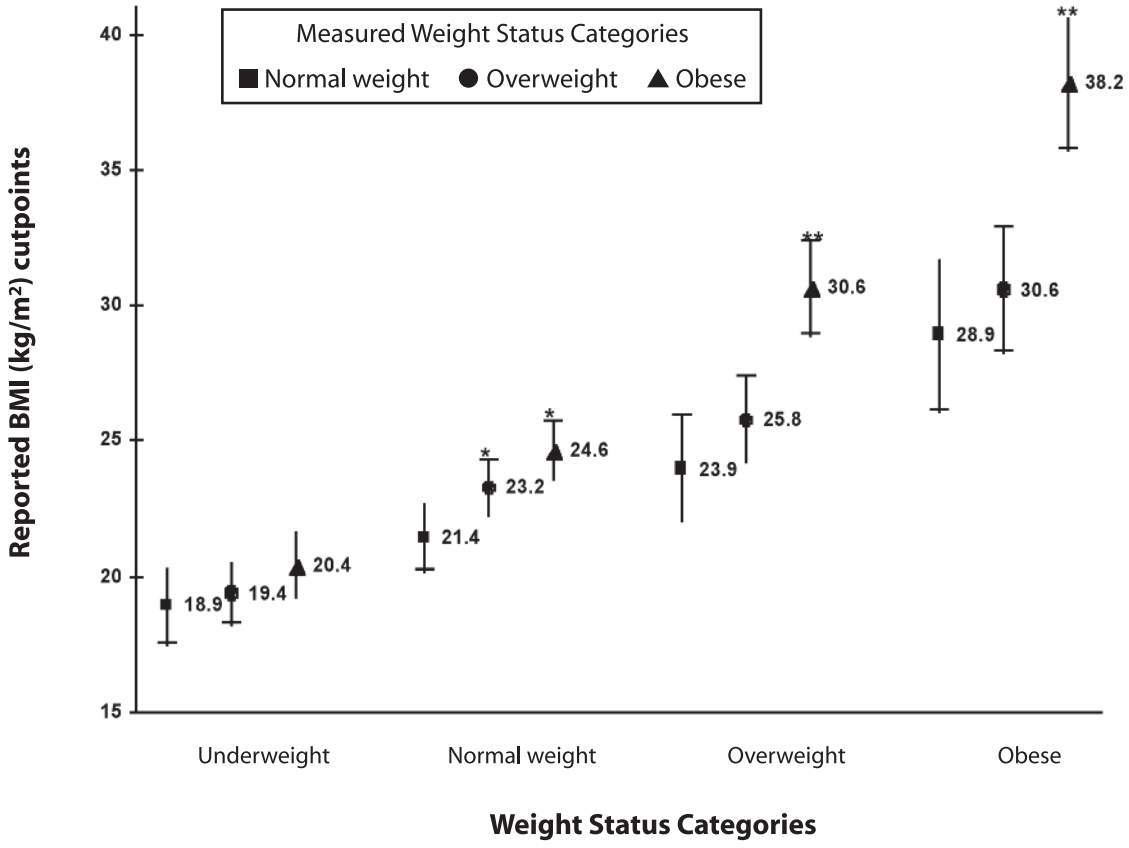
** Significantly different (p<0.05) than normal weight and overweight women.

Perceptions of how much one needed to weigh in order to be classified in each weight status category varied by gender and measured weight status. Given our findings, a normal weight woman 64 inches (5 ft, 4 in) tall would estimate overweight to be 139 pounds (BMI=23.9 kg/m^2) and obesity to be 168 pounds (BMI=28.9 kg/m^2), whereas an obese woman of the same height would estimate 178 pounds (BMI=30.6 kg/m^2) and 222 pounds (BMI=38.2 kg/m^2), respectively. A normal weight man 70 inches (5 ft, 10 in) tall would estimate normal weight to be 164 pounds (BMI=23.5 kg/m^2) and obesity to be 210 pounds (BMI=30.2 kg/m^2), whereas an obese man of the same height would estimate 186 pounds (BMI=26.7 kg/m^2) and 241 pounds (BMI=34.5 kg/m^2), respectively.

Other investigators have examined how accurately adults can identify their weight status.[11-14] Using data from the NHANES III study, Chang et al found moderate agreement between self-perceived and measured weight status (kappa= 0.48 for women and 0.45 for men).[11] Approximately 27.5% of women and 29.8% of men misclassified their weight status.[11] The smaller percentage of weight status misclassification in the Chang et al study compared to the current study may have been due to the number of categories listed. In the current study, subjects were able to select from 4 weight status categories (underweight, normal weight, overweight, obese) as opposed to the 3 categories used in the NHANES III study.[11] Australia's 1995 National Health Survey and National Survey also used only 3 weight status categories (acceptable weight, underweight, overweight) and found less misclassification (28% of women and 50.7% of men)[12] than found in the current study (40.4% of women and 51.9% of men). If we combined the overweight and obese categories in the current study, the misclassification percentage decreased to 15.4% in women and 30.8% in men and the kappa statistics increased in women (unweighted: 0.38 to 0.61, weighted: 0.45 to 0.61) and men (unweighted: 0.21 to 0.40, weighted: 0.31 to 0.43). This suggests that many women may not distinguish between overweight and obesity, whereas many men may not distinguish between normal weight and overweight.

Another possible explanation for the larger percentage of misclassification in the current study is the use of the term obese as one of the weight status categories. Wardle et al found that approximately 35% of men and women misclassified their

Figure 2.
Reported BMI Cutpoints for Underweight, Normal weight, Overweight, and Obese in Men by Measured Weight Status Category (Models were Adjusted for Age and Race.)



* Significantly different (p<0.05) than normal weight women.

** Significantly different (p<0.05) than normal weight and overweight women.

weight status;[13] however, the largest weight status category was referred to as very overweight instead of obese. In a study of Dutch men and women, Blokstra et al asked participants to describe their weight status as too fat, too thin, or just right.[14] The majority of normal weight men (79.2%) and women (73.3%) considered their weight to be just right. In addition, the majority of obese men (91.4%) and women (97.2%) considered themselves to be too fat. The findings from these studies suggest that adults may be more reluctant to label themselves obese as opposed to very overweight or too fat.

Blokstra et al asked participants their ideal body weight and converted it to BMI units.[14] The reported ideal BMI was higher among obese men and women (27.5 and 27.1 kg/m^2) compared to normal weight men and women (22.7 and 21.3 kg/m^2). Crawford et al asked participants, "Ideally, how much would you like to weigh at the moment?" and "In your opinion, what is the most you could weigh and still not consider yourself overweight?"[15] Using measured heights 1 year prior, the weights were converted into BMI units. The BMIs considered ideal and overweight were 22.7 and 23.7 kg/m^2 among women and 24.9 and 26.1 kg/m^2 among men. Both estimates increased across measured weight status categories. This is similar to our finding that as weight status increased, the reported BMI cutpoints for each weight status category increased.

Whisenhunt et al asked women to report (given specified heights) the weight range for 6 weight categories (extremely underweight, underweight, normal weight, overweight, obese, and extremely obese).[16] They found significant differences between normal weight and overweight participants in the lower and upper BMI cutpoints reported for normal weight, overweight, and obesity. For example, normal weight participants defined normal weight as 19.95 to 22.12 kg/m^2 and obesity as 26.75 to 30.83 kg/m^2, whereas obese women defined these categories as 21.65 to 24.27 kg/m^2 and 32.19 to 37.68 kg/m^2. In the current study we did not ask participants for a weight range, therefore it is plausible that differences between the categories could be due to normal weight participants reporting minimum weights and obese participants reporting maximum weights for each category.

Another potential reason for the lower percentage of obese women and men correctly identifying themselves could be their reluctance to report that they are obese to a health care researcher.

However, it is important to note that the obese subjects self-reported their current weight and height with reasonable accuracy. The main discrepancy came when they had to put a label on their weight. The term obesity can have social associations such as negative bias, stigma, and discrimination.[17] These associations may make adults more reluctant to label themselves as obese. In addition, images of obesity in popular media often show class II or III obesity (BMI≥35.0 kg/m^2). This could distort the perceived definition of obesity.

Limitations

This study has limitations that should be considered when interpreting the findings. The study sample was composed of volunteers living in specific areas of North Carolina and was not selected to be representative of a population. Therefore caution must be used in the generalization of results. Another limitation was the small sample size. We were able to detect some differences by gender and race; however, more subtle trends may have been missed including bias associated with education or employment The study design resulted in unequal distribution of normal weight, overweight, and obese women and men in each race-gender group. It is possible that ethnic differences in attitudes toward weight could have influenced our findings, although we did not find any significant or suggestive race interactions. Other investigators have shown that African American women express a greater amount of body satisfaction and acceptance at higher BMI levels compared to White women.[18-23] In addition, other studies have shown that African Americans tend to have lower rates of perceived overweight compared to Whites.[24-27]

Another limitation is that demographic variables (ie, marital status, education level) that have been shown to be associated with perceived weight status were not collected. Wardle et al found that adults in lower socioeconomic status classes were less likely (OR=0.57, 95% CI: 0.39 – 0.84) to perceive themselves as overweight compared to socioeconomic class 1 and 2 (higher social class).[28] Paeratakul et al also found higher rates of self-perceived overweight in adults with higher education level (OR=1.6, 95% CI: 1.1-2.3) and higher income level (OR=1.5, 95% CI: 1.2-1.7).[25] This study did not examine why obese women and men did not consider themselves to be obese. Possible reasons include skewed perception, denial, and reluctance to report obesity in a study setting.

CONCLUSIONS

This work suggests that women and men can report their weight and height with reasonable accuracy, but most obese women and men do not consider themselves to be obese. This has implications for research and for public health efforts. Researchers seeking to classify adults into weight status categories will obtain more accurate data by using self-reported weight and height to classify participants than by using self-report of weight status. Public health messages about the consequences of obesity may not reach their targets as obese individuals do not think of themselves as such. More research is needed in larger and more generalizable samples to help our understanding of why obese women and men do not consider themselves to be obese. This will help guide future obesity intervention research. **NCMJ**

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POLICY FORUM

Chronic Kidney Disease in North Carolina

"In North Carolina alone, almost 1 million people have CKD not including those with kidney failure."

INTRODUCTION

Policy Forum:
Chronic Kidney Disease in North Carolina

North Carolina—and indeed the nation—is facing a chronic kidney disease (CKD) epidemic. Estimates are that nearly 1 million North Carolinians have chronic kidney disease, ranging from early stage to end-stage. We think this statistic may come as a surprise to many, as it did to us. This surprise is tempered, however, when one considers that 3 of the major risk factors for CKD—hypertension, diabetes, and cardiovascular disease—are health conditions that are very common among Americans. The earliest stages of CKD often go undetected—hidden by a guise of seemingly good health and proper kidney function. The disease is eventually diagnosed once it has reached a more advanced stage and kidney function is greatly impaired. Chronic kidney disease is like an iceberg where the tip represents end-stage CKD, while the much greater bulk of the iceberg's mass beneath the water is analogous to the early stages of CKD.

We know that particular groups are at increased risk for CKD, such as those people with certain chronic diseases and those of certain racial and ethnic groups. However, many of these individuals are unaware of their increased risk status. It is imperative to reach them through the many channels of our health care system. In order to reduce the burden of CKD in North Carolina, we must take steps to prepare our health professional workforce, especially primary care providers who are truly on the front lines of this epidemic as they are the point of entry into the health care system. This is made more important in North Carolina where the ratio of nephrologists to CKD patients is very low relative to other states and recommended standards—making it very unlikely that every CKD patient in the state will have access to a nephrologist.

Primary care providers (PCPs) must have the resources—including time and information—to develop and implement clinical systems that encourage the early detection of CKD and enable a referral to specialty care when needed. Given the shortage of nephrologists, the existing demands on PCPs, the prevalence of CKD, and the chronic nature of the disease, it seems apparent that we should promote the identification and training of allied health professionals who can provide case management and specialized care to those with CKD to help them lead the most productive and healthy lives possible.

The North Carolina Institute of Medicine Task Force on Chronic Kidney Disease recently published a report outlining recommendations to reduce the impact CKD has on North Carolinians and the state. Successful implementation of these recommendations will only happen through collaborative, statewide efforts from many individuals and groups. We hope this issue inspires the public to learn more about CKD, to raise awareness of this disease in communities, and to help people incorporate behaviors that will help prevent CKD. For professionals, we hope this issue will suggest new practices and methods that can improve the prevention, early detection, and treatment of CKD.

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Chronic Kidney Disease in North Carolina

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In the middle of the last century, chronic diseases overtook communicable diseases as the leading causes of death in the United States.[1] Public health campaigns and the scientific community have responded and developed national strategies to prevent and cure diseases including cancer, diabetes, HIV/AIDS, and hypertension. While the morbidity and mortality resulting from these diseases warrant this attention, other equally serious chronic diseases unfortunately receive less attention. One of these conditions is chronic kidney disease (CKD). Death from kidney failure, the most severe form of CKD, is more common than many of the most prevalent forms of cancer. (See Figure 1.)

Chronic kidney disease encompasses various levels of kidney damage ranging from a relatively asymptomatic decline in kidney function to kidney failure. Chronic kidney disease, in all its stages, is estimated to affect 13% of the United States population.[2] In North Carolina alone, almost 1 million people have CKD not including those with kidney failure.[3] Despite the large number of people living with CKD, there is an overall lack of knowledge about the disease even among people who have it. Nationally, only about 25% of Americans diagnosed with CKD reported awareness of weak or failing kidneys.[4] Among the general population, there is even less awareness. Preliminary data from a University of North Carolina at Chapel Hill (UNC) Kidney Center study shows that many people are unfamiliar with the risk factors for CKD.[5]

The combination of high disease burden and low public awareness warranted an in-depth study of how North Carolina can best act to lower the CKD disease burden in the future.

In 2006 the North Carolina General Assembly asked the North Carolina Institute of Medicine to convene a task force to study chronic kidney disease (Session Law 2006-248). The task force was funded by the state of North Carolina through its annual appropriation to the North Carolina Institute of Medicine. Marcus Plescia, MD, MPH, chief of the Chronic Disease and Injury Section of the Division of Public Health, and Leanne Skipper, chief executive officer of the National Kidney Foundation of North Carolina, served as cochairs of the task force. The task force consisted of 39 other members representing a wide range of health care professionals, insurers, policymakers, consumers, and other interested individuals. The task force was charged with developing a plan that would reduce the occurrence of chronic kidney disease, educate health

"Addressing this public health threat [chronic kidney disease] will take a concerted and coordinated effort by actors throughout the health care system intervening at multiple points..."

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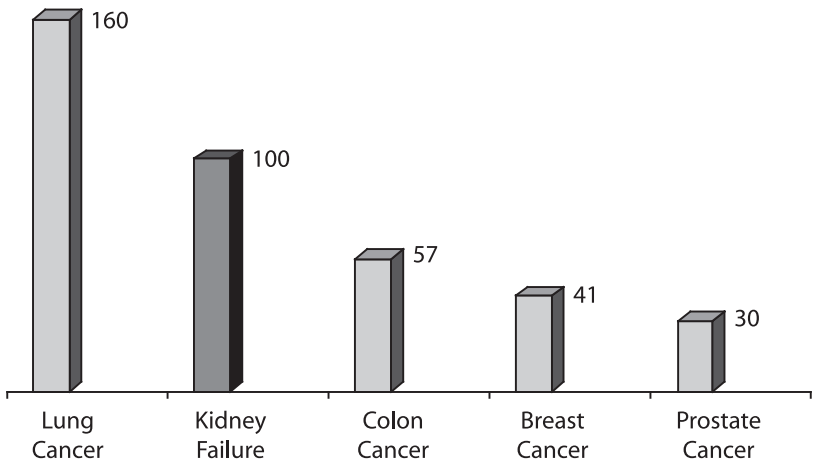
Figure 1.
Deaths Due to Kidney Failure Compared to Cancer Deaths in the US, 2000 (in thousands)



Data taken from 2004 update to Gloeckler Ries GA, Reichman ME, Riedel Lewis D, Hankey BF, Edwards BK. Cancer survival and incidence from the Surveillance, Epidemiology, and End Results (SEER) Program. *The Oncologist*. 2003;8:541-552.

care professionals and the public, identify barriers to the adoption of best practices, and include recommendations to address these barriers. The task force met over a period of 18 months and made 15 recommendations which are discussed below. Because kidney function typically declines with age, the overwhelming majority of people with CKD are adults. Thus, the task force focused its analysis and recommendations on care for adults with CKD. The pediatric CKD population is unique in its needs and complications. Maria Ferris and colleagues outline concerns specific to children in their commentary focusing on pediatric chronic kidney disease.

The kidneys function to remove waste from the blood and produce hormones that help make red blood cells, regulate blood pressure, maintain calcium for bones, and regulate normal chemical balance in the body. Loss of kidney function can lead to a decline in other bodily functions. Kidney disease contributes to high blood pressure (hypertension), high blood sugar, high lipid levels, anemia, and bone disease—all of which can exacerbate other health problems. In fact, people with kidney disease are more likely to die from cardiovascular disease than from kidney failure. However, many people with chronic kidney disease progress to kidney failure, the most severe form of CKD. These patients need treatment including dialysis or transplantation to avoid the buildup of toxins that can lead to death.[6]

People who receive treatment for their kidney failure are considered to have end-stage kidney disease (ESKD).[a,b] According to the United States Renal Data System, more than 1.8 million people suffer from ESKD worldwide including 387 000 people in the United States and 11000 people in North Carolina. The number of people with ESKD per population in North Carolina has been consistently higher than the national average.

The risk of developing ESKD is not uniform across the population; racial and ethnic minorities are at higher risk than non-minorities. African Americans have 3.7 times the risk of developing kidney failure as do Whites. Native Americans have 1.9 times and Asian Americans have 1.3 times the risk of developing kidney failure as do Whites. Some people have clinical or other sociodemographic risks that increase their likelihood of developing CKD.[7] For example, people with diabetes, high blood pressure, cardiovascular disease, autoimmune disease (eg, lupus), systemic infections, urinary tract infections, urinary stones, lower urinary tract obstruction, cancer, family history of CKD, history of acute kidney failure, decreased kidney size, exposure to drugs toxic to the kidneys, or low birth weight are at increased risk of developing CKD.[7,8] Similarly, older adults, people with low incomes or low educational achievement, or those with exposure to certain chemical and environmental conditions are in higher risk categories.[7] Suma Vupputuri includes further details of the epidemiology of CKD in her commentary.

As useful as statistics and trends can be in describing the overall burden of the condition across the state, chronic kidney disease affects individuals. Understanding the multiple challenges people with CKD face is critical to understanding how to address CKD in North Carolina. Deidra Hall and Celeste Castillo Lee offer patient perspectives in their commentary.

The work of the task force was organized into a system of care for chronic kidney disease. (See Figure 2.) Ideally, the system begins with primary prevention of the conditions (eg, hypertension, diabetes) that can lead to kidney disease. This needs to be coupled with broad consumer education and outreach to help inform the general public about CKD and the risk factors that contribute to this problem. People at higher risk of kidney disease should be screened for the disease. Individuals who are identified as having CKD should be linked into a primary care medical home and have their kidney function regularly monitored. Primary care providers should help patients treat their disease and any comorbid conditions that could otherwise exacerbate their health problems. In addition, people with CKD should receive care management and disease management services to

a End-stage kidney disease (ESKD) and end-stage renal disease (ESRD) refer to the same condition.

b Kidney failure includes those patients who are not treated with dialysis or transplantation while the term ESKD does not.[23]

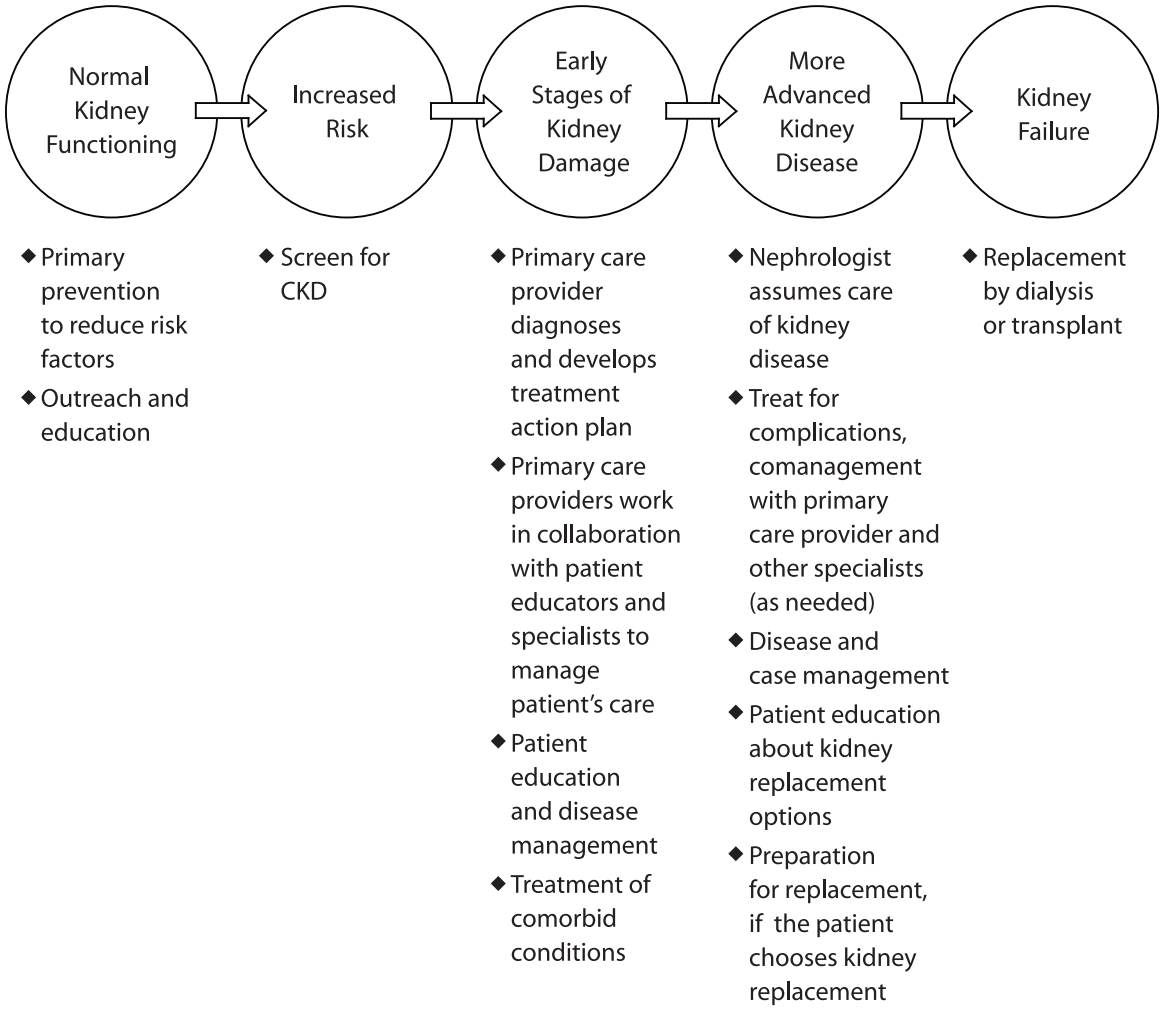
help them control their disease. As their kidney disease progresses further, patients should be referred to nephrologists who work collaboratively with primary care providers and other health care professionals to develop treatment plans and manage patients' health problems. Nephrologists should also help educate patients about options for renal replacement therapy before they progress to end-stage renal failure.

Primary Prevention, Outreach, and Education

Diabetes mellitus and hypertension are major causes of chronic kidney disease and kidney failure. Diabetes is an underlying cause in 42% of new patients diagnosed annually with CKD.[9] Almost 90% of these patients have type 2 diabetes mellitus, the prevalence of which is growing rapidly. From 2001 to 2006 the percentage of North Carolina adults who reported being told by a physician they had diabetes rose by over one-third from 6.7% to 9.1%.[10] People with uncontrolled high blood pressure also have a greater risk of developing chronic kidney disease.[11] Not only do these chronic health conditions increase the risk of someone developing CKD, they are also major contributors to kidney failure. Together, diabetes mellitus and hypertension contribute to approximately 60% of new cases of people with kidney failure.[12] North Carolina can help prevent chronic kidney disease by reducing risk factors that lead to diabetes or hypertension such as obesity, poor nutrition, and lack of exercise. The task force recommended that **existing primary prevention efforts aimed at reducing the risk factors which contribute to diabetes and hypertension be further supported and expanded**.

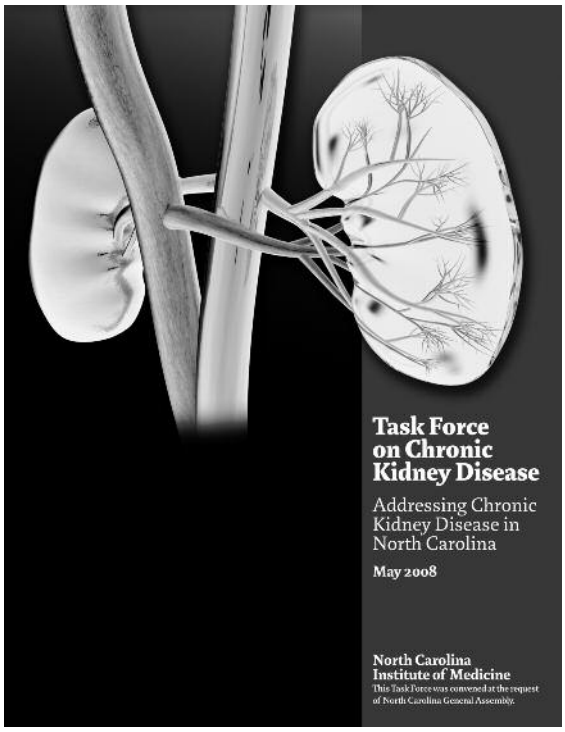
In addition to primary prevention of diabetes and hypertension, many complementary outreach strategies are

Figure 2.
Coordinated System of Care for Patients as They Progress with Kidney Disease



Adapted from: National Kidney Foundation. K/DOQI clinical practice guidelines for chronic kidney disease: evaluation, classification, and stratification. *Am J Kidney Dis*. 2002;39(2)(suppl 1):S1-S266.

needed to educate the public about kidney health and CKD. Broad-based health education efforts can be effective in reducing the primary risk factors that ultimately lead to chronic kidney disease, especially when these approaches are combined with policy and environmental change interventions.[13] There are already several community-based health education efforts that could be expanded to reach more people or different at-risk populations. Some of these initiatives are designed to increase awareness of kidney health and related risk factors for CKD; others work with targeted populations around diabetes or other health conditions. Barbara Pullen-Smith and Marcus Plescia provide an overview of programs housed within the North Carolina Division of Public Health in their commentary. Two particular programs that show promise are outlined further: Leanne Skipper focuses on National Kidney Foundation programs while Donna Harward focuses on the UNC Kidney Education Outreach Program.



Existing programs help educate the public on chronic kidney disease and other health conditions that can lead to CKD, but there is a need for greater outreach to target at-risk populations throughout the state. The task force recommended that **the North Carolina General Assembly appropriate $500,000 to the Office of Minority Health and Health Disparities to expand existing diabetes education programs that educate at-risk populations about CKD and the importance of early screening.** These programs should be developed in collaboration with community partners such as faith-based health ministries, civic organizations, and senior citizen groups and should be evaluated to determine their effectiveness. The task force also recommended that **public and private insurers should examine patient-level data to determine those at risk for or diagnosed with CKD and explore mechanisms to increase awareness of CKD among those at risk.**

Screening High-Risk Individuals

The Kidney Disease Outcomes Quality Initiative (KDOQI) of the National Kidney Foundation (see below) suggests primary care practitioners should routinely screen people with CKD risk factors (eg, diabetes, hypertension, family history of kidney disease) for kidney function and should monitor kidney function over time.[7] More recent research shows that cardiovascular disease (CVD) is also a risk factor which contributes to CKD, and therefore patients with CVD should also be screened for chronic kidney disease.[14,15] There are a variety of screening tests that are widely available, easily obtained, and relatively inexpensive.

People with health insurance generally are covered for screening, but there is no statewide screening program for people who are uninsured. To compound this problem, uninsured individuals who have been diagnosed with CKD may not be able to pay for the care and treatment needed to slow the progression of the disease. There are safety net programs in certain communities that provide ongoing primary care services to the uninsured on a sliding fee scale.[c,16] However, these organizations do not serve all areas of the state, and not all safety net organizations have the capacity to provide comprehensive and ongoing primary care services to people with chronic illnesses.

With these gaps in mind, the task force recommended that **the North Carolina General Assembly should provide $500,000 in recurring funding to the Division of Public Health to help pay for the screenings of uninsured patients who are at high risk for developing kidney disease, $2.4 million to expand safety net organizations to provide primary care to uninsured individuals with CKD,[d] $15 million to expand care to the uninsured with other chronic illnesses that can lead to CKD, and $5 million to the North Carolina Division of Public Health Purchase of Medical**

c Certain health care organizations have a legal responsibility or mission to provide ambulatory health care services to the uninsured for free or on a sliding fee basis. These include community and migrant health centers (federally qualified health centers), state-funded rural health clinics, free clinics, local health departments, hospital emergency departments or outpatient clinics, and other nonprofit community organizations. However, certain organizations—including many free clinics, health departments, and hospital emergency rooms—do not the have the capacity or resources to provide ongoing comprehensive primary care services to individuals to help them manage their chronic conditions.

d The North Carolina General Assembly already appropriates some funding to expand and strengthen the health care safety net for uninsured patients. In FY 2008 the General Assembly appropriated $2 million in recurring funds and $5 million in nonrecurring funds to the Office of Rural Health and Community Care in the North Carolina Department of Health and Human Services to expand the health care safety net. This initiative is called the Community Health Center grants program. The task force recommended that this program be expanded further to meet the primary care needs of people with CKD who do not otherwise have a medical home ($2.4 million) and for uninsured with other chronic health problems that could lead to CKD ($15 million).

Care program to help pay for nephrologist consults for uninsured patients with incomes <200% of federal poverty guidelines.

Primary Care and Collaborative Care Teams

Most people receive outpatient health care services through primary care practitioners (PCPs) who provide preventive, primary, and acute medical services and help coordinate the care that people with complex or chronic illnesses receive from specialists. While they are the principal source of outpatient medical care for most patients, PCPs face significant challenges providing all the recommended care to their patients. The practice of medicine is constantly evolving as clinical guidelines are added, deleted, or refined, making it difficult for primary care practitioners to remain current with all existing guidelines relevant to their patients.

The National Kidney Foundation, using an expert consensus process, has identified evidence-based strategies for screening, staging, and treating patients with CKD. These guidelines, called the Kidney Disease Outcomes Quality Initiative (KDOQI), recommend—as do evidence-based guidelines for treatment of patients with diabetes and hypertension—that primary care practitioners screen people at high risk and identify patients with chronic kidney disease.[e] However research suggests that chronic kidney disease is often not detected even when patients have access to primary care.[17] Some PCPs are unaware of all the risk factors or the current evidence-based guidelines for CKD.[18,19] To address this information gap among some practitioners, the task force recommended that **health professions organizations across the state collaborate to provide targeted CKD education for primary care practitioners.**

The task force spent considerable time discussing ways to reduce the barriers PCPs face in identifying people with CKD. The most specific test of kidney function tests for creatinine, a waste product in the blood. Creatinine is normally removed by the kidneys, but people with declined kidney function have increased creatinine levels. Primary care practitioners often order blood serum creatinine tests as a part of a routine screening. An estimated glomerular filtration rate (eGFR), used to measure kidney function, can be calculated by analyzing a person's blood for serum creatinine using certain patient characteristics (eg, age, race, gender). However, laboratories do not always report the eGFR when reporting lab results for routine blood serum creatinine screenings unless it is specifically ordered by the physician.[20] The task force therefore recommended that **estimated GFR values should be computed and reported on *all* creatinine determinations by clinical laboratories in North Carolina**, which should assist PCPs in identifying people with CKD. Thomas DuBose discusses this issue more fully in his commentary.

Following the KDOQI guidelines, the task force also recommended that **primary care practitioners routinely screen their patients who are at high risk for chronic kidney disease, stage patients who have been identified with CKD according to the KDOQI disease categories, follow the KDOQI or other evidence-based guidelines to manage and slow the progression of CKD, and refer patients with severely declining function to nephrologists for ongoing care.** PCPs can use the stages of CKD to help explain the disease process to their patients, develop care plans, and assess the risk of potential complications such as development of cardiovascular disease or kidney failure. As kidney function declines further, patients should be referred to nephrologists for clinical management of kidney disease. Even after referral, the PCP will still play an important role in serving as the patient's medical home and helping to manage the patient's comorbid conditions. Cynda Ann Johnson discusses the role of primary care practitioners in her commentary.

The use of disease registries can also assist primary care practitioners in identifying patients with specific chronic illnesses and can trigger the application of evidence-based screening and treatment guidelines. Some practitioners have electronic health records (EHRs) with the capacity to identify patients with chronic illnesses or to provide clinical decision support prompts. However, this capacity is not universal in EHRs. The task force recommended that **electronic health records provide the capacity for chronic disease registries and clinical decision support prompts that incorporate CKD screening and treatment measures for at-risk groups.**

Patient Education, Disease Management, and Case Management Services

In general all patients who have health problems should be educated about the course of their disease, treatment options, and management of their health conditions. Patients with chronic kidney disease need education about the role of the kidneys in maintaining their overall health, the progression of the disease, risk factors that can exacerbate CKD, recommended treatment, medication, and diet. Providing patients with the skills to better manage their own health will help improve outcomes. Primary care practitioners and nephrologists can assist in the patient education process. However, individuals often need more intensive health education than can typically be provided in a physician's office.

Patient education, disease management, and case management services can augment the information and services provided by health care practitioners. Disease management activities are generally targeted to individuals with specific health conditions or diseases such as diabetes, asthma, congestive heart failure, coronary artery disease, or hypertension. The activities are

e Both the American Diabetes Association's evidence-based guidelines for treatment of patients with diabetes[24] and the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure report (JNC 7) on evidence-based guidelines for treatment of patients with hypertension[9] recommend that practitioners obtain a serum creatinine to calculate the estimated GFR.

designed to provide individuals with the information and support necessary to assist them in monitoring their own care and adhering to recommended treatment guidelines. Case management activities can be offered in conjunction with, or separate from, disease management efforts. North Carolina insurers offer both disease management and case management activities for selected individuals.

Although many insurers and payers offer disease management and quality improvement efforts targeting people with diabetes, hypertension, or cardiovascular disease, these initiatives do not always measure how well practitioners screen high-risk individuals for chronic kidney disease. Thus, the task force recommended that **disease management and quality improvement initiatives aimed at diabetes, hypertension, or cardiovascular disease give greater emphasis to CKD prevention, screening, and management.** These services should be available to all patients with CKD once they reach stage 4. Anne Rogers discusses how the North Carolina State Health Plan has moved to strengthen CKD education and disease management in her commentary. Similarly, Annette DuBard and Jennifer Cockerham discuss how Community Care of North Carolina (CCNC), the state's Medicaid disease management program, can be changed to strengthen CKD education and management in their commentary. In addition to the existing disease and care management programs that reach Medicaid-only populations, CCNC is developing plans to extend the program to Medicare and dually-eligible beneficiaries. Because the likelihood of having CKD increases as people age, the task force recommended **the creation of a CKD specific disease management and quality improvement initiative if CCNC is expanded to include the Medicare population.**

The University of North Carolina at Chapel Hill, in conjunction with the North Carolina Community College System, has developed a proposal for a certification program for kidney care managers to ensure the availability of care managers appropriately trained in the management of people with chronic kidney disease. The task force recommended that **North Carolina foundations provide funding to the University of North Carolina at Chapel Hill to pilot test and evaluate the effectiveness of the Kidney Care Prevention Program, and that public and private payers and insurers provide reimbursement for CKD trained educators if determined to be effective and cost-efficient.** Donna Harward and Ronald J. Falk discusses the program more fully in their commentary. The task force also recommended that **disease management or case managers who manage patients with diabetes, hypertension, or cardiovascular disease should be cross-trained in disease management for people with chronic kidney disease, and the North Carolina General Assembly should support the infrastructure needed to expand the Division of Public Health Diabetes Education Recognition Program with a special focus on CKD screening and management.**

Initiatives aimed at improving the quality of health care rely on evidence-based performance measures such as those recognized by the National Quality Forum, National Committee for Quality Assurance, or other disease-specific organizations. However, quality measures do not exist for all evidence-based guidelines. North Carolina health care professionals are more likely to adopt new performance measures if they have been nationally recognized. Thus, the task force recommended that **national health professions organizations that focus on kidney disease should work with national quality and standard setting organizations to devise quality performance measures that assess the degree to which practitioners screen and manage patients with or at risk of developing chronic kidney disease in accordance with nationally recognized guidelines.**

Nephrologists

Nephrologists play a critical role in the effective management of patients with kidney disease, but there are too few nephrologists to assume the care of everyone with CKD. In North Carolina there are 215 nephrologists or about 3.4 nephrologists per 10 000 people with CKD stages 2-5.[21] In contrast there are approximately 9 primary care practitioners for every 10 000 people in North Carolina.[22] Because of the low relative number of nephrologists, most of their work is limited to people who have more advanced forms of kidney disease. Paul Bolin discusses the coordination of care between nephrologists and primary care practitioners in his commentary. The task force recognized the critical importance of creating a collaborative team of primary care providers, nephrologists, and other health care professionals to manage the care of people with CKD throughout the course of their disease. Therefore the task force recommended that **nephrologists should actively build collaborative relationships with primary care practitioners. In addition, professional associations of nephrologists should actively encourage and educate their peers on the importance of developing these collaborative relationships and should distribute tools to assist in consulting with PCPs.**

Nephrologists should assume more active management of patients as their disease begins to approach kidney failure (stage 4 of the KDOQI guidelines). One of the issues nephrologists should discuss with CKD patients is the choice of kidney replacement therapy (including the option of no therapy if that is the patient's preference). Kidney replacement therapy includes peritoneal and home dialysis, in-center dialysis, and transplantation. Linda Upchurch focuses on the various modalities of dialysis in her commentary. In addition, nephrologists or other care managers should help educate patients about the need for early vascular access prior to starting dialysis; this can prevent possible medical complications that may arise in the event of emergency medical treatment for kidney failure. The task force recommended that **nephrologists help educate patients about different renal replacement options and early vascular access well in advance of kidney failure.**

Although it has relatively low awareness among the general public, chronic kidney disease imposes a high burden of disease on nearly a million North Carolinians. As discussed above, a number of recommendations emanated from the North Carolina Institute of Medicine Task Force on Chronic Kidney Disease, and the commentaries included in this issue

complement and extend these recommendations. Addressing this public health threat will take a concerted and coordinated effort by actors throughout the health care system intervening at multiple points to decrease the number of people developing CKD, slow the progression of the disease, and improve the care provided to those with CKD. Like many of our most pressing challenges in health policy, no one solution will be able to effectively manage this threat. But by leveraging the efforts of many organizations, we can lessen the impact of chronic kidney disease on nearly one million fellow North Carolinians facing this condition every day. **NCMJ**

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Epidemiology and Costs of Chronic Kidney Disease in North Carolina

Suma Vupputuri, PhD, MPH

End-stage kidney disease (ESKD) is an irreversible and debilitating disease that represents the last stage in the progression and long duration of chronic kidney disease. Chronic kidney disease (CKD) is not only a personal tragedy for patients and their families but is also a serious public health and financial burden for the United States. The burden of CKD in the US and worldwide has reached epidemic levels and is expected to continue to rise.

Epidemiology

Currently the unadjusted prevalence and incidence rates of end-stage (stage 5) kidney disease are 1585 and 350.7 per million, respectively.[1] These numbers do not reflect the burden of earlier stages of CKD (stages 1-4) which are estimated to affect 13.1% of the population nationwide, or 26.3 million Americans.[2] Throughout the duration of the disease, most of these people will experience adverse conditions and/or events such as cardiovascular disease, congestive heart failure, and premature death. Those who survive the comorbidities associated with CKD will eventually develop ESKD and require dialysis or kidney transplantation.[3]

North Carolina currently ranks as the 10th highest state in the US for prevalence of ESKD and 12th highest for incidence of ESKD with rates of 175.7 and 37.5 per 100 000 population, respectively. The statewide geographical distribution of ESKD tends to cluster in rural counties which are also disproportionately burdened with Medicare beneficiaries. The North Carolina counties with the highest prevalence of ESKD are Martin, Northampton, Swain, Lenoir, and Bertie, with rates ranging from 347.5 to 350.0 per 100 000 (Figure 1).[4] Within North Carolina, kidney disease is the 10th most common cause of death, accounting for 7161 deaths between 2001 and 2005. The age-adjusted kidney disease death rate was 18.6 per 100 000 in 2005 and was twice as high for minorities than for Whites.[4]

The rates of incident and prevalent ESKD in North Carolina have demonstrated progressive increases between 1994 and 2005, and these rates have been consistently higher in North Carolina than in the US population. Observed racial differences in North Carolina showed the incidence rate for Black men was 3.3 times higher than it was for White men, and the incidence rate for Black women was 4.3 times higher than for White women.[4]

There are no current measures of prevalence for CKD stages 1-4 in North Carolina. However, if national CKD estimates developed from the National Health and Nutrition Examination Survey (NHANES) are applied to the North Carolina population, an estimated 941 770 North Carolinians may currently be affected by early CKD.

"Due to underdiagnosis, undertreatment, and low awareness of early chronic kidney disease in the population, studies of the estimated cost of chronic kidney disease in the US likely report gross underestimates of the true costs."

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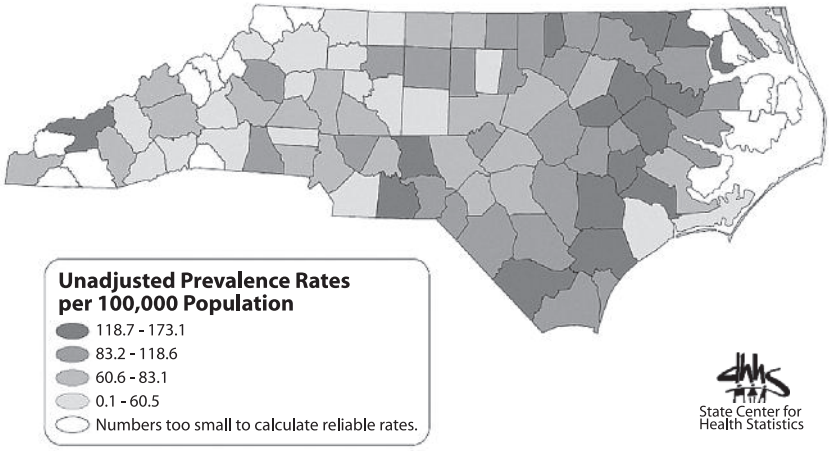
Figure 1.
Prevalence of End-State Kidney Disease in North Carolina by County, 1990



SOURCE: US Renal Data System

Cost of Different Treatment Modalities

The economic burden imposed on the health care system by the treatment of ESKD, chronic kidney disease, and chronic kidney disease-related comorbidities is staggering. The US Renal Data System reports Medicare costs for the ESKD program are steadily increasing and now exceed $20 billion (6.4% of the total Medicare budget). In the Medicare population, the 2005 per person per year cost of dialysis treatment was $68,585 compared to $102,637 for patients receiving a kidney transplant. Transitional costs have been on the rise, with costs of care in the month of dialysis initiation at $16,035 (up $2927 from 1994), and the costs in the last month of the life of patients who do not reach ESKD at $12,405 (up $4171 from 1994). The total inpatient person per year cost is about 8 times greater for patients with ESKD than for patients with CKD. Outpatient costs are, as expected, much higher among ESKD patients whose person per year dialysis costs reach almost $12,000 and whose therapy with erythropoiesis stimulating agents is $6000. Further, treatment expenditures differ based on comorbidities. For example, Medicare patients with CKD and diabetes have approximate per person per year costs of $3000, while patients with CKD and hypertension have approximate per person per year costs of $4000. CKD patients with both diabetes and hypertension have per person per year costs of $5000.[1]

Several recent publications have reported the economic impact of CKD in the US. In a study by Kaiser Permanente Northwest, among 43 178 residents of the greater Portland, Oregon area, investigators compared health care costs of patients with CKD to age-matched controls without CKD.[5] During the follow-up period, patients with CKD incurred higher health care costs and showed higher utilization patterns than controls. Overall, the study found increased per person per year costs of between $2578 and $4676 in patients with CKD (depending on stage) compared to patients without CKD. Compared to controls, patients with CKD had 1.9-2.5 times as many prescriptions, had 1.3-1.9 times as many office visits, and were 1.6-2.2 times as likely to be hospitalized.

In the RENAAL (Reduction of Endpoints in Non-insulin dependent diabetes mellitus [NIDDM] with the Angiotensin II Receptor Antagonist Losartan) study, costs associated with Losartan-treated ESKD were examined.[6] (Losartan is a type of angiotensin II receptor blocker (ARB) that is used to treat hypertension but has also been indicated in delaying kidney disease progression in diabetic nephropathy.[7]) The study included 751 patients treated with Losartan and 762 patients in a placebo-treated conventional antihypertensive treatment group. A significant reduction in costs associated with ESKD was found in the Losartan group compared to the placebo group. After taking into account the cost of Losartan, the total net savings for ESKD-related costs was $3522 for patients in the Losartan group. These savings held true for patients at all levels of baseline albuminuria.[6]

A Medicare cost-benefit analysis was performed to examine the potential cost-effectiveness for first-dollar coverage (no patient cost sharing) of angiotensin-converting enzyme (ACE) inhibitors, which are shown to be effective in slowing the progression of kidney disease. Authors hypothesized that the expense of ACE inhibitors was a barrier to patients who would benefit from the drug. Results of this analysis showed that first-dollar coverage of ACE inhibitors saved both money and lives compared to the Medicare drug benefit. Lifetime savings of $922 per beneficiary were estimated due to the prevention of medical events, especially kidney disease.[8]

Anemia is also a costly condition common among patients with CKD. In a study of managed care members, CKD-related anemia was associated with the highest average annual costs ($41,292 per patient) compared to those costs associated with other anemia-related diseases (eg, HIV, rheumatoid arthritis, congestive heart failure, cancer).[9]

Finally, a study using the US Renal Data System population examined the economic impact of slowing the progression of CKD. Using mathematical models, this analysis assessed the effect of slowing CKD progression. Results showed that among patients with a glomerular filtration rate (GFR) less than 60 ml/min/1.73m^2 after December 31, 1999, the cumulative health care savings through 2010 would be $19, $39, and $61 billion dollars for patients with a reduced GFR of 10%, 20%, and 30%, respectively.[10]

These studies provide documentation of the heavy economic burden of CKD in the United States and dramatic evidence for the cost-saving potential of CKD prevention. Due to underdiagnosis, undertreatment, and low awareness of early

chronic kidney disease in the population, studies of the estimated cost of chronic kidney disease in the US likely report gross underestimates of the true costs.

In order to successfully manage chronic kidney disease and reduce the burden of the disease, it is crucial that early detection and treatment programs are implemented. The primary health care system is already overextended in its ability to adequately manage chronic diseases. Even when CKD is detected early, there are long delays in referral to nephrologists due in part to the limited number of practicing nephrologists and the limited number of non-dialysis patients able to be seen in the outpatient setting. Thus, it is paramount that other strategies be developed, such as encouraging proactive behavior among patients through targeted health plan or community-based education programs and expanding the health care management team to include CKD case workers to provide assistance to primary care providers. **NCMJ**

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Pediatric Chronic Kidney Disease in North Carolina

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Chronic kidney disease (CKD) in children, adolescents, and young adults differs from that in adults both in terms of etiology as well as management. The typical causes of CKD are congenital or genetic in younger children and are acquired in adolescents and young adults.[1] Figure 1 depicts the primary causes of CKD in pediatric kidney transplant patients from the 2007 Report of the North American Pediatric Renal Trials and Collaborative Studies (NAPRTCS), a national representative registry. In addition to routine medical therapy, pediatric CKD management is often complex because it must incorporate the impact of CKD on physical health, growth and development, psychological issues, family dynamics, and educational development. There are a limited number of centers providing comprehensive pediatric nephrology care. Although transplantation is the preferred therapy for nearly all pediatric CKD patients with end-stage kidney failure, many patients remain on chronic dialysis. Similar to adults, treatment of pediatric CKD is expensive and burdensome (to the patient, the patient's family, and the health care system). Pediatric CKD is also associated with higher morbidity and mortality when compared to morbidity and mortality rates in the general pediatric population.[2]

"With the rising incidence of obesity and type 2 diabetes mellitus in young children and adolescents, the incidence of CKD in adulthood is expected to increase over the coming years."

Across the spectrum of mild to severe disease, the prevalence of pediatric CKD is unknown. The incidence and prevalence of CKD in the most severe stage of end-stage renal disease (ESRD) requiring renal replacement therapy (RRT) via dialysis or transplantation are known. The national incidence of pediatric ESRD is 15 cases per million per year, and the estimated prevalence is 82 cases per million.[3] The incidence of ESRD increases with age, from 13.0 to 32.6 per million per year in 13 and 19 year-old patients, respectively.[1] Minorities are disproportionally affected by CKD in adolescence and young adulthood in part due to the higher incidence of certain glomerulonephritis in minority populations. The most common causes of CKD in adults (diabetes mellitus and hypertension) often have their

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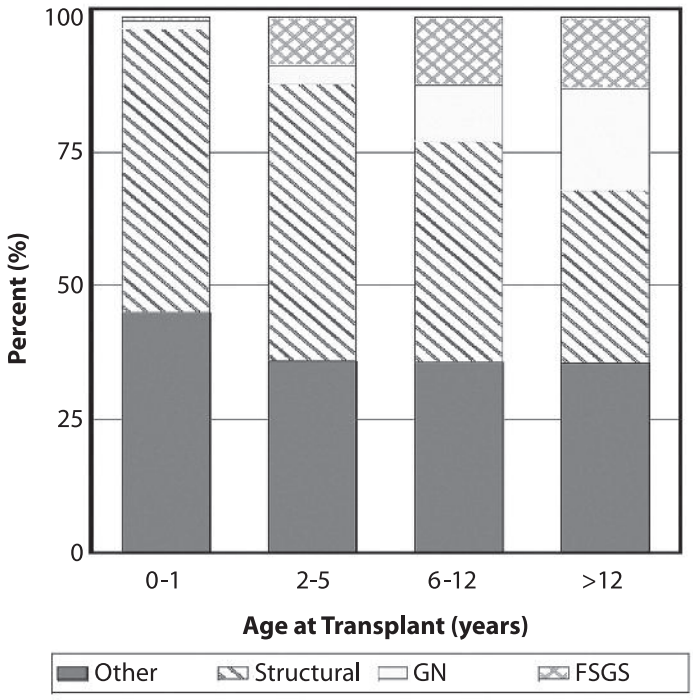
Figure 1.
Transplant and Primary Diagnosis by Age, 2007, Among Pediatric Patients



Structural - includes congenital abnormalities of the kidneys, ureters, or bladder; GN - glomerulonephritis; FSGS - focal segmental glomerulosclerosis.
SOURCE: NAPTRCS 2007 Annual Report.

origins in childhood but typically do not lead to kidney disease until adulthood. With the rising incidence of obesity and type 2 diabetes mellitus in young children and adolescents, the incidence of CKD in adulthood is expected to increase over the coming years.

In North Carolina during 2005, there were 407 children, adolescents, and young adults less than 24 years old with ESRD.[1] The Organ Procurement and Transplantation Network (OPTN) reports that from 1988 to 2007, 365 kidney transplants have been performed in North Carolina pediatric patients (representing 2.6% of all pediatric kidney transplants in the US). And as of March 7, 2008, there were 38 active potential recipients on the kidney waiting list.[4]

The cost of ESRD in 2002 for all patients in the US was $25.2 billion (6% of the Medicare budget). North Carolina has the 10th highest prevalence of ESRD in the nation and accounts for 3.4% of the US ESRD population.[1] As of 2006 in NC, 6884 patients of all ages were covered under Medicare/Medicaid for SFY2006 and encumbered $839 million dollars for all medical expenses (Medicaid estimated cost data provided by A. Yow, Division of Medical Assistance, personal communication January 2008). With 1% of ESRD occurring in pediatric patients,[1] we can estimate the cost of pediatric ESRD through public insurance at over $8 million in North Carolina for state fiscal year 2006. Private insurance and self-pay contributions are not included in these estimates. The cost of dialysis for children is high: $100,000 annually per patient. This tends to be higher than the cost for adults since a higher staff-to-patient ratio is required for pediatric patients and pediatric nephrologists fees are higher. Medication also contributes to the high costs, eg erythropoietin for anemia may cost $5000-$7000 per year and anti-rejection medication typically costs $7000-$20,000 per year.[5,6]

Medical and Cognitive Issues of Pediatric CKD

Similar to adults, the onset of CKD may be subtle in children. The signs and symptoms of the primary kidney disease and complications of progressive CKD may masquerade as other common childhood problems. Polyuria, polydypsia and delayed urinary continence are common symptoms of infants and children with congenital structural anomalies such as obstructive uropathy from posterior urethral valves and renal dysplasia. A number of metabolic complications occur, including metabolic acidosis, growth failure, rickets and anemia. Metabolic acidosis results from bicarbonate wasting and retention of organic acids. Uncontrolled metabolic acidosis, anorexia, protein-calorie malnutrition, and resistance to naturally occurring growth hormone in severe kidney disease can contribute to weight and statural growth failure. Impaired growth often leads to impaired self-esteem with lasting effects on overall quality of life in adult survivors of childhood onset CKD. Bone disease due to retention of phosphorus and eventual secondary hyperparathyroidism may cause orthopedic abnormalities such as rickets, genu valgum deformity, or slipped capital femoral epiphysis. Most patients with moderate to severe CKD develop anemia from inadequate erythropoietin production, but the availability of recombinant erythropoietin and iron supplementation provides an effective treatment.

The complexity of managing CKD and its associated comorbidities in children requires a specialized multidisciplinary medical team. Younger children with CKD require more surgical procedures than adolescents/young adults to treat urinary tract anomalies, orthopedic abnormalities, malnutrition (gastrostomy tube placement), or gastrointestinal dysmotility (fundoplication). The medical treatment of CKD includes phosphorus binders, bicarbonate supplementation, antihypertensives, erythropoietin, vitamin D analogues, recombinant human growth hormone, and immunosuppressive medication for certain forms of glomerulonephritis, autoimmune diseases, and transplantation.

Cardiovascular disease is a particularly concerning cause of

morbidity and mortality among adolescents and young adults with pediatric-onset CKD. For patients 15 to 19 years of age, cardiovascular event rates are nearly 1000-fold greater among patients with ESRD when compared to their age-matched peers from the general population.[7] The cardiovascular risk for survivors of childhood CKD remains very high. Cardiovascular mortality rates among patients with ESRD between the ages of 25-34 years of age are similar to members of the general population who are in their 80s.[8] Monitoring for hypertension and adequate treatment is paramount at all CKD stages for children because of its pivotal role in the development of cardiovascular disease. Left ventricular hypertrophy is a marker of end-organ damage of uncontrolled hypertension in childhood. With normalization of blood pressure, the hypertrophy resolves. Other concomitant cardiovascular risk factors include hyperlipidemia, obesity, type 2 diabetes, tobacco use, and specific disease states such as nephrotic syndrome, systemic lupus erythematosus, and vasculitis require special attention. Unfortunately, lipid testing for all pediatric patients with ESRD is only 56% for Whites and 48% for Blacks.[9]

Risk factors for adult development of CKD and/or hypertension may be seen in childhood. Prenatal events may predict chronic comorbidities later in life by impacting processes such as nephrogenesis that could result in reduced nephron number.[10] In turn, low glomerular number may lead to glomerular hyperfiltration, hypertension, and glomerulosclerosis.[11] The most studied *in utero* risk factors include low birth weight and prematurity. A recent study found that low birth weight was associated with a 70% increased risk for ESRD in a large birth registry from Norway over periods up to 38 years.[12]

Cognitive and academic achievement of children and adolescents are negatively affected by CKD.[13] Cross-sectional and longitudinal cohorts have demonstrated worsening intelligence quotient, memory, and attention as CKD progresses to ESRD.[14,15] These abnormalities are compounded by the presence of anemia, nutritional deficiencies, and uremic toxins. After transplantation, cognitive function often improves but does not completely normalize despite normal kidney function.[16,17]

For pediatric ESRD patients, hemodialysis and peritoneal dialysis are the 2 available forms of chronic dialysis therapy. ESRD patients under the care of pediatric nephrologists receive peritoneal dialysis 2 times greater than hemodialysis.[18] Hemodialysis is not ideal, yet it is the more common form of renal replacement therapy among adolescents and young adults in the US[2] (as a great number of them are under the care of internal medicine nephrologists) due to the disruption of school participation with thrice weekly hemodialysis therapy, poor volume and hypertension control with intermittent therapy, and difficult vascular access. In adults hemodialysis access is accomplished optimally by surgical creation of an arterio-venous fistula, but this is not feasible in an infant or small child.[18] Consequently, infants and young children dependent on hemodialysis often utilize a central venous catheter for access. These catheters provide a portal of entry for pathogens with resulting insertion site infections and bacteremia. Typical community-based hemodialysis facilities do not provide services for children. Thus children who are hemodialysis dependent often travel to tertiary care facilities for routine hemodialysis. Parent-provided home peritoneal dialysis requires the surgical placement of a Tenckhoff catheter in the abdomen. Infections of the catheter site and peritonitis are the most common complications of peritoneal dialysis. These can be prevented completely or in part by strict attention to sterile technique. Peritoneal dialysis facilitates more regular school attendance. Nutrition and fluid intake may be more liberal when compared to hemodialysis and volume control improved due to the daily nature of peritoneal dialysis therapy.[18]

Transplantation is the preferred renal replacement therapy for nearly all children with ESRD, but minorities receive less kidney transplants compared to Whites.[2] Unlike adults, virtually all pediatric CKD patients are transplant candidates, and approximately 50% of pediatric transplants come from living donors. As an infant nears a body weight of 10 kg, renal transplant is feasible. Children typically do well after transplantation with 5-year graft survival rates of approximately 85% for living donor transplants and 80% for transplants from deceased donors. Young infants and teenagers do less well, the former largely due to technical factors and the latter due to nonadherence to the medical regime.[1]

Successful transplantation resolves many of the problems associated with CKD. Unfortunately, some health conditions persist and others develop such as opportunistic infections, steroid-related impaired growth, osteoporosis, hypertension, and increased risk for malignancy. The medication regime is often complicated, requiring administration of several medications 2 or 3 times a day and contributes to the risk of nonadherence and transplant loss. The transplanted organ is expected to provide kidney function for an average of 12 years but may range from 0 to 30 years.

Pediatric ESRD Mortality, Hospitalizations, and Immunizations

According to the 2007 US Renal Data System (USRDS) report, since 1991 adjusted mortality rates from pediatric ESRD have increased 5% to 26.6 per million population in 2005 with girls having a higher rate than boys (28% related to cardiovascular events and 32% due to infectious diseases). The 5-year mortality rate for children less than 4 years of age on dialysis is 69%, which is higher than rates for children of other age groups.

When compared to adults, all cause hospitalization rates were 14% higher in children (2.1 vs. 17 per patient per year risk) in 2005. Admissions due to cardiovascular conditions increased 54% in boys and 64% in girls from 1993 to 2005. This is very concerning due to these patients' age. The same 2007 USRDS report highlighted the low immunization rate at no more than 30% for influenza, pneumococcus, and hepatitis B.[9]

Family and Psychosocial Issues of Pediatric CKD

Despite medical advances, the current leading cause for kidney transplant loss in adolescents is nonadherence to medical treatment.[19] Adherence among adolescents is compromised by both poor understanding and poor recognition of consequence, leading to inconsistent commitment to treatment regimen. A major impediment is that knowledge about their medical conditions is largely dependent on their parents' literacy. In 1997 the levels of literacy in North Carolina ranked 41st in the US with 52% of its population at a literacy level of ≤2 out of 5 on National Adult Literacy Survey (NALS) literacy scales.[20] People with ≤2 literacy levels cannot perform basic tasks like reading tables, graphs, or maps; and following complicated medical routines may be difficult. We have assessed literacy in 34 parents of children on peritoneal dialysis and demonstrated that children whose parents have lower literacy scores have significantly more peritonitis episodes and worse adherence to treatment than patients whose parents have higher literacy scores. Lower literacy was more prevalent among minorities. (See Figure 2.)

Chronic kidney disease places tremendous emotional, physical, and financial stresses on the family. Work schedules are interrupted as days or weeks are spent with the child in the hospital or attending medical appointments. Siblings often miss school while accompanying parents to medical appointments or feel neglected when the parent(s) spend so much time away from home. They also miss out on activities and emotional support since the parent is frequently immersed in the care of the child with CKD.[21] Time spent traveling to health clinics is a major problem; the financial burden is huge and difficult to measure as only certain costs are covered by medical insurance. There is usually no reimbursement for travel, parking, and meal costs. Physician and pharmacy copays can add up to hundreds of dollars per month. The Medicare Part D "doughnut hole" is a major problem for many families requiring them to pay substantial pharmaceutical costs. Moreover, parents of children with CKD experience high divorce rates.[22]

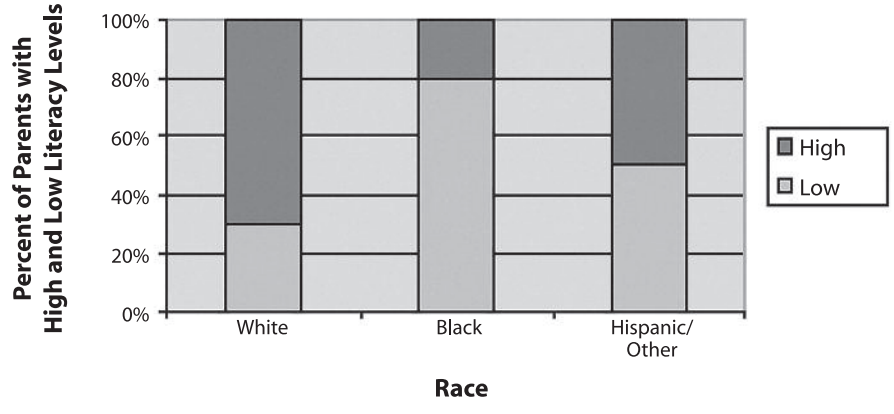
Respite services for parents of these children are needed but not typically available. Single week kidney camps are available for school age children (National Kidney Foundation Camp Wiwanawi, Camp Kaleidoscope, and Victory Junction Gang Camp) but do not provide consistent opportunities for respite care. Alternative support services such as patient and family support groups may be beneficial in identifying potential resources and for educational opportunities. Given the distance that families travel to see the pediatric nephrologists at tertiary care centers, utilization of parent and patient support groups is low.

Pediatric CKD patients require significant amounts of time and effort to coordinate their care. Although many patients have public or private health insurance, care coordination services are not reimbursed. The new North Carolina IMPACC (Improving Pediatric Access through Collaborative Care) program is evaluating the effectiveness of care coordination through case managers located at tertiary institutions. Most but not all pediatric patients become eligible for Medicare when they begin dialysis or receive a transplant. Each center also cares for undocumented immigrants for whom care becomes more complicated. Many are supported, at least in part, by the generosity of programs at the respective institutions and the communities that embrace them. These children are not eligible to receive a renal transplant in the US, so they must remain on dialysis or return to their native country, sometimes where neither dialysis nor transplant is available.

Pediatric Nephrologists in North Carolina

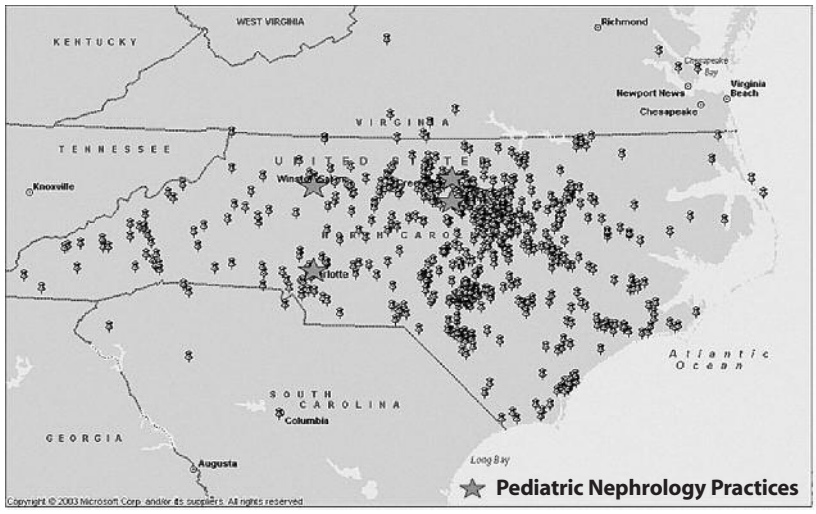
The pediatric nephrologist to population ratio varies greatly across the United States, with some states having no pediatric nephrologists at all, and others having as many as 1 per approximately 350 000 population.[23] In North Carolina, there are currently 9 full-time pediatric nephrologist equivalents providing clinical care, or about 1 pediatric nephrologist per 1 million population. These pediatric nephrologists are located in Chapel Hill, Charlotte, Durham, and Winston-Salem. Most internal medicine nephrologists are uncomfortable seeing children, especially those under age 12, and general pediatricians are not trained to care for the specialty needs of these children. This means that the entire eastern portion of North Carolina has no subspecialty services for children with kidney disease. In fact, based on the North Carolina Medicaid Access patient care-coordination registry at the University of North Carolina at Chapel Hill, the mean number of miles patients travel for nephrology

Figure 2.
Literacy Levels in Parents of Pediatric Peritoneal Dialysis



services, (including thrice weekly hemodialysis), is 79.8 (standard deviation 25.2). Figure 3 depicts the home ZIP codes of children who have CKD who are in pediatric nephrology practices in North Carolina; the stars represent the location of these practices.

Figure 3.
Home ZIP Codes of Children Who Have CKD and Who Are in Pediatric Nephrology Practices in North Carolina



Transition and Pediatric CKD

Adolescents must begin the process of transition from parent-directed care to disease self-management and eventual transfer to internal medicine nephrology practices. Transition involves patients, families, and pediatric and adult health care providers. It also requires planning and coordination. With the help of a transition coordinator, the University of North Carolina (UNC) Kidney Center has developed and is currently validating tools for the transition process, including a medical passport, a self-administered transition-readiness survey, and the UNC T.RxA.N.S.I.T.I.O.N. Score.[a] The Children and Youth Branch in the North Carolina Division of Public Health is developing a Transition Tool Kit for health care providers, families, and youth with special health care needs (YSHCN) through the Carolina Health and Transition (CHAT) Project. With funding from the US Health Resources and Services Administration (HRSA), the CHAT project targets barriers in the availability of, and access to, quality health care services by broadening awareness, teaching specific skills, and changing systems of practice for YSHCN, their families, and medical providers.

Once young patients reach age 19 and if they are no longer in school, they typically are no longer eligible for their parent's insurance coverage. These young adults are unlikely to gain employment with medical benefits. This creates a major problem and contributes to morbidity and sometimes to loss of an otherwise successful transplant since the patient cannot obtain the necessary anti-rejection medications.

Opportunities for the Management of Pediatric CKD in North Carolina

Given the shortage of pediatric nephrologists in the US and North Carolina, communication between specialists and primary care physicians is essential for effective co-management of children with chronic health problems.[24-26] Co-management of children with CKD in North Carolina requires effective collaboration, especially when many patients are located far from specialty care. Improving the rate of preventive primary services such as influenza and pneumococcal immunizations and increasing lipid testing rates may in turn decrease morbidity and mortality associated with infectious processes and cardiovascular risk factors.

Systems such as NC health-link (a consultative telephone resource) help with this problem. But despite multiple apparent advances in technology assisted communication (eg, electronic medical records), timely and effective communication is often prevented by delays in completing records, incompatibilities between electronic systems, and the endless pressures of time for both specialists and primary care physicians.[26] Parents are often required to be the primary communicators among physicians.[27] Efforts should be made to standardize electronic medical records and emphasize timely, effective communication among providers.

Continued support of outreach education programs by pediatric nephrologists for primary care providers via the NC Area Health Education Centers (AHEC) program and through Internet-based educational modules is paramount. Education of internal medicine nephrologists in the care of certain pediatric problems may be a partial solution to the successful transition of adolescents and young adults into community-based health care.

In addition, acquisition of disease self-management skills in the context of transition will facilitate improved health outcomes among adult survivors of childhood-onset CKD. Culturally-sensitive patient education efforts need to take into consideration the lower literacy levels of some of the patients and families being served. This in turn may increase transplantation rates for underrepresented minorities.

Recognition of the complexity involved in treating children with CKD is essential and requires an interdisciplinary

a Information about the Smooth Transition to Adulthood with Renal Disease (STARx) program and its components can be found at http://unckidneycenter.org/hcprofessionals/transition.html.

approach with care coordinators to facilitate disease management. Yet, the number of pediatric nephrology care coordinators in NC is low and reimbursement for case management-related services is poor. An interdisciplinary approach to pediatric CKD, one that includes nutritionists, social workers, nurses, psychologist, educators, physician extenders, and physicians, indeed has been established as standard of care. Yet many of the team members needed for a successful interdisciplinary care are not always available. Similarly, access to care is hindered by patients' limited access to tertiary care centers.

Early detection of pediatric kidney disease may minimize complications, improve care, and decrease costs. One method may be to expand the reporting of estimated glomerular filtration rate (eGFR), the most direct reflection of overall kidney function, from laboratory reports of serum creatinine. The provision of an eGFR for adults appears to have improved recognition of kidney function impairment in adults. This could be accomplished with an automated identification program such as Schwartz eGFR auto-calculator.

Prevention of congenital causes of pediatric CKD is difficult, but early detection with prenatal ultrasound leading to early interventions will improve outcomes for many of these children. Recognition of urinary tract infections to identify children with urinary tract anomalies is critical, as is screening siblings of patients with vesico-ureteral reflux. Other preventive/early identification efforts should include screening children of adult patients with hereditary kidney disease.

Some forms of acquired kidney disease can be avoided such as obesity-related nephropathy, type 2 diabetes mellitus, and diabetic nephropathy, many of which begin during the pediatric ages. Early detection of children with hypertension will allow more effective treatment and may decrease cardiovascular morbidity later in life. Accurate measurement of blood pressure requires standardized techniques, availability of appropriate size cuffs at primary care clinics, and automated blood pressure percentile calculators.

Understanding the increase in the last 16 years in cardiovascular-related hospitalizations and deaths in pediatric CKD patients is paramount. A statewide registry of pediatric CKD cases would provide longitudinal information to track incidence, prevalence, disease progression, financial/physical/family impact, hospitalization, and morbidity/mortality rates. The registry could also track the transition process for these patients—while low in number—need care that poses significant costs to the state. A population-based registry may validate generally accepted but incompletely validated decision support algorithms, and may provide insight related to the increase in hospitalization and mortality rates that pediatric ESRD patients are experiencing. **NCMJ**

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Automatic Reporting of the Estimated Glomerular Filtration Rate (eGFR)

Thomas D. DuBose, Jr, MD, MACP

Chronic Kidney Disease as a Public Health Threat

Although the prevalence of end-stage kidney disease (ESKD) in the United States has stabilized over the last 2-3 years at 400 000 patients, it has been estimated that as many as 13% (26.3 million) of the population of the United States has chronic kidney disease (CKD).[1] While approximately 15.5 million Americans have stage 3 and approximately 10.1 million have stage 1 or 2 CKD, recent evidence suggests that as many as 80% of patients with stage 3 CKD are not aware of having this diagnosis.[1-3] It is widely acknowledged that CKD progresses to ESKD, yet the risk for progression is about 4 times higher in African Americans, and overall, the percentage of patients with CKD progressing to ESKD is 3 times greater in the US than in Norway.[2,3] While precise data are not available for the state of North Carolina, one can safely assume that at least 450 000 individuals in our state have stage 3 CKD, an equal number have stage 2 CKD, and approximately 35 000 have either stage 4 or 5 CKD.[1] This population of CKD patients in North Carolina is at risk for progression to ESKD or dying from cardiovascular disease before reaching dialysis.

Chronic kidney disease represents a public health threat due to (1) the high burden of the disease; (2) the evidence that the problem is distributed unfairly with regard to ethnicity; (3) the undisputed evidence that upstream preventive strategies could reduce the burden of the condition; and (4) the fact that preventive strategies are not yet in place.[3,4]

Two Simple Diagnostic Tests to Diagnose CKD Earlier

Because CKD is a progressive disease, it must be diagnosed earlier in the course of the disease to facilitate the initiation of appropriate therapy in order to slow progression to ESKD. The National Kidney Disease Education Program (NKDEP) has emphasized the importance of 2 simple tests to identify those patients with CKD:[5]

1. The urine albumin to creatinine ratio on a voided, untimed urine specimen
2. An estimated glomerular filtration rate (eGFR) from the serum creatinine using the MDRD (Modification of Diet in Renal Disease) study equation[6-9]

"…a wider availability of eGFR will be a necessary first step in the accurate diagnosis and treatment of this devastating illness."

Although the serum creatinine is the usual means of assessing kidney function, the creatinine concentration in isolation has a complex relationship to the GFR. Failure to recognize CKD at an early stage may result in the failure to prescribe medication proven to slow the progression of CKD.[5,9,10-13]

The Estimated Glomerular Filtration Rate (eGFR)

The eGFR calculation from the MDRD equation requires the following variables: the serum creatinine, age and sex of the individual, and designation of whether the patient is African American or not.[6] Moreover, the MDRD formula for eGFR is simple, straightforward, and does not necessitate a 24-hour urine collection. This equation is available through a number of electronic resources,[7] can be easily downloaded and incorporated

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into laboratory computer-based reporting systems, and can be calculated instantaneously by supplying the 4 variables whenever the serum creatinine is measured. The MDRD eGFR is the most thoroughly evaluated and validated equation available to date.[14] While the method is less accurate with higher values for eGFR (>60), it is currently being evaluated additionally in individuals with a normal GFR.

What Subspecialty Societies Recommend

A number of subspecialty societies and organizations including the American Society of Nephrology, the American Diabetes Association, the American Association of Clinical Chemistry, the College of American Pathologists, and the National Kidney Disease Education Program, have emphasized that automatic eGFR reporting is the most desirable method of identification of patients with CKD. The National Kidney Disease Education Program has recommended the routine use of the eGFR instead of the serum creatinine alone in order to more accurately assess kidney function and thus the presence of CKD in adults over the age of 18.[15]

Given concerns about the precision of the MDRD formula for eGFR values greater than 60 mL/min/1.73m^2, it has been recommended specifically that laboratories should report the calculated eGFR (when calculated as above 60 mL/m) as ">60" rather than denoting the actual calculated value.[7,8,16]

Why Should We Screen for CKD?

Since chronic kidney disease generally progresses in the absence of symptoms, early detection of CKD is critically important for both surveillance and for the implementation of specific strategies to slow progression. That this silent disease is both underdiagnosed and undertreated can be attributed in part to the fact that kidney function is not intuitively evident from measurement and reporting of the serum creatinine alone. A case study approach to test the physician's ability to assess the patient's kidney function from interpretation of a serum creatinine was recently shown to be associated with systematic overestimation of kidney function.[17] Routine reporting of the eGFR for all serum creatinine determinations by hospital, commercial, and physician office clinical laboratories has been recommended.[5,18] When this practice has been adopted voluntarily, physician appreciation of the diagnosis of CKD has improved significantly.[11,19]

How Prevalent is eGFR Reporting?

Despite such effort, it is likely that only 35% of clinical laboratories calculate and report the eGFR routinely, while adoption of this practice by physician office laboratories is even lower. One can conclude, therefore, that the majority of laboratories in the United States are not reporting eGFR. Such data are of concern because a low acceptance of automatic reporting of eGFR creates the potential for significant underrecognition of chronic kidney disease and missed opportunities to both diagnose this condition, and to provide appropriate and proven therapy to slow the progression of CKD.

Risk Factors for CKD

The risks for chronic kidney disease include diabetes mellitus, hypertension, cardiovascular disease, obesity, older age, proteinuria, the presence of peripheral vascular disease, cigarette smoking, hypercholesterolemia, sedentary lifestyle, dietary salt intake, and a history of receiving nephrotoxic drugs or contrast agents.[12,13,20] Of the 100 000 new end-stage kidney disease patients in the United States annually, 42% have diabetes mellitus, and 90% of the diabetics have type 2 diabetes mellitus.[20,21] Since the prevalence of type 2 diabetes mellitus is growing at a significant rate, progressively larger numbers of patients are at risk for developing CKD. Therefore surveillance for the presence of CKD is extremely important in the diabetic population. It would be prudent to measure the urine albumin to creatinine ratio and the eGFR annually in this at-risk population, especially in those with type 2 diabetes or a family history of ESKD.[22,23]

When There Is No Surveillance, There Is No Recognition or Treatment

Given the low level of automatic eGFR reporting, it should not be surprising that, based on Medicare enrollment and claims data, it appears that some primary care practices screen no more than 20% of Medicare patients with diabetes for the presence of CKD through application of the eGFR or microalbumin excretion.[24] In addition, less than one-third of those patients diagnosed with CKD receive an Angiotensin-Converting Enzyme (ACE) inhibitor or an Angiotensin Receptor Blocker (ARB).[24]

CKD and CVD: Dual Risk Factors

Chronic Kidney Disease should be recognized and treated as early as possible because of the increasing prevalence of both CKD and ESKD and because CKD is a major and independent risk factor for the presence and progression of cardiovascular disease (CVD).[25,26] The majority of patients with stages 2 and 3 CKD die from CVD before progressing to ESKD. A mortality rate of approximately 24% has been observed for stage 2 and stage 3 chronic kidney disease, but the mortality rate reaches 45% for stage 4 CKD. The reverse relationship has also been proven recently: CVD is associated with a higher prevalence of CKD.[27] As many as 23% of patients with coronary artery disease, 33% of patients with acute myocardial infarction, and 46% of patients with congestive heart failure have an eGFR of less than 60 mL/m.[28-30]

Who Should Care For CKD Patients?

Based on the growing population of patients in the United States with stage 3 or higher CKD (15.5 million) and with only

5000 full-time practicing nephrologists, there is an inadequate nephrology workforce to provide care for these patients without the involvement of primary care physicians.[19] It is important, therefore, that primary care physicians develop an increasing awareness of the diagnosis of chronic kidney disease. The North Carolina Institute of Medicine has recommended that all physicians encourage clinical laboratories to provide and report an estimated GFR every time a serum creatinine is ordered.[31] These same providers are encouraged to work with nephrologists in partnership to provide testing and treatment for CKD. A practical disease management paradigm for the coordinated care of chronic kidney disease involving both primary care and nephrology physicians is badly needed.

Voluntary Versus Mandatory Reporting

Statutory language has been adopted in a few states requiring calculation of the eGFR for all determinations of serum creatinine by clinical laboratories.[32] The College of American Pathologists and the National Kidney Foundation issued a joint statement, and the American Medical Association adopted a resolution, opposing mandating automatic reporting through state statutes.[33,34] Concern was voiced regarding automatic reporting of eGFR as an example of legislative mandate of clinical practice. It should be emphasized that neither group opposes the voluntary adoption of eGFR reporting.

A recent workgroup on automatic GFR reporting was convened as a component of the North Carolina Institute of Medicine Task Force on Chronic Kidney Disease. This workgroup recommended that clinical laboratories in North Carolina be encouraged to report eGFR values on all creatinine determinations voluntarily rather than through a legislative mandate. However, because the diagnosis and staging of chronic kidney disease requires knowledge of a value for GFR, the full task force strongly supported that laboratories automatically calculate eGFR whenever the provider orders a creatinine measurement. Furthermore, the task force recommended that if North Carolina laboratories do not voluntarily begin computing the eGFR on all creatinine determinations, the General Assembly should mandate automatic reporting.

Conclusion

With wider adaptation of automatic reporting of eGFR, a more evidence-based and coordinated method of care can be adopted more widely. Several professional societies are planning to develop a paradigm for the coordinated management of CKD by primary care physicians and nephrologists. While such an approach will be necessary because of the need for primary care coordination of chronic disease management, it is clear that a wider availability of eGFR will be a necessary first step in the accurate diagnosis and treatment of this devastating illness. **NCMJ**

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The Role of Nephrologists in Coordinating Care with Primary Care Practitioners

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Estimates based upon data from the most recent National Health and Nutrition and Examination Survey (NHANES III) and 2006 population estimates suggest more than 20 million Americans and almost 1 million North Carolinians have chronic kidney disease (CKD).[1,2] This increased rate of CKD is associated with and possibly exacerbated by poor access to health care and high rates of poverty (North Carolina ranks 12th worst in the nation), obesity (17th worst), diabetes (9th worst), and hypertension (10th worst).[3] In addition, minorities are at increased risk for CKD, and North Carolina ranks 8th highest in the nation for percent minorities in the population. The relatively higher prevalence of these risk factors in certain geographical areas of North Carolina is magnified by a lack of resources to manage the problem of CKD. This has led to an inordinately high prevalence of end-stage kidney disease (ESKD) in parts of North Carolina, primarily eastern North Carolina.

Presently in the United States, there are 7473 practicing nephrologists. Considering there are 20 million individuals with CKD in the US, each nephrologist would need to assume care for almost 3000 patients with CKD to manage this expanding problem. Of further concern are estimates that suggest North Carolina has 5% of the total US population with CKD but only 2.8% of the nephrologists in the US.[4,5] Realistically, it is not possible for the nephrology community to take care of this problem without forming partnerships with primary care providers. With the length of the average physician visit continuing to decline, primary care physicians will be unable to treat CKD without a more efficient approach. Clearly a new model of care is needed.

The prevention of CKD progression is an obvious alternative to stretching our already thin resources. Screening for kidney disease identifies individuals with or at risk for kidney disease and is the first step in delaying or stopping the progress of the disease. Several groups have made a significant contribution by screening for CKD in North Carolina. However, recent studies have demonstrated that only aggressive long-term management of multiple risk factors can slow the progression of kidney failure, with most studies only demonstrating an impact after several years of intervention.[6,7] CKD requires prolonged, methodical management strategies to achieve a measured improvement in outcomes. Thus, screening without long-term management will probably not impact outcomes.

The Kidney Disease Outcomes Quality Initiative (KDOQI) clinical practice guidelines are a complicated, very detailed series of recommendations that unfortunately are frequently beyond the capacity of a busy clinician to implement—especially given the multitude of preventive guidelines primary care providers are asked to follow.[8,9] Both the National Kidney Foundation (NKF) and the Renal Physicians Association (RPA) have developed toolkits to aid clinicians with the management of patients with CKD. However, neither set of guidelines provides clear recommendations for the operational management of CKD in a busy clinic setting.

"…it is not possible for the nephrology community to take care of this problem without forming partnerships with primary care providers."

Primary care physicians want continuity of care with full

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knowledge of what is going on with their patients and have demonstrated their ability to take on the CKD guidelines. Furthermore, there has been improvement in the rate of compliance with recommendations to initiate angiotensin converting enzyme inhibitors (ACEI) and angiotensin receptor blockers (ARB). Recent information suggests that the decline in the increasing incidence of ESKD may be attributed to widespread utilization of these medications along with careful control of diabetes and blood pressure.[10] However, the remaining CKD guidelines are more complex and less well-supported by evidence-based medicine. Many of the guidelines involve the purchase and administration of expensive injectables. As new and sometimes contradicting data emerge, the interpretation of these guidelines adds an additional layer of complexity for the primary care physician to sort through. Clearly the CKD treatment guidelines, beyond prescribing ACEIs and ARBs, are more difficult to effect in a primary care setting.

The nephrology community wants to stem the growing tide of ESKD though the magnitude of the CKD and ESKD problem precludes nephrology from managing it alone. Nephrology providers want to be involved. They want to develop a relationship with a patient and their primary care physician before the patient reaches ESKD. The KDOQI guidelines, NKF toolkit, and the RPA toolkit have given us a great start in slowing the CKD epidemic; however, we must develop a second generation approach. In fact, a commentary in this issue of the *North Carolina Medical Journal* discusses the importance of kidney care educators and care managers. The East Carolina Center for the Study of Kidney Disease has inserted nephrologists into primary care resident clinics to ensure our trainees are capable of managing CKD after residency. We are now piloting the insertion of nephrology teams into primary care clinics in eastern North Carolina. These teams will work side by side with their primary care colleagues as they demonstrate a hands-on approach to the institution of KDOQI guidelines. Long-term follow up will be needed to determine the efficacy of these new efforts. Models beyond standard consultation are needed.

Most importantly, patients want and deserve a medical home. Dependence on multiple providers is necessary but complicates care. With the recent downturn in the economy, regular follow-up with multiple providers is at even greater risk, especially when significant travel is involved. The primary care and nephrology communities in North Carolina have done much to improve the care of patients with CKD, but it is clear that patients need convenient and effective preventive strategies to slow the progression of CKD as well as one for primary prevention. Communication between primary and subspecialty providers must be strengthened to manage the multiple complex comorbidities involved in this population.

A substantial amount of work has been done to reduce the heavy burden of CKD in our state, but in light of the significant financial and human cost of CKD, we must do more. With rising health care costs, decreasing resources, and a patient population that deserves and needs coordinated care, we will need to explore more effective options for delivery of subspecialty preventive care. **NCMJ**

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The Chronic Kidney Disease Primary Care Practice

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I am intrigued by the implications of the title of this commentary. "Chronic Kidney Disease" could easily be replaced by "Diabetes" or "Asthma" or "Heart Disease." Primary care figures prominently in all of these chronic diseases. This presents a tremendous management challenge when primary care providers' time is being consumed by chronic disease management, while recognition of the importance of primary prevention is at an unprecedented high and is generating calls for even more attention. For example, the number of available and recommended immunizations for all age groups has dramatically multiplied in the last decade after years of incremental growth, and patients must still be seen for acute care with the expectation that access is timely. All the while, primary care providers are ordering tests and making referrals for patients on- and off-site. The practice of primary care is a daunting task, and I know as well as anyone that the environment is one of declining reimbursement for physician services.

Within primary care, we each have our own area of specific interest and expertise, which develops for a variety of reasons such as innate interest, location of practice, patient base, and happenstance. The latter reason stimulated my interest in chronic kidney disease (CKD). In 2000 I agreed to be the primary care representative on the KDOQI task force to develop evidence-based guidelines for CKD. Through the process I became convinced of the importance of this condition and the impact we can make on CKD through appropriate interventions in the primary care setting. In some respects, I became a CKD primary care practitioner. I could not say the same for myself about many other conditions.

Since the KDOQI guidelines were published in 2002, I have urged our primary care community to heighten awareness of CKD, screen individuals at high risk for CKD, and use KDOQI staging for those individuals found to have CKD (see Table 1). Fundamentally, I believe the literature that states early diagnosis and intervention can slow the progress of CKD, and I strongly urge primary care doctors to adopt those modalities likely to result in improved outcomes.

When I graduated from medical school in 1977, it was almost possible to commit to memory most of the information needed to practice medicine on a daily basis. Now it would be ludicrous to even try. Over 3 decades, advances in research areas such as basic and molecular sciences, genomics, proteomics, and clinical nanomedicine have vastly increased the volume and complexity of the information required to practice medicine.

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Further, until relatively recently, neither the physician nor the patient had virtual access to this expanse of information. Today, the solution to information overload is to utilize the many tools available to manage access to information. Electronic journal resources facilitate evidence-based practice, while the adoption of electronic health records offers coordinated patient information systems. Adoption of the modalities recommended by the KDOQI task force further supports this integrated approach by reducing fragmented specialist care and diffusing expertise among health care providers.

Given the unevenness of our individual expertise, consider the following model. For those of us who commit to a generalist

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Table 1.
Stages of Chronic Kidney Disease: A Clinical Action Plan

Stage	Description	GFR (mL/min/1.73 m^2)	Action*
	At increased risk	>60 (CKD risk factors)	Screening, CVD risk reduction
1	Kidney damage with normal or ↑ GFR	≥90	Diagnosis and treatment, Treatment of comorbid conditions, Slowing progression, CVD risk reduction
2	Kidney damage with mild ↓ GFR	60-89	Estimating progression
3	Moderate ↓ GFR	30-59	Evaluating and treating complications
4	Severe ↓ GFR	15-29	Preparing for kidney replacement therapy
5	Kidney failure	<15 (or dialysis)	Replacement (if urernia present)

*Includes actions from preceding stages.
Abbreviations: CVD, cardiovascular disease

practice, we must prepare to undertake screening and primary prevention activities with our patient population. We need to begin with ourselves—as lifelong learners—to be familiar with evolving evidence-based practice. Using CKD as an example, this means knowing that the KDOQI guidelines exist and being familiar with them. The guidelines should then be incorporated into our practice. We can meet this challenge electronically using such modalities as prompts from our electronic health records to screen our high-risk patients. We need quick access to information on screening methodology that can also be accessed electronically. To be successful, the system of practice itself must be the underpinning to personalized, evidence-based care. As pointed out in the issue brief and by Thomas DuBose in his commentary, the laboratory should report estimated glomerular filtration rate (eGFR) without the physician's specific request. If necessary we should join our nephrology colleagues in advocating for our reference laboratories to report, in all cases, an eGFR. When we do identify a patient with CKD requiring specialty assistance and order a consultation, the response must be timely and standardized, whether from nephrologists, dietitians, or patient educators. If the care is not provided seamlessly, it is frustrating to all involved. And more importantly, the quality of the care diminishes.

The system of practice must be there for the primary care provider, but the provider must know when and how to access it so that recommended aspects of care are not overlooked. For example, the primary care provider, who has interest in and knowledge about CKD and who understands and follows the KDOQI guidelines, may be able to provide the preponderance of care to these patients. At the other end of the spectrum would be the practice that performs only the "first contact" in primary care—identifying the patient who should be screened for CKD. The patient is then entered into another part of the integrated system. Confidence in the process results in decreased stress on the primary care provider and increased enjoyment in practicing medicine.

What are the key KDOQI guidelines that present the opportunity for early diagnosis and intervention in the CKD patient?[a] First is familiarity with risk factors for CKD, including diabetes, hypertension, family history of CKD, and certain racial/ethnic groups including African American, Native American, Hispanic, and Asian and Pacific Islander. Individuals with any of these risk factors should undergo screening for CKD. Second is understanding—even a cursory understanding—of screening guidelines. These guidelines are much less complex—and more physician and patient friendly—than those we have used in the past, and they are evidenced-based. Quite simply, they consist of assessment of eGFR and of proteinuria.

Serum creatinine level, when used alone, is too inaccurate to determine kidney function in an individual patient. Rather, eGFR should be based on a prediction equation. Commonly used is the 4-variable MDRD (Modification of Diet in Renal Disease) equation which factors in serum creatinine, age, gender, and race. The result can be reported out as "African American" or "non African American" if the race is unknown. Age can be determined from the patient identifier. Usually gender can also be determined, but if not, the eGFR should be reported for both male and female. Automatic laboratory reporting of

a CKD as defined by KDOQI is a structural or functional abnormality of the kidney for ≥3 months, as manifested by either kidney damage with or without decreased GFR, or GFR<60 ml/min/1.73m^2, with or without kidney damage.

eGFR makes this process seamless for the patient and physician.

Initial assessment of proteinuria is as simple as dipstick testing using an untimed spot urine sample. Although a first morning urine sample is preferred, a random specimen is acceptable and does not add a step to the process. Most primary care providers (and patients) are pleased to learn that routine collection of 24-hour urine samples is unnecessary and required only in select circumstances. Patients with a positive dipstick test (≥1+) should undergo confirmation of proteinuria by a quantitative measurement. An albumin-to-creatinine ratio is the preferred technique in adults. Once again, an untimed spot urine sample can be used. Patients with 2 or more positive quantitative tests temporally spaced by 1 to 2 weeks should be diagnosed with persistent proteinuria.

For patients determined to have CKD, staging is based on the level of kidney function, irrespective of diagnosis, according to the KDOQI classification. Using this classification universally supports communication among providers and their patients, untangling the ambiguities caused by vague terms such as "chronic renal insufficiency" and "chronic renal failure." Specific interventions in slowing the progression of CKD include the following:

- Lowering low-density lipoprotein (LDL) cholesterol to less than 100 mg/dl
- Lowering blood pressure to less than 130/80 mmHg
- Drug therapy with an Angiotensin-Converting Enzyme (ACE) Inhibitor or an Angiotensin Receptor Blocker (ARB) to slow progression of proteinuria (titrating to reach the target blood pressure and to decrease proteinuria to less than 1 gram)

The preceding interventions are ones the majority of primary care practices would want to carry out within their own settings. All practices should examine their systems and incorporate these interventions. Then, the interested and motivated practices will incorporate some of the remaining guidelines (15 in all) into electronic prompts. Practical examples include annual testing for anemia and evidence of disorders of bone metabolism beginning when the eGFR falls below 60 ml/minute.

With repetition, the primary care physician can become familiar with the broader array of the frequently used guidelines. Given the scope of the CKD problem, it is the hope of the North Carolina Institute of Medicine Task Force on Chronic Kidney Disease that the KDOQI guidelines are among those recognized and implemented regularly in practice. **NCMJ**

Public Health Initiatives to Prevent and Detect Chronic Kidney Disease in North Carolina

Barbara Pullen-Smith, MPH; Marcus Plescia, MD, MPH

Chronic kidney disease (CKD) is a significant and increasing public health problem. It is the tenth most common cause of death in North Carolina, and almost 1 million North Carolinians have an early stage of the disease.[1] As with many chronic diseases, CKD takes its greatest toll on minority communities, people who live in poverty, and the uninsured and underinsured. Racial and ethnic health disparities among the incidence of CKD and its complications, especially end-stage renal disease (ESRD), have been well documented. Compared to Whites, African Americans are 3 to 4 times more likely to have CKD that has progressed to end-stage renal disease, the most ominous complication, and they are twice as likely to die from this condition.[1]

Much of the public health approach to CKD is focused on the underlying risk factors for CKD, especially high blood pressure, diabetes, and obesity. These conditions can be prevented, in large part, through protective health behaviors (primary prevention). Affected individuals can avoid medical complications, like CKD, through early detection and control of high blood pressure and diabetes with health behavior change and medication use (secondary prevention). Outreach to underserved communities is particularly important to control these conditions. This requires community-based participatory approaches focused on public awareness, education, screening, and access to care. This article highlights some of the state's community-based efforts to increase education, outreach, screening, and care management for people with different types of chronic illnesses. While many of these initiatives do not focus on management of people with CKD, these initiatives should nonetheless help reduce the incidence of CKD by reducing some of the common risk factors.

North Carolina has many primary prevention programs aimed at reducing risk factors that lead to obesity, diabetes, and hypertension. Some of these programs operate statewide while others are focused in particular counties. Eat Smart, Move More is a statewide social marketing campaign to help North Carolina residents eat healthier and exercise more by changing social norms and practices in schools, worksites, communities, and health care settings. Another statewide health promotion program provides funding to local health departments to focus on barriers to physical activity and good nutrition at the community level. In addition, the Office of Healthy Carolinians within the Division of Public Health supports local coalitions that assess and address community health priorities for a wide range of health issues. Most local coalitions address obesity, diabetes, and hypertension.

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Another community-based program that focuses on diabetes prevention and control is the Division of Public Health Diabetes Today program. Diabetes Today is based in 4 local health departments that serve as lead agencies and collaborate with surrounding health departments to increase the availability of community-based programs that promote diabetes awareness, education, and prevention strategies. Local health department staff work with community members, health professionals, and community institutions to understand and respond to the burden of diabetes. Through the Diabetes Today training initiatives,

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the Diabetes Prevention and Control Program in the Division of Public Health reaches the populations who are at greatest risk for diabetes. Diabetes Today has been implemented in 29 counties in North Carolina.

Primary prevention is not sufficient to reduce the burden of diabetes. Individuals who already have diabetes must be taught self-management skills. Indeed, self-management education is such a critical part of diabetes care that medical treatment of diabetes without self-management education is considered inadequate. Yet a 2006 report from the State Center for Health Statistics shows that 46% of adult North Carolinians with diabetes have never taken a class on how to manage their diabetes.[2] In addition, a 2005 survey of all 85 local health departments in North Carolina demonstrated that only 58% of these departments report the capacity to provide health education services for persons with diabetes.[3] Health departments currently lack the staff and funding to support further expansion of diabetes self-management education.

The Division of Public Health (DPH) has taken steps to address this problem. The division created the North Carolina Diabetes Education Program to expand the availability of diabetes self-management education in local health departments for at-risk populations. In addition, DPH applied to the American Diabetes Association to become an umbrella program recognized to provide diabetes self-management education. Once recognized as an umbrella organization, DPH will partner with local health departments to train and certify diabetes educators. The purpose is to increase access in all areas of the state for people with diabetes to get needed self-management training while providing reimbursement to local health departments. The additional reimbursement will build capacity at the local level to provide self-management education for the uninsured and underinsured as well. Although this reimbursement is limited to people with diabetes, it is a source of funding to support CKD education as diabetes educators must include information about kidney disease as a potential complication of diabetes.

The Division of Public Health has developed similar education, outreach, and screening programs for heart diseases and other chronic conditions. The Well-Integrated Screening and Evaluation for Women Across the Nation (WISEWOMAN) program is a federal program that helps underserved women gain access to screening and lifestyle interventions to reduce their risk for heart disease and other chronic diseases. The program targets women who are receiving screening services through the Breast and Cervical Cancer Prevention program. Eligible women are between 40 and 64 years of age and have little or no health insurance. Special emphasis is placed on reaching racial and ethnic minority populations. WISEWOMAN is active in 33 counties in the state and includes screening for hypertension, obesity, and poor dietary habits as well as specially developed nutrition, exercise, and smoking cessation counseling. The national program has demonstrated improvements in blood pressure control and dietary habits.

In addition to the primary and secondary prevention efforts offered through local health departments, new strategies are needed to reach underserved populations. Many uninsured, low-income racial and ethnic minorities do not routinely seek medical care services. Partnering with community groups and local leaders offers the advantage of being able to reach people in a non-health care setting. The Office of Minority Health and Health Disparities (OMHHD) provides grants to a network of local organizations to address health disparities. The OMHHD grant program, Community Focused Eliminating Health Disparities Initiative, works to build the capacity of community-based organizations, faith-based organizations, American Indian Tribes, and local health departments to improve the health of racial and ethnic minority populations. These community-based strategies extend existing public health services by providing awareness, prevention, screening, and health care services after regular business hours in the evenings and on weekends. The University of North Carolina Kidney Center adopted a similar approach in its outreach efforts described elsewhere in this issue.

The use of lay health advisors has emerged as a focus of many interventions, particularly those in racial and ethnic communities. Lay health advisor projects seek to identify and recruit "natural helpers" in a community and provide training and support for them to advise and assist their neighbors and peers with a variety of health issues. Lay health advisor models enhance empowerment and capacity building by promoting and supporting individuals who assume responsibility for community improvement, seek new knowledge and skills, and actively engage and recruit others. Lay health advisor programs have demonstrated changes in the attitudes of community members about their control over health issues and in their willingness to consider behavioral changes.[4]

The Office of Minority Health and Health Disparities Community Health Ambassador Program (CHAP) trains trusted community leaders in the African American, American Indian, and Hispanic/Latino communities to serve as lay health advisors in their communities. CHAP began in the spring of 2006. OMHHD partners with the North Carolina Community College System, Community Care of North Carolina, the Old North State Medical Society, the University of North Carolina at Greensboro Nursing Program, and community- and faith-based organizations to help identify and train community health ambassadors (CHAs). CHAs must successfully complete 20 hours of classroom education and pass a competency examination. The program has trained more than 300 CHAs from 14 counties with goals to expand the program statewide as funding becomes available. These volunteers help bridge the gap between community members, their health concerns, and health service providers. CHAs educate community members about ways to prevent illnesses, recognize early warning signs, and access services. Currently, CHAP focuses on diabetes and cancer education. However, there are plans to develop modules to address other health disparity issues including CKD, cardiovascular disease, and HIV/AIDS. The goal of the program is to help community members prevent chronic diseases and decrease morbidity and mortality.

Screening for hypertension is an established, evidence-based practice in the medical setting. Most clinical practice settings

measure blood pressure as routine vital signs for all patients at every visit. Screening for diabetes is generally targeted to patients at risk because of family history or comorbidities. Screening in the community setting is more controversial. There is concern that individuals identified in community-based hypertension or diabetes screening seek and receive appropriate medical follow-up particularly if they are uninsured or underinsured. For this reason, federal policy precludes use of federal funds for community-based screening. There are no state funds to support these activities.

In addition to the preventive components described above, the state diabetes program also includes a state kidney program. This program provides funds to reimburse transportation, medication, and emergency-related expenses for persons meeting the eligibility requirements for the State Kidney Program when there is no other source of reimbursement. The purpose of the State Kidney Program is to enable greater access to kidney dialysis for a significant number of North Carolinians. The program provides secondary and tertiary preventive services to persons at risk for end-stage renal disease, and helps to reduce the further risk and consequences of persons with end-stage renal disease by paying for some of their expenses for dialysis, medications, incidental supplies, and transportation.

Community-based and community-led strategies play a significant role in public health efforts to prevent chronic diseases and conditions. Nontraditional groups including community-based organizations, faith-based organizations, and American Indian tribes are very effective partners. When armed with key health information and resources, these partners are able to reach individuals where they live, play, work, and pray. As illustrated, there are numerous public health programs and initiatives working to prevent and/or control the chronic diseases and conditions that may lead to chronic kidney disease and ultimately to end-stage renal disease. Unfortunately, while many of these programs implement evidenced-based strategies, the current level of resources invested in these programs is not adequate to demonstrate the desired outcomes of chronic kidney disease prevention and/or control. Additional resources are needed to fully implement these evidence-based primary and secondary prevention strategies among at-risk populations. Early investment in these community-based participation strategies hold great promise to lead to improved health, greater productivity, and reduced health spending. **NCMJ**

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SIDEBAR

The National Kidney Foundation of North Carolina

Leanne Skipper

The National Kidney Foundation of North Carolina (NKFNC) is committed to reducing the burden of chronic kidney disease (CKD) in North Carolina by preventing or delaying kidney disease from becoming kidney failure. The NKFNC provides access and education to individuals affected by CKD, launches public awareness initiatives designed to put a spotlight on the growing problem of CKD in North Carolina, and educates health care professionals about their critical role in detecting and managing CKD in their patient populations.

In April 2003, the National Kidney Foundation launched its Kidney Learning System (KLS) which focuses on education, early patient identification, prevention, and clinical applications that improve outcomes. KLS provides high-quality live programs, multimedia, and printed materials for physicians, allied health care professionals, CKD patients, those at increased risk, and the public. KLS materials are categorized by CKD stages along the continuum of care. This is consistent with the accepted medical classification of CKD.

The Kidney Learning System provides materials that focus on the following:

- Public awareness of risk factors such as diabetes, high blood pressure, and family history of kidney disease
- Awareness of the 5 stages of CKD and what can be done to treat CKD even in the early stages
- "How to" information for early identification and treatment
- Patient and family education and support for living better in any of the 5 stages
- How kidney transplant recipients fit into the 5 stages
- Education and support to health care professionals in every discipline and specialty who care for people who are at risk for CKD, patients in the early stages of CKD, patients in later stages, and kidney transplant recipients
- Tools for using evidence-based clinical practice guidelines and recommendations

To identify individuals at increased risk for kidney disease due to complications resulting from diabetes or high blood pressure, or who have first-degree relatives with hypertension, diabetes, or kidney disease, the National Kidney Foundation offers the Kidney Early Evaluation Program (KEEP). KEEP is a free kidney health screening program designed to raise awareness about kidney disease among high-risk individuals and to provide free testing and educational information so that kidney disease and its complications can be prevented or delayed.

The goals of KEEP are to:

- Raise awareness of kidney disease especially among "high-risk" individuals.
- Provide free testing for people at increased risk for kidney disease.
- Encourage people at risk to visit a doctor and follow the recommended treatment plan.
- Provide educational information so that at-risk individuals can prevent or delay kidney damage.
- Provide doctor referrals for follow-up care, if needed.
- Provide ongoing information and support.

Individuals should attend a KEEP screening if they are 18 years or older and have one or more of the following CKD risk factors:

- Diabetes
- High blood pressure
- A parent, grandparent, brother, or sister with diabetes, high blood pressure, or kidney disease

One or more of these services will be provided at the screening:

- Blood pressure and weight measurements
- Blood and urine tests for signs of diabetes and kidney disease including:
  - Blood glucose test (to check blood sugar levels)
  - Hemoglobin blood test (to screen for anemia)
  - Urine dipstick test for pyuria (to detect white blood cell count in urine)
  - Urine dipstick test for hematuria (to detect red blood cell count in urine)
  - Albumin to creatinine ratio (to detect protein levels in urine)
  - Serum creatinine (to measure how well kidneys are filtering blood)
  - Estimated Glomerular Filtration Rate (to test for overall kidney function)

Test results are provided on-site by a doctor or other qualified health professional.

Free educational materials are also available through KEEP.

Upon completion of the KEEP screening, the National Kidney Foundation will:

- Contact individuals with their results.
- With permission, send the results to the individual's doctor.
- Refer people with positive screens to a doctor or public health facility, if needed
- Provide additional information, education, and support.

The National Kidney Foundation of North Carolina believes that it is critical for the public to understand the risk factors for chronic kidney disease and to be proactive in their own health care to reduce their chances of being affected.

For more information visit the NKFNC at www.kidneync.org or visit the national Web site at www.kidney.org.

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SIDEBAR

The Kidney Education Outreach Program:
HEY DOC, HOW ARE MY KIDNEYS?

Donna H. Harward

The University of North Carolina Kidney Center has developed an innovative, community-based outreach program targeted to at-risk populations who are unaware of the major factors leading to the development of chronic kidney disease. The Kidney Education Outreach Program (KEOP) was launched in the fall of 2005 with the support of an Abbott Laboratories education grant. The program targets 17 counties with high prevalence rates of end-stage kidney disease. The goals of this outreach initiative are to educate the public about chronic kidney disease, screen at-risk populations, and work with physicians to provide early interventions to stop or slow the progression of the disease.[1-4]

KEOP staff have conducted 17 focus groups and spoken with more than 1300 at-risk individuals to assess community understanding of kidney disease. The staff use the information gathered from these discussions to develop customized awareness, prevention, and outreach activities for at-risk populations. In addition, KEOP identifies local community leaders to serve as spokespersons for community-based media campaigns focusing on the primary risk factors for CKD. The media campaigns and outreach materials remind people to check on their kidney health by using the KEOP motto: "Remember to Ask…HEY DOC, HOW ARE MY KIDNEYS?"

KEOP has also provided free screenings to more than 1500 at-risk individuals in partnership with local agencies and faith-based organizations. To further expand outreach and screening efforts, KEOP recently purchased a mobile outreach unit with support from the Kate B. Reynolds Charitable Trust, the UNC Health Care System, and public donations. People who are screened receive a personal consult and medical information to be shared with their primary care provider. KEOP staff also help individuals identify appropriate community-based resources if the individual does not have a primary care provider.

KEOP's success is rooted in relationships developed with community-based lay leaders, agencies, and institutions. KEOP works with county commissioners, health departments, faith-based organizations and ministries, civic clubs, local businesses, and community colleges to raise awareness about the high prevalence of CKD and its comorbid diseases. The outreach to these community organizations has helped KEOP identify local lay leaders and organizations that can work collaboratively with KEOP program staff to provide key outreach activities. In addition, community-based partners, spokespersons, and lay leaders help promote awareness about the major risk factors for CKD. Further collaboration with other North Carolina agencies and community-based outreach organizations that target comorbid diseases (diabetes, hypertension, heart disease) will ensure that KEOP continues to educate at-risk North Carolinians about the importance of asking, "HEY DOC, HOW ARE MY KIDNEYS?"

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Community Care of North Carolina and the Medical Home Approach to Chronic Kidney Disease

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While the prevalence of end-stage kidney disease (ESKD) has more than tripled in North Carolina over the past 20 years,[1] the number of Medicaid recipients with ESKD has grown to over 10 000. According to the NC Division of Medical Assistance Quality, Evaluation, and Health Outcomes Unit, Medicaid spending for ESKD patients exceeded $340 million in SFY 2007 (written communication, June 2008).[a]

Too often, kidney disease progresses undetected or poorly managed for years before the onset of kidney failure. The consequent pattern of accessing care for late-stage symptoms through hospital emergency rooms—with urgent need for kidney replacement therapy—sets the stage for long hospital stays and costly medical complications. Such scenarios are terrifying for patients and families, frustrating for healthcare providers, and of significant cost burden to Medicaid.

A patient-centered response to the escalation of kidney disease in North Carolina requires an upstream focus on prevention and risk factor management. Primary care, as the principal point of contact for most individuals into the health care system, must be central to this effort. From the patient's perspective, the primary care practice should be a "medical home," where one is assured of reliable access to preventive care, chronic disease management, education, support, and advocacy in the often complex navigation of the health care system. Primary care providers are best positioned to identify individuals at risk for chronic kidney disease (CKD), recognize CKD in its early stages, initiate appropriate therapy, manage comorbid risk factors, monitor disease progression, and coordinate comprehensive team-based care according to individual patient need. Incumbent upon Medicaid and all purchasers of health care is the need to identify and implement effective mechanisms of support for the medical home to facilitate optimal care for CKD patients and at-risk populations.

Community Care of North Carolina

The Community Care of North Carolina (CCNC) program was established in 1998 to help North Carolina proactively face the perpetual challenge of providing cost-efficient, high-quality care to its Medicaid population by assuring recipient access to community-based primary care, improving care coordination, and promoting evidence-based best practices.[2,3] Over the past decade, CCNC has grown into a robust system of statewide community health networks, organized and operated by local physicians, hospitals, health departments, and departments of

"A patient-centered response to the escalation of kidney disease in North Carolina requires an upstream focus on prevention and risk factor management."

a Estimates include pre-dialysis end-stage kidney disease, dialysis, and kidney transplant patients. Medicare costs are not included.

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social services. These private, not-for-profit provider networks are establishing the local systems necessary to achieve long-term quality, cost, access, and utilization objectives in the management of care for Medicaid patients. Currently, 14 networks with more than 3000 participating primary care physicians are working together to improve health outcomes for approximately 786 000 Medicaid enrollees.

CCNC is an enhanced primary care case management model in which participating practices receive $2.50 per member per month to assure access to a medical home and to support quality improvement activities. Regional networks receive $3 per member per month to support local care coordination and key disease management/population management initiatives. The CCNC model seeks to transform Medicaid operations from a regulatory process to a health management function, with careful balance of cost containment with quality improvement efforts. Decision making is driven by data and outcomes, and activities are designed to engage physicians, hospitals, and service providers in collaborative response to cost or quality issues.

Current Initiatives

Statewide CCNC programs include asthma, diabetes, and heart failure disease management; emergency department utilization/medical home; pharmacy management and prescribing initiatives; and care management of high-cost/high-risk patients. Pilot projects are underway for mental health co-location, chronic obstructive pulmonary disease (COPD), chronic pain management, and childhood obesity, among others.

Of particular relevance to chronic kidney disease is the CCNC Diabetes Quality Improvement Initiative. Diabetes is a leading cause of heart disease, stroke, blindness, and death and is the number one cause of kidney failure requiring dialysis in North Carolina. The CCNC approach to diabetes quality improvement emphasizes evidence-based process improvement for delivery of comprehensive diabetes care in the medical home as well as patient education and self-management support. Program-wide, CCNC has exceeded thresholds established by the National Committee for Quality Assurance (NCQA) Diabetes Physician Recognition Program for 5 out of 7 diabetes quality of care measures including glycemic control, blood pressure control, and cholesterol control. Based on chart audits of over 10 000 people with diabetes enrolled in CCNC, over 90% are attending continued care visits with their primary care provider; over 70% are up-to-date with lipid tests, foot exams, and A1C testing; and the average A1C value is 7.7%.

More recently, with support from the Kate B. Reynolds Charitable Trust and the North Carolina Foundation for Advancement of Health Programs, CCNC has launched a pilot initiative targeting Medicaid enrollees with hypertension. This initiative has 2 related goals: to promote global cardiovascular risk screening and aggressive risk factor management in the medical home, and to engage patients in better understanding of cardiovascular risk, self-management, and medication adherence. The overlap of risk factors for cardiovascular disease and kidney disease, and kidney disease as an independent risk factor for cardiovascular disease, will be emphasized within this initiative.

Pilots known as "Chronic Care," targeting Medicaid recipients with disability, are underway in 12 CCNC networks. After reports of cost savings achieved through CCNC for Medicaid children and families were estimated at $124 million in SFY 2004 (Mercer Government Human Services Consulting, personal communication, March 2005) the North Carolina Legislature called upon CCNC to expand activities to more fully address the needs of elderly and disabled enrollees. The complex array of physical and mental health comorbidities, and the longterm care needs of this population, demand new models of comprehensive care management, new models for advancing quality improvement in the medical home, and broader community coalitions of providers and institutions involved in the care of the patient.[4] Early experience from these pilot efforts has made clear that single disease-focused initiatives are not sufficient for this population. Kidney disease (like diabetes, heart failure, lung disease, depression, or any other condition) rarely exists in isolation, and must be approached in the full context of the care needs of the individual.

Shining the Spotlight on CKD

Risk factors for chronic kidney disease are highly prevalent among Medicaid recipients. Over 200 000 Medicaid-enrolled adults (including 70 000 CCNC enrollees) have hypertension; over one-third of these also have diabetes. Among elderly or disabled CCNC enrollees, 1 in 5 has diabetes, and the prevalence of hypertension nears 40%. CCNC has an important opportunity to reach tens of thousands of high-risk North Carolinians before the onset of end-stage kidney disease.

With the impetus of the North Carolina Institute of Medicine (NC IOM) Task Force on Chronic Kidney Disease over the past year, CCNC and the North Carolina Division of Medical Assistance have begun to identify gaps in the detection and management of CKD for North Carolina Medicaid recipients. Our findings are startling, yet point to specific opportunities to improve the quality of CKD care:

- Among adult Medicaid recipients with hypertension managed in the primary care setting, over one-third have a calculated estimated glomerular filtration rate (eGFR)<60, which signifies stage 3 CKD or worse. Only 46% of these CKD patients have been prescribed an ACE Inhibitor (ACE) or Angiotensin Receptor Blocker (ARB), and only 8% have their blood pressure controlled to the recommended level of below 130/80. It is probable that CKD is largely unrecognized in this population:

well over half of these patients have a serum creatinine near the normal range (≤1.5 mg/dL).[b,5]

- Among Medicaid recipients with both hypertension and diabetes, only 54% are prescribed an ACE or ARB, and only 27% have their blood pressure controlled to the recommended level of below 130/80.[b,5]
- Approximately one-quarter of CCNC enrollees with diabetes have not had recommended nephropathy management. These patients have not been screened for microalbuminuria in the past year *and* are not currently taking an ACE or ARB.[c]

Promoting Best Care for Early Kidney Disease

These gaps in quality of care related to early CKD detection and management demand attention. CCNC networks are well-positioned to work with primary care practices across the state to both improve care and reduce costs related to CKD. Building upon existing infrastructure, ongoing initiatives, demonstrated high achievements in diabetes care management, and the recommendations of the NC IOM CKD Task Force, local networks could consider a variety of strategies:

- Primary care provider education about evidence-based CKD management, including screening criteria and therapeutic recommendations by stage. Emphasis should include screening for reduced eGFR and urinary protein excretion in patients at risk; the preferential use of ACE inhibitors or ARBs for people with diabetes with hypertension or microalbuminuria and for most patients with eGFR <60; and the aggressive management of blood pressure to target levels <130/80 for people with diabetes and patients with eGFR<60.
- Practice education and assistance to assure more widespread detection of early CKD by arranging for automatic eGFR reporting from referral laboratories when creatinine is ordered.
- Support of practice system redesign to incorporate point-of-care reminders into chart flowsheets, registry systems, or electronic health records.
- Chart audits and performance feedback on CKD-related quality of care measures.
- CCNC case manager education about CKD to better address kidney-related issues with patients at risk, and to better facilitate coordinated care between consulting nephrologists and the medical home.
- Use of a prescription drug fill database to identify patients with poor adherence patterns to kidney-protective medication for targeted self-management support.
- Monitoring of hospital, practice, or referral laboratory data to identify enrolled patients with declining eGFR, for targeted educational outreach and care coordination.

Aligning Incentives for Better Management of Advanced Kidney Disease

Alignment of financial incentives is key to the implementation and sustainability of initiatives such as those outlined above. Among Medicaid recipients with end-stage kidney disease (with ongoing or imminent need for kidney replacement therapy), only 17% are enrolled in the CCNC program, and over two-thirds are also covered by Medicare. For these "dually eligible" patients, improvements in the quality of preventive and outpatient care may be expected to incur savings through reduced hospital utilization. Under typical financing arrangements, savings accomplished through CCNC efforts may largely accrue to the federal Medicare program rather than the state Medicaid program. North Carolina Community Care Networks, Inc. is currently seeking a federal waiver to allow for a demonstration of how the CCNC managed care model can achieve cost savings in this higher risk population, such that shared savings could be reinvested into community/network efforts and the medical home. If approved, such a waiver may allow involved networks to explore active enrollment and more intensive care management of advanced CKD patients. Future focus areas may then include patient and family education about kidney replacement therapy options, improved systems for care coordination between nephrologists, primary care and other specialty providers, and assurance of early vascular access for kidney replacement therapy.

We must also recognize that the many uninsured North Carolinians at risk of kidney disease should be the concern of Medicaid and Medicare programs now. It is estimated, for example, that over 200 000 hypertensive adults in North Carolina lack health insurance. Some of those individuals will not have access to health care until they become eligible for Medicaid and/or Medicare on the basis of end-stage kidney disease or other late disabling complications of uncontrolled blood pressure. A number of CCNC networks have expanded their infrastructure to include care management of uninsured individuals in their regions, and to help assure access to a medical home for chronic and preventive care and access to specialty care when needed. In a health care system where advanced age or disability are prerequisites for publicly financed health care coverage, the sustainability and spread of these programs will require proactive leadership and greater resource commitments.

Change is Local

Community Care of North Carolina is a unique approach to Medicaid managed care because it is directed by the physicians who care for the patients. CCNC works at the local level, and networks can only be as strong as their participating providers and community partners. Expanding network activities to focus attention on CKD management, deploying any of the

b Based on a 2006 chart review of 3793 adult North Carolina Medicaid enrollees with hypertension managed in the primary care setting. Patients receiving dialysis were excluded.

c Based on Medicaid claims review of 6455 non-dual CCNC-enrollees with diabetes, April 2008.

strategies suggested above, will require a commitment of resources. Network success in this area will rely upon local champions and cooperation between hospitals, specialists, laboratories, ancillary services, and the primary care provider in the medical home. Contact information for local CCNC networks can be found at www.communitycarenc.com. **NCMJ**

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The Kidney Care Prevention Program:
An Innovative Approach to Chronic Kidney Disease Prevention

Donna H. Harward; Ronald J. Falk, MD

Traditional methods of health care delivery do not adequately address the needs of individual citizens or populations with chronic kidney disease (CKD). One in 9 North Carolinians has CKD.[1] Without early intervention, many people with CKD will progress to end-stage kidney disease (ESKD), an irreversible and debilitating disease that represents the last stage in the long duration of chronic kidney disease. ESKD is not only a personal and financial tragedy for patients and their families, but it also generates a serious financial burden for society as a whole.[1-4]

North Carolina's rural, underserved areas tend to have the highest rates of ESKD. However, the relative dearth of primary care physicians in rural areas does not fully explain the lack of access to preventive, primary care services including screening and early intervention for CKD.[5] Primary care physicians, irrespective of practice location, frequently diagnose patients in late stages of CKD—missing the opportunity to stop the disease or to significantly slow its progression.[6] Individuals' lack of awareness about CKD and its risk factors creates an additional barrier to obtaining preventive care. Jurkovitz and colleagues found that even though African Americans are nearly 7 times as likely to report a positive family history of ESKD, their perceptions of personal risk do not reflect their actual increased risk.[7] Further, citizens in rural communities with struggling economies and modest employment opportunities are often uninsured or underinsured and are unlikely to pay out of pocket for preventive care services. In 2005, it was estimated that only 25% of North Carolina's uninsured population receives services from North Carolina safety net organizations.[8] There is an immediate need to create a community-based, systematic, and targeted intervention to reduce the number of North Carolina citizens that progress to ESKD.[1]

The Kidney Care Prevention Program (KCPP) is a collaboration between the University of North Carolina (UNC) Kidney Center and the North Carolina Community College System (NCCCS). KCPP is designed to reduce the mortality, morbidity, and cost associated with kidney disease through an aggressive combination of community-based, targeted educational outreach; free screenings; and sustained, personalized disease management by trained kidney care coordinators. The KCPP has 2 innovative components: (1) Fully equipped mobile outreach units that will travel the eastern, central, and western regions of North Carolina to provide immediate screening and intervention for North Carolinians at risk for developing chronic kidney disease, and (2) A new curriculum offered through the NCCCS, that will lead to certification of allied health professionals who can serve as kidney care educators and care managers.

"Trained kidney care coordinator/educators can intervene early in the disease and help individuals with early-stage CKD monitor and manage their conditions."

Screenings

The first level of intervention is to provide free screenings to targeted, at-risk populations, in order to identify people with early stages of CKD. In a recent review of the principles of screening and diagnostic testing in the context of CKD, Jaar et al concluded that "in order to decrease the societal burden of kidney

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disease and reduce the high morbidity and mortality associated with CKD, detection of CKD—particularly at early stages—is essential because therapeutic interventions are likely to be effective if they are implemented early in the course of the disease."[9]

The screenings will be provided across the state by 3 fully-equipped mobile outreach units (MOU). The first MOU, purchased by the UNC Kidney Center, is providing screenings in 17 target counties as part of the Kidney Education Outreach Program. Two additional units will be purchased and managed by Wake Forest University Bowman Gray School of Medicine and East Carolina University Brody School of Medicine. The goal of this immediate intervention is to have statewide coverage through dedicated mobile outreach units. Staff and volunteers from each of the 3 medical schools will oversee the screenings. Additional manpower will be provided through partnerships with the local community colleges' allied health programs, as well as through trained, local lay leaders.

Early identification of people with CKD is not sufficient to ensure that they receive the education and services needed to help them manage their disease. Individuals who have been identified as having early stages of CKD or who are at risk of developing CKD should also be linked to primary care providers (PCPs). As Cynda Johnson notes in her commentary, PCPs should screen individuals who are at risk, stage them according to the KDOQI guidelines, and help the patients manage their comorbid conditions.[10] However, there is a lack of primary care providers in many areas of the state, with 11 counties and parts of 27 other counties identified as persistent primary care shortage areas.[a,11] Further, PCPs face challenges managing the growing number of patients with chronic illnesses even in communities with adequate numbers of PCPs. This is made even more difficult given the current reimbursement structure that favors procedures rather than more time-intensive patient education and disease management. Referring patients to nephrologists in the early stages of the disease is not a realistic alternative given the lack of nephrologists needed to treat the growing number of CKD patients.[12] These 2 factors underline the importance of a new strategy to achieve earlier diagnosis and personalized management of patients in early-stage CKD if North Carolina is to be successful in reducing the burden of CKD. Early identification needs to be coupled with linkages to primary care providers and to trained care managers who can help primary care physicians monitor patients' vital signs, promote healthier lifestyles, and teach patients self-management strategies.

Long-term Intervention: The Kidney Care Coordinator/Educator (KCCE)

The second major component of the KCPP is the development of a curriculum to train allied health professionals to monitor and manage patients with or at risk for CKD. Learning outcomes, developed by a committee including primary care nurses, PCPs, nephrologists, community-based social workers, and health educators, will guide the content of the KCCE curriculum. These outcomes will anchor the development of the test specifications table used to develop both the formative self-assessment tests and the summative certification examination. Individuals who successfully complete the 4-course curriculum and achieve a passing score on the criterion-reference summative examination will be certified as trained KCCEs. Under the auspices of a primary care physician, certified KCCEs will provide preventive management and monitoring as well as teach self-management skills both to patients at risk for CKD as well as to patients with early-stage CKD and related chronic diseases. In addition, the KCCE will be required to complete continuing medical education every 2 years to retain certification. The kidney curriculum will be offered to practicing and future allied health professionals through the North Carolina Community College System. The KCCE program will be evaluated by comparing short- and long-term assessment of participating patients' clinical outcomes, self-management skills, and quality of life self-assessments to those of a comparable group of patients who receive only written instruction/guidelines for monitoring their CKD risk factors and comorbid conditions. In contrast to certified diabetes educators, the kidney disease care coordinator/educator will be trained for early intervention focused on prevention of CKD, self-management instruction, and the monitoring of patients' comorbid conditions. While diabetes educators would be excellent candidates for this additional certification, the KCCE role can also be filled by a broad range of allied health professionals. It is anticipated that if the evaluation of a KCCE pilot project shows evidence of improved health outcomes for participating patients, there should be strong potential to obtain reimbursement from private and public payers for the KCCE's services, similar to the Center for Medicare and Medicaid Services' reimbursement for physician-referred American Diabetes Association-approved diabetes self-management training.

Case management is recognized as an important way to provide care for patients with chronic diseases and as being a way to promote a team approach to providing quality patient care. Wagner, in his discussion of the role of patient care teams in chronic disease management, emphasizes that successful management of chronic disease often requires that other members of the health care team competently conduct important aspects of care that the physician may not "have the training or time to do well."[13] Case management has been found to provide benefits to both the patients and the larger health care system in smoking cessation initiatives and glycemic and hypertension control programs.[14-18] In addition, care managers have been shown to increase patient adherence to treatment protocols, and to help patients make difficult lifestyle changes. For example, Stafford and colleagues describe a cardiac case management program and note that "By intensively following patients over time, case management may be better

a A persistent health professional shortage area (PHPSA) is a county, or part of a county, that has been designated by the Health Resources and Services Administration within the US Department of Health and Human Services as a primary care health professional shortage area in 6 of the last 7 years.

able to facilitate guideline-concordant care, educate and empower patients to make challenging lifestyle changes, improve patient adherence and quality of life in response to therapies, and coordinate patients' multiplicity of conditions and providers."[19]

Community Care of North Carolina (CCNC) has long used diabetes case managers in the care of Medicaid recipients with diabetes. Between 2000-2004, CCNC saw an increase in compliance with nationally recognized clinical practice guidelines, which has lead to improved health status. For example, there was a 10% increase in referrals for eye exams, a 62% increase in flu vaccines, a 7% improvement in continued care visits since baseline, an 18% improvement in foot exams since baseline, and an 11% increase in lipid testing.[20] These improvements are estimated to have saved the Diabetes Case Management program $2.1 million from 2000-2002.[21] In addition, patients have benefited from improved management of their chronic disease. These findings can be even more impressive when CKD is added to the list of desired and measured outcomes.

There is every reason to believe that a state kidney care management program offered by trained kidney care coordinator/educators would yield similar results. Trained kidney care coordinator/educators can intervene early in the disease and help individuals with early-stage CKD monitor and manage their conditions. Equally as important, KCCEs can educate patients about the importance of self-management for comorbid diseases while providing support for improved health behaviors and outcomes. Often referred to as a shadow disease, CKD usually occurs in conjunction with other comorbid diseases such as diabetes, hypertension, and heart disease. Optimal care for patients with early CKD or for those at increased risk of CKD requires coordinated care between the primary care physician and the specialist, often a cardiologist, and in many cases a nephrologist.[22,23] On a clinical level, KCCEs, much like diabetes educators and case managers, can monitor patients' blood pressure, weight, and A1C evaluation; promote self-directed care; and educate and counsel patients about healthy lifestyle behaviors such as smoking cessation, diet, and physical activity. At an administrative level, the KCCE can coordinate care among physicians.

Summary: Filling the CKD Prevention and Service Gap

The Kidney Care Prevention Program is an idea whose time has come. A statewide screening program that targets high-risk citizens in local settings and regardless of ability to pay can significantly retard the predicted growth of the CKD epidemic and help reduce the number of North Carolina citizens that find themselves dependent on dialysis or in need of a kidney transplant. The introduction of a new health provider certification program, developed and delivered in conjunction with the North Carolina Community College System, provides a venue for allied health professionals to obtain certification in the management of CKD and its comorbid diseases. This allows primary care physicians to provide the best of case management and coaching for at-risk patients with the potential for reimbursement through private and public insurers. Equally as important, the KCPP provides at-risk patients access to the personalized care that will support and promote lifestyle and health behavior changes. Care management will be provided throughout the progression of the disease. Most importantly, care management can be made available before clinical symptoms are apparent, when there is the greatest opportunity for preventing or slowing the progression of CKD. **NCMJ**

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NC Health*Smart*:
Supporting North Carolina State Health Plan Members with Chronic Kidney Disease

Anne B. Rogers, RN, BSN, MPH

The North Carolina State Health Plan (State Health Plan) covers approximately 647 000 teachers, state employees, retirees, current and former lawmakers, state university and community college personnel, state hospital staff, and their dependents. The State Health Plan also administers NC Health Choice, a fee-for-service program that provides health insurance to more than 122 000 uninsured children in North Carolina.

In January 2002 the State Health Plan began to offer targeted case management services to members with chronic kidney disease (CKD). Since that time, multiple programs and services have been implemented to provide a continuum of support as disease progression impacts members' needs.

NC Health*Smart*, an initiative launched in 2005, encourages members to make healthier lifestyle choices and become partners in meeting their health care needs. This innovative program includes health promotion and disease prevention through health coaching, worksite wellness programs, and Web-based educational materials and services. NC Health*Smart* includes disease and case management programs to assist members with chronic illnesses including CKD as well as members whose medical situations requires intensive intervention.

In 2006 the State Health Plan first offered a preferred provider organization (PPO) benefit plan in addition to the traditional indemnity plan. The PPO improved members' access to primary prevention services by offering coverage for all preventive services rendered in a physician's office through a single copayment. Preventive services include screenings for hypertension and diabetes, which are known precursors to CKD. Once a member is diagnosed with a chronic illness (such as hypertension or diabetes), NC Health*Smart* encourages secondary prevention through member education and screenings for chronic kidney disease.

In addition to these value-based services, NC Health*Smart* includes an information tool for physicians called the SMART Registry. Through the SMART Registry, primary care physicians receive information about clinical gaps in care for eligible members. One measure reported is microalbuminuria testing for members with diabetes, a KDOQI[1] (Kidney Disease Outcomes Quality Initiative) guideline for kidney disease management.

"With early identification of members with chronic kidney disease and referrals to care management services, the goal of the NC State Health Plan is to prevent or delay disease progression or decrease disease-associated complications."

a The only members who are eligible for NC Health*Smart* program services are those with the NC State Health Plan as their primary insurer. Members with Medicare as their primary insurer or members on COBRA are not eligible for NC Health*Smart* services.

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Provider services specialists are available to assist physicians with questions about the SMART Registry and other NC Health*Smart* programs.

NC Health*Smart* also uses targeted marketing to reach State Health Plan members with chronic disease. Part of this targeted marketing includes an informational flyer about kidney disease. The flyer contains instructions on how to contact a NC Health*Smart* health coach for assistance and disease management support. Health coaches are available 24 hours a day, 7 days a week, to provide disease-specific information. They also assist members with early-stage kidney disease with the best way to address questions and concerns with their physicians.

For eligible members with chronic kidney disease that has progressed to a more advanced stage, the State Health Plan offers intensive care management services through Renaissance Health Care. Trained and experienced kidney disease care managers provide patient education, disease management, and care management services to patients with an eGFR of less than or equal to 45 (stage 3 in KDOQI guidelines). Members are referred to Renaissance Health Care from other State Health Plan vendors and providers and are identified through claims analysis. They are then contacted directly and offered care management support. With early identification of members with chronic kidney disease and referrals to care management services, the goal of the NC State Health Plan is to prevent or delay disease progression or decrease disease-associated complications.

Renaissance Health Care helps identify clinical gaps in care for patients with CKD. Care managers work with members and treating providers to improve clinical indicators such as blood pressure control for patients with coronary artery disease or hypertension and blood glucose control for patients with diabetes. In addition, each State Health Plan member with advanced CKD is offered intensive care management and education services as they prepare for transition to renal replacement therapy. Educational modules that describe the various treatment modalities are provided along with an explanation of the benefits and challenges of each option. Taking a holistic approach, the care management needs assessment also includes depression screening. Members identified as having depression are referred for treatment if that is an appropriate strategy. As of December 2007 there were 235 State Health Plan members active in chronic kidney disease care management.

A claims data review does not identify all patients with CKD. As a result, the State Health Plan has been working to understand the barriers to member identification and care management engagement. One effort involves partnering with the University of North Carolina (UNC) Kidney Clinic to develop alternative methods of identifying members for care management. The UNC Kidney Clinic has identified State Health Plan members in their patient panel who are appropriate for referral to Renaissance Health Care. Within the first 3 months of the program (fourth quarter 2007), there were over 30 new referrals and an 85% enrollment rate (screened and engaged with a care manager). Other results showed an increase in immunization rates and an increase in the use of Angiotensin-Converting Enzyme Inhibitor/Angiotensin Receptor Blocker (ACE/ARB) medications (also a KDOQI guideline). Additional efforts to improve the identification of members with CKD include enhancements to the data provided to Renaissance Health Care from the claims processing contractor as well as the review of Renaissance data mining processes.

The care management and patient education services provided by Renaissance Health Care have contributed to positive health outcomes for people with advanced stages of kidney disease. The following outcomes have been reported of the members with CKD who have been participating in Renaissance Health Care care management for at least 180 days:

- 80% of members completed educational modules on dialysis modalities.
- 90% of members had an appropriate hemoglobin level.
- 80% of members initiated dialysis with a permanent access in place.
- 50% of members initiated dialysis without the use of a central venous catheter (to include fistula and peritoneal dialysis catheters).
- 50% of members transitioned to dialysis on an outpatient basis (in contrast to requiring emergency inpatient hospitalization to begin dialysis)

The North Carolina State Health Plan was an active participant on the North Carolina Institute of Medicine Task Force on Chronic Kidney Disease and supports the task forces recommendations. As a result, the State Health Plan drafted a letter to laboratory providers to be cosigned with Blue Cross Blue Shield of North Carolina (BCBSNC) that requests automatic eGFR reporting when serum creatinine levels are ordered by a physician, a priority recommendation of the task force. To date, most of the task force's recommendations for health plans regarding CKD have been implemented by the State Health Plan. Through the implementation of these recommendations, the North Carolina State Health Plan will continue its support of chronic kidney disease prevention, treatment, and management.

Lessons Learned Include:

- From a health plan perspective, the complex needs of members with kidney disease can be addressed effectively through a partnership between a specialized care management vendor, the attending physician, and laboratory providers. The care management vendor utilizes claims data to identify members who may benefit from services, while the physician has the ability to refer members for services when a need is identified. Laboratory data provide information on kidney disease progression through eGFR values and informs the provider and care management vendor of the members' status. The partnership affords the opportunity for timely access to care management services.
- The most successful strategy for early identification of members with chronic kidney disease is a combination approach including claims and lab data monitoring and

direct referrals to care management services from providers and other disease and case management vendors.
- The care management vendor should have the knowledge and experience needed to assist members with chronic kidney disease to manage their condition, provide oversight of clinical quality measures, and ensure education and support for members transitioning to renal replacement therapy. The provision of these services on a coordinated basis leads to better outcomes for members with chronic kidney disease. **NCMJ**

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Hey Doc, Here's What I See

Deidra Hall; Celeste Castillo Lee

We appreciated being given the opportunity to participate in the North Carolina Institute of Medicine Task Force on Chronic Kidney Disease and also being given space in this issue of the *North Carolina Medical Journal* to provide a voice for those affected by chronic kidney disease (CKD). Representing the interests of thousands of patients and families is an honor for us. Together we have a combined total of 43 years of experience living with CKD, end-state kidney disease (ESKD), and/or transplantation. Deidra Hall explores *Hey Doc, here's what I see* with a pediatric perspective on CKD and the ways we can make an impact. Celeste Castillo Lee has a conversation with "Doc" from a vantage point of what she *does* and *does not* see for patients with end-stage kidney disease.

Deidra Hall

Kidney disease—with no warning signs that it would come, no preparation on how to handle it—is a scary term for a family that has never known sickness. What did we do wrong? Is it something I could die from? Oh my goodness…is it contagious? Could I give it to my little sister? I was 12, and all these questions ran though my head the day I visited my pediatrician with what I thought was a sinus infection. My face and body were so swollen I couldn't fit into my normal clothes. Previously a fairly thin and athletic girl, I now had to wear extra large sweat suits. We knew something was wrong—but this?

Every family of a child with kidney disease goes through the unfortunate reality of having to cope with newfound information for every stage their child reaches in the progress of the illness. Doctors play a critical role in that journey. So what are the steps a doctor can take to help make sure this child survives for as long as possible and in a healthy way? After living through chronic kidney disease and living with a healthy transplanted kidney for over 13 years now, it was in my heart to start a nonprofit organization. I started the Kidney Coaching Foundation, Inc. (KCF), to directly target the pediatric nephrology population and their families. In doing so, KCF has introduced 3 key messages for the population it serves. So, *Hey Doc, here's what I see...*

> *"In order for me to fight this war, I had to know my enemy. I had to realize that my enemy was not my doctor, it wasn't my mother, and it certainly wasn't me."*

Message 1: Personal advocacy. Every child will handle his or her disease differently. I wanted to be as involved in my care as I possibly could. Early in my treatment, I had a doctor who would only talk to my mother—even though I was sitting only inches away from him. I hated that feeling of being ignored, as if talking to me didn't matter. If this was going to work, I needed to be included. From that point on, I knew there were some decisions that I could not make, but for the most part I was going to be an integral part of the decision-making team. One thing I genuinely believe is that it is important to make your patients own their disease. They need to be involved in every aspect—asking questions and being educated. Not including them in discussions and allowing them to disconnect allows

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Celeste Castillo Lee is the chief of staff to Victor Dzau, MD, chancellor for Health Affairs at Duke University and president and CEO of Duke University Health Systems.

room for noncompliance. If young patients feel that "mom will handle everything," then it is easy to put the blame on mom in the event that they become sicker.

Self-advocacy also includes education. In order for me to fight this war, I had to know my enemy. I had to realize that my enemy was not my doctor, it wasn't my mother, and it certainly wasn't me. Realizing this helped me to have the correct perspective on *what* I was fighting, not who. My enemy was the disease. The more I knew, the more empowered I was. I was empowered to ask important questions for the present and hard questions for the future. In KCF, we make sure each child and caregiver researches their disease, interviews others who live with it, and does whatever else it takes to know their disease better. It is true that "the more you know, the more you grow!" Being an advocate also includes being honest, responsible, and accountable. Patients can own up to their accomplishments as well as their mistakes. In this organization the coaches don't allow the patients to play the blame game or the victim card; they encourage each individual to see what role he or she had in the way things played out. Then they give them ownership again by asking what they might do differently in the future. The coaches also teach responsibility and being proactive. In this context, being proactive means making sure the patients ask for help in advance. Invincible teens sometimes have a hard time asking for help, but the failure to ask for help in advance can lead to trouble down the road. Part of being responsible is knowing when and how to ask for help and understanding the fine line between needing help and being needy.

Message 2: Discovery. Patients always need to be in discovery, not only about the disease but also about themselves. Fostering the urge to find out more goes a long way toward being healthy. Questioning and wanting to know more is exactly how new ideas are created! Patients should not settle for what people tell them they *cannot* do (eg, a poor kid with CKD cannot reach her dreams because she is too sick). Rather, encourage young people with CKD to discover for themselves *who* they can be. This will give them a sense of purpose and something to live for. The result is twofold success: first, they have a goal for the future, which will hopefully help them to also become active citizens and important contributors in their communities, and second, they have a reason to be compliant with their treatment which may ultimately lead to better management of their disease.

"Let's challenge the status quo of health care delivery."

Message 3: "You can do this!" It is so easy for teens to be depressed even without the added stress of being sick. But teens will not feel as alone if they are constantly told, "You can do this!" Those 4 words are a pick-me-up when the teen gets off track with their treatment and feel as if they have failed. These words are reinforcements to those striving to lead healthy and purposeful lives. Saying those words with passion and love lets the young patient know many things: I can go to college and be successful; I can have a family of my own when I'm older; I can help others who are down about their disease. *I* can do this—live a healthy life—be successful in everything I do—survive!

Instilling just these few messages will serve youth well in their everyday lives and will also create informed, involved, and most importantly, compliant patients. When it's time for them to transition out of their parents' care and into the phase of life where they take the lead for their care, they'll be prepared, and you'll be satisfied in knowing you helped in that preparation.

Celeste Castillo Lee

Hey Doc, here's what I see as an end-stage kidney disease (ESKD) patient in North Carolina.

On Tuesday, Thursday, and Saturday mornings from 7:00 to 10:00, I sit in a lazy-boy recliner pulling off the last 48-72 hours worth of liquids and toxins in my bloodstream. I read, work, and—thanks to the wireless age—explore the Internet. Together with my fellow patients, I share in the collective experience of undergoing a lifesaving treatment available to those with ESKD. We also share, in the chapters of our individual lives, heartaches, frustrations, joys, fears, successes, and setbacks. These are all part of our daily existence with ESKD, and I would argue, part of life in general. We reluctantly come together from a variety of backgrounds, experiences, and cultures.

However, Doc, I see a disproportionate number of African Americans and Latinos on dialysis. I see them missing treatments, and missing toes, missing fingers, missing feet, and missing eyesight. I wonder why. I see a receptionist becoming a dialysis technician in 8 weeks with no state certification required, while the person who gives me a hair cut has to be licensed by the state. Again, I wonder why. I see our facility getting older, our technicians and nurses becoming disillusioned and leaving, our nutritionist and social worker overburdened and understaffed. I see patients discussing their history to the fourth new rounding physician we have had within the past year, only to have him respond to patients in a patronizing tone no matter a patient's age, gender, ethnicity, or educational background. Yet again, I wonder why.

Doc, what I don't see is any pre-education for chronic kidney disease (CKD) patients in stages 3 or 4, or any case management, or any coordinated care. I see new patients arriving at our unit, scared and unsure of what to expect, never having been given the opportunity to choose their preferred modality of dialysis (if one could use the word "preferred"). Most simply arrive in the unit with a catheter inserted in their chest, like a stranger in a strange land. Because of what I see, I want to say "shame on us." Shame on a system that covers services to people once they have ESKD, but puts in so little preventive effort to help people control illness prior to getting ESKD. Shame on a system that provides only bare assistance to people in making the transition to dialysis.

From the confines of my lazy-boy I am an ESKD patient, and I experience the lack of control in a routine yet invasive treatment. I don't want others to join me in my chair, Doc. I want them to know what their kidneys do and how they function. I want them to know how to control their blood pressure, blood sugar, and diet to keep them out of this unit and out of my chair. I want them to have access to preventive health care, case managers, nursing assistants, and physician assistants. I want them to be part of a new model of care that guides them in their journey as a CKD patient and finds best practices that help them adhere to proper medical regimens. And if after all that, even in the best of circumstances, they still are headed towards ESKD, I want them to be empowered. I want them to know what to expect financially, personally, physically, and emotionally. They should be given the information to make the best choices for themselves and their families. And once they have come to dialysis, I want them to be able to lead a quality life. I know that if a patient is empowered, encouraged, and guided, he or she can continue to work and contribute to society. We can only do this if the treatment we offer and receive is high quality, safe, and affordable.

Doc, we have our job cut out for us, and we have to do it now. If the statistics are correct, and there are thousands more CKD patients transitioning to ESKD and taking seats next to me in my lazy-boy, we really will be in a financial bind. We can't afford to wait any longer, both in terms of human capital and medical dollars.

Doc, I also see opportunities. We are in such a state of need that innovation is our only tool to address these challenges. Let's be "disruptive." Let's challenge the *status quo* of health care delivery. Let's ask "what if"—what if we change the way we bring treatments to the perpetual patient, what if health care providers no longer see ESKD patients as just "kidney" patients but whole persons, what if different components of our health care systems learn to communicate with each other, what if we invest in trying to stop early the progression of diseases before ESKD, what if we do more education to bring CKD and ESKD to the conscience of the public?

The time is now for us to build a grassroots effort to educate the public about the causes and effects of CKD. Look at what a powerful and unified voice has done to increase public awareness of and research and funding for breast cancer. If 1 in 9 people in this country have CKD, then we have a huge group of patient advocates who, if educated and motivated, could become a powerful force for change.

Doc, I am dedicated to being an advocate and educator wherever and whenever possible. As the chair of the Executive Committee of the Patient and Family Council of the National Kidney Foundation, I know firsthand the potential we have to make a difference because of the commitment of patients and their families. Doc, I invite you to join me in being an instrument of change—to change what I see and change what I don't see. **NCMJ**

Running the Numbers

A Periodic Feature to Inform North Carolina Health Care Professionals About Current Topics in Health Statistics

From the State Center for Health Statistics, North Carolina Department of Health and Human Services
http://www.schs.state.nc.us/SCHS

Selected Data on Chronic Kidney Disease in North Carolina

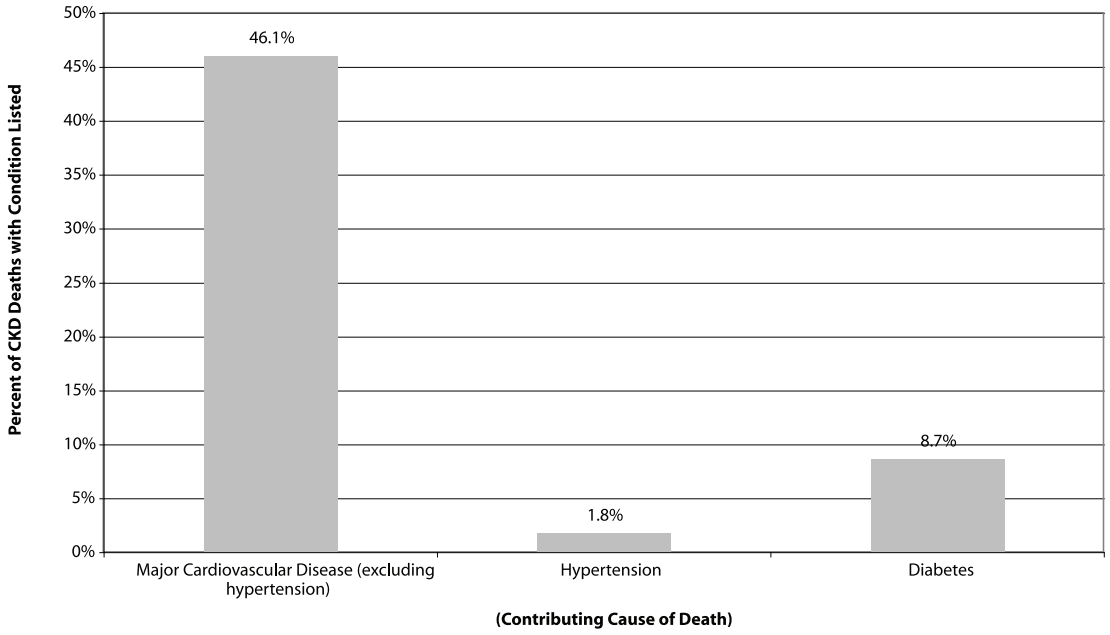
Chronic kidney disease (CKD) is the 10th leading cause of death among North Carolina residents, based on the primary or underlying cause of death. In 2006, there were 1631 deaths with CKD attributed as the primary cause, representing 2% of all 74 419 deaths of North Carolina residents in 2006. This is based on the International Classification of Diseases, Tenth Revision (ICD-10) cause-of-death codes N00-N07, N17-N19, and N25-N27 (nephritis, nephrotic syndrome, and nephrosis).

Another article in this issue by Suma Vupputuri addresses the epidemiology and costs of CKD. Among her findings are that the age-adjusted CKD death rate for minorities is more than twice as high as the rate for Whites. The incidence rate of end-stage kidney disease (ESKD) for African American men is 3.3 times as high as the rate for White men, and the ESKD incidence rate for African American women is 4.3 times as high as the rate for White women. Other data show that the age-adjusted CKD death rate for males is about 25% higher than the CKD death rate for females and that the CKD death rate is many times as high in the oldest age groups compared to younger age groups.

In addition to the 1631 deaths in 2006 where CKD was assigned as the primary cause, there were an additional 5706 deaths where another primary cause of death was assigned, but CKD was listed as a contributing cause of death. Adding these 2 numbers results in an estimate of nearly 10% of all North Carolina deaths having CKD as the primary or a contributing cause. This does not indicate the total morbidity of CKD at the time of death but only those deaths where CKD was determined by the certifying physician on the death certificate to have contributed directly or indirectly to the death. Because of the many comorbidities and complications associated with CKD, the 10% figure may substantially underestimate the total contribution of CKD to deaths in North Carolina.

Diabetes, hypertension, and cardiovascular disease are frequent comorbidities with CKD. These are risk factors that can contribute to the development of CKD, and CKD can lead to cardiovascular disease or hypertension. Figures 1 and 2 show the relationships between CKD and these conditions based on data from the 2006 death certificates. In general, these data indicate substantial interrelationships between CKD and cardiovascular disease, hypertension, and diabetes. Note that in Figure 1 the contributing diagnoses are not mutually exclusive; a decedent could have had one or more of these conditions listed on the death certificate with CKD as the primary cause. The low percentage for hypertension as a contributing factor for deaths with CKD as the primary cause (Figure 1) does not necessarily indicate a low prevalence of hypertension in this group; perhaps hypertension led to a major cardiovascular disease that contributed more directly to the CKD death and was therefore recorded on the death certificate. The results in Figures 1 and 2 are a function of the death certificate certifying practices of physicians in North Carolina.

Figure 1.
2006 North Carolina Resident Deaths with Chronic Kidney Disease as the Primary Cause: Percentage with Selected Conditions Indicated as a Contributing Cause of Death



Until recently, there have been no direct estimates for the total prevalence of CKD in North Carolina. Since Medicare pays for services for all patients with ESKD, there are complete data on ESKD prevalence in the state. (See Vupputuri article.) But less than one-fourth of 1% of North Carolinians have ESKD. Data from the 1999-2000 National Health and Nutrition Examination Survey (NHANES) show that approximately 12% of the US population had CKD in any stage, based on direct creatinine measurements.[1] The 1999-2000 NHANES also asked the survey subjects if they had ever been told by a doctor or other health professional that they had weak or failing kidneys. Only 2% responded "yes" to this question, indicating low awareness of kidney disease; even those with substantially decreased kidney function had relatively low awareness.[1]

Beginning in 2007, the North Carolina BRFSS (Behavioral Risk Factor Surveillance System) random telephone survey of adults (ages 18+) included the question, *Have you ever been told by a doctor, nurse, or other health professional that you have some form of kidney disease including chronic kidney disease, nephritis, nephrosis, renal disease, or end-stage renal disease?* There were 6842 BRFSS respondents who answered this question in 2007. The results are based on self-report over the telephone by the BRFSS respondents. The information in Table 1 provides a first look at these new BRFSS data on the awareness of CKD among North Carolina adults.

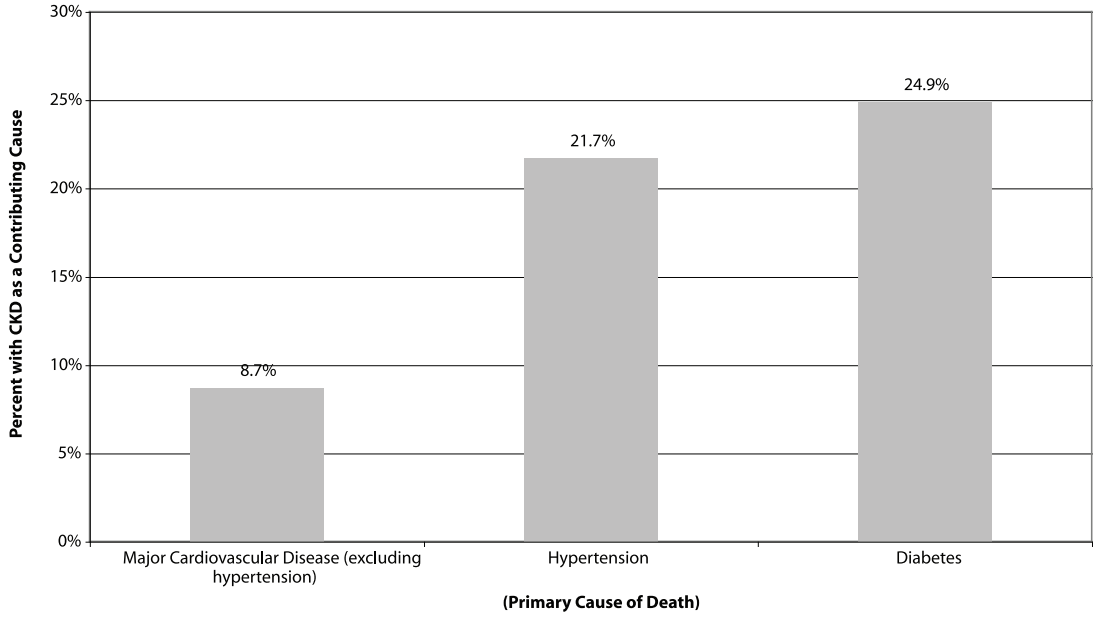
These data show that 2.6% of North Carolina adults reported in 2007 that they had been told by a health professional that they had some form of kidney disease, much lower than the NHANES results based on physical measurement (12%), but higher than the self-reported data from NHANES (2%). The NHANES measurements

Table 1.
Percentage of North Carolina Adults with Kidney Disease (and 95% Confidence Interval, CI) by Selected Respondent Characteristics: 2007 Self-Reported BRFSS Data

	% (CI)		% (CI)
Total	2.6 (2.1-3.1)	Age 18-24	0.1 (0.0-0.6)
		Age 25-34	0.9 (0.4-1.8)
Male	2.8 (2.1-3.7)	Age 35-44	1.9 (1.1-3.3)
Female	2.3 (1.9-2.9)	Age 45-54	3.1 (2.0-4.8)
		Age 55-64	3.5 (2.3-5.2)
White	2.7 (2.2-3.3)	Age 65-74	4.5 (3.1-6.3)
African American	2.3 (1.5-3.7)	Age 75+	6.6 (4.6-9.4)
Disability	5.4 (4.3-6.7)	< $15,000 Income	5.5 (3.5-8.4)
No Disability	1.4 (1.0-1.9)	$15,000-$24,999	3.0 (2.0-4.3)
		$25,000-$34,999	2.5 (1.4-4.5)
Diabetes	8.9 (6.5-12.0)	$35,000-$49,999	2.3 (1.4-3.7)
No Diabetes	1.9 (1.5-2.4)	$50,000-$74,999	3.1 (1.9-5.2)
		$75,000+ Income	1.4 (0.8-2.5)
Hypertension	5.6 (4.4-6.9)		
No Hypertension	1.2 (0.8-1.6)		

of creatinine may pick up many early-stage kidney disease cases that have not been diagnosed by a health professional. The accuracy of self-reporting over the telephone is also an issue. Nevertheless, the data in Table 1 suggest that the percentage with diagnosed kidney disease is higher for males than females, higher for people with a disability, higher for those with diabetes or hypertension, higher for older people, and higher for people with lower household incomes. African Americans have a slightly lower percentage of self-reported kidney disease than Whites, which may in part indicate differences in access to health care and therefore the opportunity for a diagnosis. However, the 1999-2000 NHANES data based on physical measurement indicated that Whites and African Americans have approximately the same overall prevalence of CKD, despite much higher ESKD rates and CKD death rates among African Americans.[1] Based on non-overlapping confidence intervals, the statistically significant differences in kidney disease in Table 1 are disability versus no disability, diabetes versus no diabetes, hypertension versus no hypertension, the oldest age groups versus the youngest, and the lowest income group versus the highest.

Figure 2.
2006 North Carolina Resident Deaths with Cardiovascular Disease, Hypertension, and Diabetes as the Primary Cause: Percentage with Chronic Kidney Disease Indicated as a Contributing Cause of Death



The data in this report show that CKD is responsible for, or contributes to, at least 10% of all deaths in North Carolina. In addition, CKD is an important cause of morbidity in North Carolina's population. In 2005 in North Carolina, there were more than 10 000 inpatient hospital discharges with CKD listed as the principal diagnosis, with associated hospital charges of more than $190 million. There were another 55 400 inpatient hospital discharges in 2005 with CKD listed as a contributing diagnosis with associated hospital charges of more than $1.8 billion. Clearly, efforts are needed to reduce the burden of CKD in North Carolina in terms of mortality, morbidity, and medical care costs.

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Contributed by Paul A. Buescher, PhD
State Center for Health Statistics, North Carolina Division of Public Health

Genetics and Kidney Disease
Duke Med Scholars Program

Jeri F. Krentz

Michelle P. Winn, MD

At Duke University, geneticists have made advances in studying multiple sclerosis, neural tube defects, and age-related macular degeneration.

One recent discovery may lead to a genetic test to see whether a person is at risk of developing coronary artery disease. Other research has identified gene mutations that cause trichotillomania, a psychiatric disorder that causes people to pull out their hair.

Michelle P. Winn, a physician scientist from Duke's Department of Medicine, focuses her research on a kidney disease called focal and segmental glomerulosclerosis or FSGS. In 2005, her team identified a gene mutation that causes the disease to run in families—a discovery that may lead to slowing its progress.

"We've made great strides in the last 10 years to understand FSGS better," says Winn, an assistant professor in the Division of Nephrology. "But we still have a lot to learn." Winn's work won extra support in 2007 when she became a Duke Med Scholar, a new faculty development program at the School of Medicine that rewards promising junior scientists. Funding comes in part from The Duke Endowment, a private foundation in Charlotte that awards millions in grants each year to health care, rural churches, children's services, and higher education in North Carolina and South Carolina.

A faculty committee selected the first class of Duke Med Scholars in February 2007; 3 more were named in December. The Scholars are researching stem cells, lung inflammation, the genesis of a brain tumor, and human joint replacement. They receive funding for 3 to 5 years for their work.

R. Sanders Williams, senior vice chancellor for academic affairs at Duke University Medical Center, says the program empowers successful junior faculty members to launch into "bolder" research at a time in their career when large outside grants may be difficult to come by. It also helps Duke attract—and keep—top scientists.

"We find ourselves competing with other leading medical schools for such exceptionally talented individuals," Williams says. "The Duke Med Scholars program helps us attract and retain key faculty and it accelerates research that's highly creative and important to medicine. Michelle is a prototype for what this is designed to do."

The award helped Winn buy equipment for her laboratory and hire extra researchers. Winn explains that while most people with FSGS don't have a family history of kidney disease, her research team has identified a large number of families across the world with more than one member who has familial FSGS. The team identified a mutation in the transient potential cation channel 6 gene as a cause.

"You study familial or hereditary diseases in order to better understand the pathophysiology of sporadic disease," Winn says. "We're trying to understand how prevalent the mutation is."

The goals are to slow the progress of FSGS and find a therapeutic target.

"FSGS can be so aggressive that once you're diagnosed, you can be on dialysis within 1 to 2 years," Winn says. "Prevention would be the ultimate goal, but we have to take small steps."

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Readers' Forum

To the Editor:

Neckties, Typewriters, and Jabots

For many centuries neckties have been associated with thoughtful, appropriate, and dignified behavior. We now know, however, that approximately 5% of men over 50 years of age have 50% occlusions of at least 1 carotid artery, ie, the 5-50-50 syndrome.

Various kinds of neckbands have been popular among both primitive and highly civilized people, but perhaps two-thirds of modern civilizations do not now endorse such decorations. Our Supreme Court persists in their traditional, sanctioned ruffles, but many in our Congress now meet while wearing no ties. Our president and the new presidential candidates are often open-necked. (Spats, starched cuffs, and most wing-tips are also gone.)

Has the "dress-down Friday" movement been initiated by ear nose & throat physicians, who are carotid sensitive?

When one inspects the MRIs, SPECTs, and CTs of "healthy" normal volunteers in the seventh, eighth, or ninth decades, one sees multiple, unexplained radiologic wonders. These can often be well-correlated with interesting, lateralized cervical carotid reflections on ultrasound. Additionally, Alzheimer's type dementias have a statistical association with such carotid findings.

Neckties have been popular to display the names of sports heroes and the Mona Lisa. Necktie producers still seem to be enthusiastic in the larger malls. Should we be concerned about threatening their livelihood? They could still prosper without neckties. The shirt collar? An open collar or collarless shirt is not a health threat.

The recommendation to abandon neckties is not bold. (Ear and nose studs will be discussed later.) As physicians we have an obligation to point out potential threats while anticipating more alarming scientific statistics in a few more years.[1,2,3]

Even though one branch of our own military, the army, still requires neckties during formal assemblies, this tradition could be quickly altered (relaxed). It may be time for the Veterans Administration to point out how we should change.

Say goodbye necktie.

Ed Spudis, MD
Winston-Salem, NC

William Satterwhite, MD
Winston-Salem, NC

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Spotlight on the Safety Net

A Community Collaboration
Christine Nielsen, MPH

North Carolina Diabetes Collaborative

In 1998, the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), and the Institute for Healthcare Improvement (IHI) joined together to create the national Health Disparities Collaboratives program. The program focuses on "decreasing health disparities through adoption of improvement processes by health centers."[1] A major focus of the Health Disparities Collaboratives program has been diabetes, which is far more prevalent among African Americans and Latinos than among Whites. The National Diabetes Collaborative has been in place since 1999 and has been implemented in more than 260 health centers nationwide.[2] The North Carolina Diabetes Collaborative was founded in 2003 to address the needs of diabetic patients utilizing North Carolina's safety net organizations. The North Carolina Diabetes Collaborative is part of the Southeast Atlantic Cluster of the National Diabetes Collaborative and is currently in place in health centers throughout the state. This *Spotlight on the Safety Net* highlights 2 programs participating in the Collaborative.

Blue Ridge Community Health Services

Blue Ridge Community Health Services (BRCHS) provides reduced-cost health care services for North Carolinians living in the Hendersonville area. BRCHS has 4 sites, including a family practice site, a pediatric site, a dental center, and a school-based health center. As a community health center, Blue Ridge Community Health Services serves patients who are low-income, uninsured, and underinsured.

The family practice site of BRCHS has been a part of the North Carolina Diabetes Collaborative since 2004. The clinic team works with the Chronic Care Model,[3] as well as an improvement process model called PDSA (Plan, Do, Study, Act), as a way to improve goals and patient care. As Collaborative participants, the clinic staff collect data, report to HRSA monthly, attend quarterly meetings and learning sessions with other programs in the state, and also attend an annual HRSA/Health Disparities Collaboratives national meeting.

Since its inception in 2004, BRCHS has tracked over 500 diabetic patients. BRCHS sees a largely Latino population (47.9%) followed by White (44%) and African American (6.9%). Diabetic patients are entered into a database application that is designed to assist care providers as well as management in tracking the quality of care provided to patients. The database tracks clinical indicators such as their hemoglobin A1Cs and intermediate density lipoproteins (IDLs). Glomerular filtration rates (GFRs) are also tracked for all patients who have certain blood panels run. A record of recommended screenings, such as foot exams, as well as the patient's self-management goals are recorded as well.

A care management team convenes monthly to review reports that are generated from the database and check for any goals that are not being reached, any gaps in services, or any potential warning signs that the disease could be worsening. The team then selects 1 or 2 goals to focus on, such as hemoglobin A1C levels. The indicator is then examined for all diabetic patients over the previous several months. Patients are followed up with accordingly and may be contacted to schedule an appointment. The team works to ensure that each diabetic patient comes into the clinic every 3 months for a diabetic check. Before each visit, the team does a chart review to check if the patient needs any lab work, immunizations, eye exams, or other services.

If a patient starts to show signs of chronic kidney diseasae (CKD), the case management team refers them to a kidney doctor and monitors their labs. They may also make referrals to local specialists and work with patients to help them afford needed care. Finally, BRCHS provides diabetes education in addition to

contracting with a 340B pharmacy to assist patients in getting reduced price glucose test strips. The program has made an impact in preventing chronic kidney disease as it has made providers, staff, and patients more aware of the disease.

Bertie County Rural Health Association

The Bertie County Rural Health Association is a federally-qualified health clinic that was founded in 1984 in Windsor, North Carolina. The Bertie County Rural Health Association (BCRHA) provides sliding fee scale services including primary care, dental care, diagnostics, and emergency services. The clinic also has arrangements for patients to receive pharmaceuticals and transportation at reduced or no cost. The association serves a large underserved area and provides care to a population that is overwhelmingly African American and/or living in poverty.

With support from the Kate B. Reynolds Charitable Trust, the BCRHA started the Diabetes Collaborative program in 2003. The program is part of the National Diabetes Collaborative and the North Carolina Diabetes Collaborative. Since 2003, the BCRHA has tracked more than 900 patients with diabetes. Bertie County is home to a large number of diabetic and CKD patients, many of whom face additional challenges such as geographic and rural isolation, lack of transportation, and poverty. The collaborative began as a response to these issues.

Diabetic patients have some type of medical exposure (ie, physician visit or health education session) at least once every 6-8 weeks. The staff check hemoglobin A1C levels and ensure that medications are being taken. BCRHA also provides free glucose monitors and a hotline for patients to call if they are concerned their blood sugar is rising.

The Bertie County Rural Health Association also places a high value on health education. In addition to running an educational video in the waiting room of the clinic, a health educator holds a monthly program at the clinic to discuss nutrition as well as any new developments in the treatment of diabetes. The health educator discusses realistic food options so that patients are more likely to adhere to a nutrition plan. Additionally, health educators and physicians strongly encourage their diabetic patients to use the walking trails around the local elementary schools. Health educators also make house calls to discuss diabetes with the diabetic patient as well as his or her family. The hope is that greater family involvement will lead to improved outcomes for the patient and also for the rest of the family. The Bertie County Rural Health Association also maintains close relationships with the local African American churches and uses these relationships as a conduit to conduct outreach and health education through events such as screenings and health fairs.

The Bertie County Rural Health Association is seeing fewer patients on dialysis as a result of the Diabetes Collaborative. Staff also report seeing significant weight loss, fewer ulcers, and less surgery needed for diabetes-related conditions such as gangrene. But perhaps most importantly, the BCRHA patients are now more actively engaged in their health due, in part, to the concern and attention that the BCRHA staff show their diabetic patients as a result of the Collaborative and the improved diabetes protocol.

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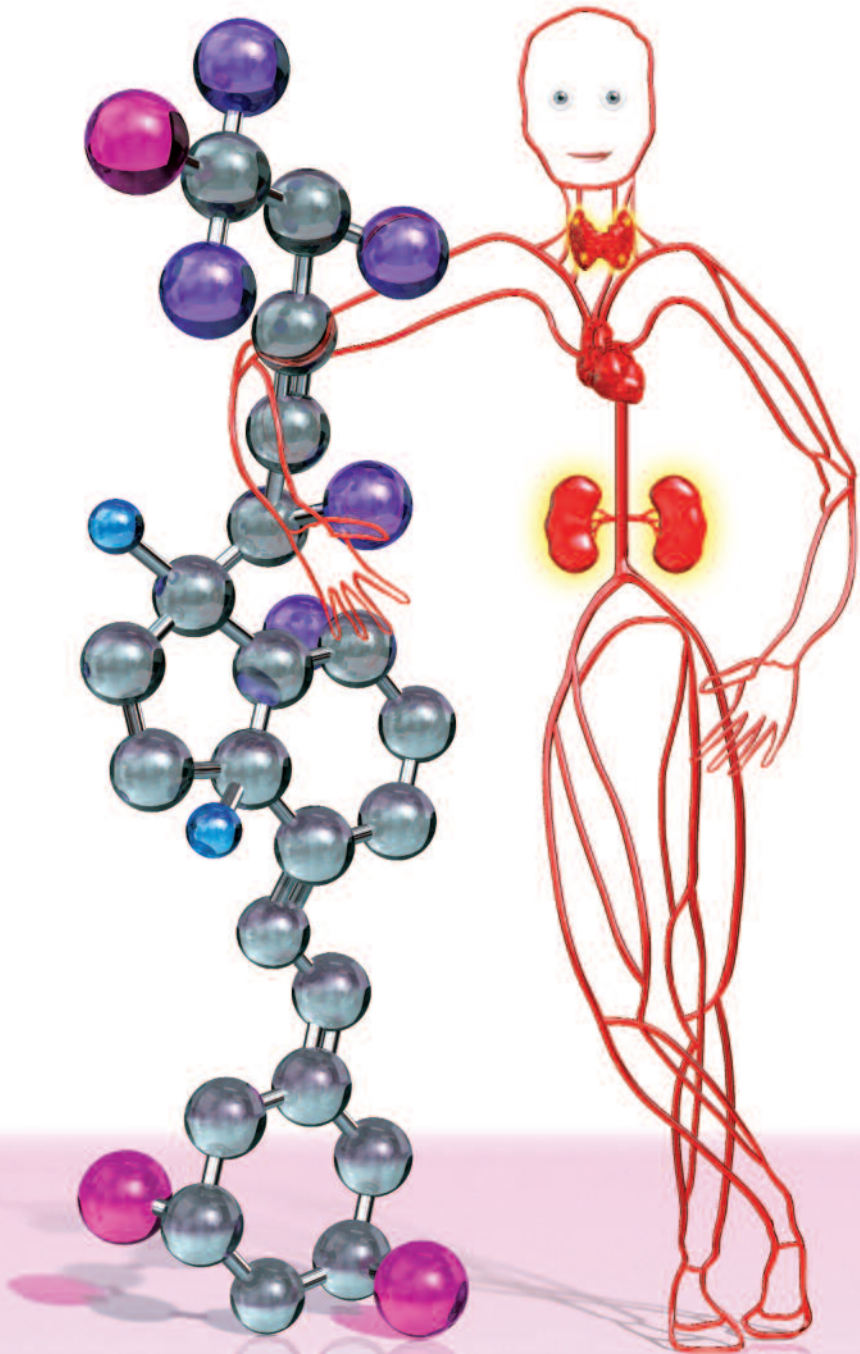
Barbara Fletcher, chief operating officer of Blue Ridge Community Health Services, and Dr Albert Thompson, health director of the Bertie County Rural Health Association, contributed to this article.

When treating SHPT in CKD Stages 3 and 4 patients

Embrace the Potential...

Abbott
A Promise for Life



†Based on three 24-week, double-blind, placebo-controlled, randomized, multicenter, phase 3 clinical studies (N = 220) in patients with SHPT and CKD Stages 3 and 4. Two studies used an identical 3-times-weekly dosing design; one study used a once-daily dosing design. At each visit, changes from baseline were also observed for patients who had data at the time.

*Glomerular filtration rate (GFR) 15 to 59 mL/min/1.73 m^2.[3]

KDOQI is a trademark of the National Kidney Foundation.

References: **1.** ZEMPLAR Capsules [package insert]. North Chicago, IL: Abbott Laboratories; 2005. **2.** Coyne D, Acharya M, Qiu P, et al. Paricalcitol capsule for the treatment of secondary hyperparathyroidism in stages 3 and 4 CKD. *Am J Kidney Dis.* 2006;47:263-276. **3.** National Kidney Foundation. K/DOQI clinical practice guidelines for bone metabolism and disease in chronic kidney disease. *Am J Kidney Dis.* 2003;42(suppl 3):S1-S201.

Please see adjacent brief summary of full Prescribing Information.

For more information, please contact your Abbott Renal Care representative or visit **www.zemplar.com**.

For prevention and treatment of secondary hyperparathyroidism (SHPT) in patients with chronic kidney disease (CKD) Stages 3 and 4*

Be selective.

Depend on ZEMPLAR Capsules.

ZEMPLAR helps provide effective PTH reduction while maintaining phosphorus and calcium within target ranges[1-3]

- **91% of ZEMPLAR-treated patients** achieved the primary efficacy endpoint in lowering intact parathyroid hormone (iPTH) vs **13% of placebo-treated patients** ($P<0.001$)[1,2†]
  - — Primary endpoint: 2 consecutive reductions ≥30% from baseline for iPTH
- iPTH reductions sustained throughout the 24-week study[1,2]
- ZEMPLAR maintained serum phosphorus and calcium levels within Kidney Disease Outcomes Quality Initiative™ (KDOQI) target ranges throughout the 24-week study[2,3]

ZEMPLAR®
(PARICALCITOL) CAPSULES

Embrace the Potential

Important Safety Information

- Contraindicated in patients with evidence of vitamin D toxicity, hypercalcemia, or hypersensitivity to any product ingredient
- Excessive administration of vitamin D compounds can cause oversuppression of PTH, hypercalcemia, hypercalciuria, hyperphosphatemia, and adynamic bone disease. High intake of calcium and phosphate may lead to similar abnormalities. Progressive hypercalcemia due to overdosage of vitamin D may require immediate medical attention. Chronic hypercalcemia can lead to vascular and soft-tissue calcifications
- Withhold pharmacologic doses of vitamin D compounds during treatment with ZEMPLAR
- Hypercalcemia may potentiate digitalis toxicity, cardiac arrhythmias, and seizures; use caution with these types of patients
- PTH, calcium, and phosphorus levels should be monitored at least every 2 weeks for 3 months after initiation of ZEMPLAR therapy or following dose adjustments, then monthly for 3 months, and every 3 months thereafter. Patient monitoring and individualized dose titration are required to maintain physiologic targets and optimum reduction/levels of PTH. The dose of ZEMPLAR should be reduced or interrupted if hypercalcemia or elevated Ca × P is observed
- Patients should be informed to comply with dosage instructions, to adhere to their diet and phosphorus restriction, to take prescribed phosphate binders, and should be knowledgeable about the symptoms of hypercalcemia
- Adverse events reported by at least 5% of the ZEMPLAR treated patients and at a frequency of at least twice that of placebo were: allergic reaction (6% vs 2%), rash (6% vs 3%), arthritis (5% vs 1%), and vertigo (5% vs 0%)

Abbott
A Promise for Life

PROFESSIONAL BRIEF SUMMARY
CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION

Zemplar®

(paricalcitol) Capsules

℞ only

INDICATIONS AND USAGE

Zemplar Capsules are indicated for the prevention and treatment of secondary hyperparathyroidism associated with chronic kidney disease (CKD) Stage 3 and 4.

CONTRAINDICATIONS

Zemplar Capsules should not be given to patients with evidence of vitamin D toxicity, hypercalcemia, or hypersensitivity to any ingredient in this product (see **WARNINGS**).

WARNINGS

Excessive administration of vitamin D compounds, including Zemplar Capsules, can cause over suppression of PTH, hypercalcemia, hypercalciuria, hyperphosphatemia, and adynamic bone disease. Progressive hypercalcemia due to overdosage of vitamin D and its metabolites may be so severe as to require emergency attention. Acute hypercalcemia may exacerbate tendencies for cardiac arrhythmias and seizures and may potentiate the action of digitalis. Chronic hypercalcemia can lead to generalized vascular calcification and other soft-tissue calcification. High intake of calcium and phosphate concomitant with vitamin D compounds may lead to similar abnormalities and patient monitoring and individualized dose titration is required.

Pharmacologic doses of vitamin D and its derivatives should be withheld during Zemplar treatment to avoid hypercalcemia.

PRECAUTIONS

General

Digitalis toxicity is potentiated by hypercalcemia of any cause, so caution should be applied when digitalis compounds are prescribed concomitantly with Zemplar Capsules.

Information for Patients

The patient or guardian should be informed about compliance with dosage instructions, adherence to instructions about diet and phosphorus restriction, and avoidance of the use of unapproved nonprescription drugs. Phosphate-binding agents may be needed to control serum phosphorus levels in patients, but excessive use of aluminum containing compounds should be avoided. Patients also should be informed about the symptoms of elevated calcium (see **ADVERSE REACTIONS**).

Laboratory Tests

During the initial dosing or following any dose adjustment of medication, serum calcium, serum phosphorus, and serum or plasma iPTH should be monitored at least every two weeks for 3 months after initiation of Zemplar therapy or following dose-adjustments in Zemplar therapy, then monthly for 3 months, and every 3 months thereafter.

Drug Interactions

Paricalcitol is not expected to inhibit the clearance of drugs metabolized by cytochrome P450 enzymes CYP1A2, CYP2A6, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP2E1 or CYP3A nor induce the clearance of drugs metabolized by CYP2B6, CYP2C9 or CYP3A.

A multiple dose drug-drug interaction study demonstrated that ketoconazole approximately doubled paricalcitol $AUC_{0-\infty}$. Since paricalcitol is partially metabolized by CYP3A and ketoconazole is known to be a strong inhibitor of cytochrome P450 3A enzyme, care should be taken while dosing paricalcitol with ketoconazole and other strong P450 3A inhibitors including atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin or voriconazole. Dose adjustment of Zemplar Capsules may be required, and iPTH and serum calcium concentrations should be closely monitored if a patient initiates or discontinues therapy with a strong CYP3A4 inhibitor such as ketoconazole.

Drugs that impair intestinal absorption of fat-soluble vitamins, such as cholestyramine, may interfere with the absorption of Zemplar Capsules.

Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 104-week carcinogenicity study in CD-1 mice, an increased incidence of uterine leiomyoma and leiomyosarcoma was observed at subcutaneous doses of 1, 3, 10 mcg/kg given three times weekly (2 to 15 times the AUC at a human dose of 14 mcg, equivalent to 0.24 mcg/kg based on AUC). The incidence rate of uterine leiomyoma was significantly different than the control group at the highest dose of 10 mcg/kg. In a 104-week carcinogenicity study in rats, there was an increased incidence of benign adrenal pheochromocytoma at subcutaneous doses of 0.15, 0.5, 1.5 mcg/kg (< 1 to 7 times the exposure following a human dose of 14 mcg, equivalent to 0.24 mcg/kg based on AUC). The increased incidence of pheochromocytomas in rats may be related to the alteration of calcium homeostasis by paricalcitol. Paricalcitol did not exhibit genetic toxicity *in vitro* with or without metabolic activation in the microbial mutagenesis assay (Ames Assay), mouse lymphoma mutagenesis assay (L5178Y), or a human lymphocyte cell chromosomal aberration assay. There was also no evidence of genetic toxicity in an *in vivo* mouse micronucleus assay. Paricalcitol had no effect on fertility (male or female) in rats at intravenous doses up to 20 mcg/kg/dose (equivalent to 13 times a human dose of 14 mcg based on surface area, mcg/m^2).

Pregnancy

Pregnancy category C

Paricalcitol has been shown to cause minimal decreases in fetal viability (5%) when administered daily to rabbits at a dose 0.5 times a human dose of 14 mcg or 0.24 mcg/kg (based on body surface area, mcg/m^2), and when administered to rats at a dose two times the 0.24 mcg/kg human dose (based on body surface area, mcg/m^2). At the highest dose tested, 20 mcg/kg administered three times per week in rats (13 times the 14 mcg human dose based on surface area, mcg/m^2), there was a significant increase in the mortality of newborn rats at doses that were maternally toxic and are known to produce hypercalcemia in rats. No other effects on offspring development were observed. Paricalcitol was not teratogenic at the doses tested.

Paricalcitol (20 mcg/kg) has been shown to cross the placental barrier in rats.

There are no adequate and well-controlled clinical studies in pregnant women. Zemplar Capsules should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the fetus.

Nursing Mothers

Studies in rats have shown that paricalcitol is present in the milk. It is not known whether paricalcitol is excreted in human milk. In the nursing patient, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Geriatric Use

Of the total number (n = 220) of patients in clinical studies of Zemplar Capsules, 49% were 65 and over, while 17% were 75 and over. No overall differences in safety and effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Pediatric Use

Safety and efficacy of Zemplar Capsules in pediatric patients have not been established.

ADVERSE REACTIONS

The safety of Zemplar Capsules has been evaluated in three 24-week (approximately six-month), double-blind, placebo-controlled, multicenter clinical studies involving 220 CKD Stage 3 and 4 patients. Six percent (6%) of Zemplar Capsules treated patients and 4% of placebo treated patients discontinued from clinical studies due to an adverse event. All reported adverse events occurring in at least 2% in either treatment group are presented in Table 3.

Table 3. Treatment - Emergent Adverse Events by Body System Occurring in ≥ 2% of Subjects in the Zemplar-Treated Group of Three, Double-Blind, Placebo-Controlled, Phase 3, CKD Stage 3 and 4 Studies; All Treated Patients

	Number (%) of Subjects			
Body System[a] COSTART V Term	**Zemplar Capsules (n = 107)**		**Placebo (n = 113)**	
Overall	**88**	**(82%)**	**86**	**(76%)**
Body as a Whole	**49**	**(46%)**	**40**	**(35%)**
Accidental Injury	10	(9%)	8	(7%)
Pain	8	(7%)	7	(6%)
Viral Infection	8	(7%)	8	(7%)
Allergic Reaction	6	(6%)	2	(2%)
Headache	5	(5%)	5	(4%)
Abdominal Pain	4	(4%)	2	(2%)
Back Pain	4	(4%)	1	(1%)
Infection	4	(4%)	4	(4%)
Asthena	3	(3%)	2	(2%)
Chest Pain	3	(3%)	1	(1%)
Fever	3	(3%)	1	(1%)
Infection Fungal	3	(3%)	0	(0%)
Cyst	2	(2%)	0	(0%)
Flu Syndrome	2	(2%)	1	(1%)
Infection Bacterial	2	(2%)	1	(1%)
Cardiovascular	**27**	**(25%)**	**19**	**(17%)**
Hypertension	7	(7%)	4	(4%)
Hypotension	5	(5%)	3	(3%)
Syncope	3	(3%)	1	(1%)
Cardiomyopathy	2	(2%)	0	(0%)
Congestive Heart Failure	2	(2%)	5	(4%)
Myocardial Infarct	2	(2%)	0	(0%)
Postural Hypotension	2	(2%)	0	(0%)
Digestive	**29**	**(27%)**	**31**	**(27%)**
Diarrhea	7	(7%)	5	(4%)
Nausea	6	(6%)	4	(4%)
Vomiting	6	(6%)	5	(4%)
Constipation	4	(4%)	4	(4%)
Gastroenteritis	3	(3%)	3	(3%)
Dyspepsia	2	(2%)	2	(2%)
Gastritis	2	(2%)	4	(4%)
Rectal Disorder	2	(2%)	0	(0%)
Hemic and Lymphatic System	**4**	**(4%)**	**10**	**(9%)**
Hypervolemia	2	(2%)	4	(4%)
Ecchymosis	2	(2%)	4	(4%)
Metabolic and Nutritional Disorders	**24**	**(22%)**	**34**	**(30%)**
Edema	7	(7%)	5	(4%)
Uremia	7	(7%)	9	(8%)
Gout	4	(4%)	6	(5%)
Dehydration	3	(3%)	1	(1%)
Acidosis	2	(2%)	1	(1%)
Hyperkalemia	2	(2%)	3	(3%)
Hyperphosphatemia	2	(2%)	4	(4%)
Hypoglycemia	2	(2%)	4	(4%)
Hypokalemia	2	(2%)	1	(1%)
Musculoskeletal	**12**	**(11%)**	**9**	**(8%)**
Arthritis	5	(5%)	1	(1%)
Leg Cramps	3	(3%)	0	(0%)
Myalgia	2	(2%)	5	(4%)
Nervous	**18**	**(17%)**	**12**	**(11%)**
Dizziness	5	(5%)	5	(4%)
Vertigo	5	(5%)	0	(0%)
Depression	3	(3%)	0	(0%)
Insomnia	2	(2%)	2	(2%)
Neuropathy	2	(2%)	1	(1%)
Respiratory	**26**	**(24%)**	**25**	**(22%)**
Pharyngitis	11	(10%)	12	(11%)
Rhinitis	5	(5%)	4	(4%)
Bronchitis	3	(3%)	1	(1%)
Cough Increased	3	(3%)	2	(2%)
Sinusitis	3	(3%)	1	(1%)
Epistaxis	2	(2%)	1	(1%)
Pneumonia	2	(2%)	0	(0%)
Skin and Appendages	**17**	**(16%)**	**10**	**(9%)**
Rash	6	(6%)	3	(3%)
Pruritus	3	(3%)	3	(3%)
Skin Ulcer	3	(3%)	0	(0%)
Skin Hypertrophy	2	(2%)	0	(0%)
Vesiculobullous Rash	2	(2%)	1	(1%)
Special Senses	**9**	**(8%)**	**11**	**(10%)**
Amblyopia	2	(2%)	0	(0%)
Retinal Disorder	2	(2%)	0	(0%)
Urogenital System	**10**	**(9%)**	**10**	**(9%)**
Urinary Tract Infection	3	(3%)	1	(1%)
Kidney Function Abnormal	2	(2%)	1	(1%)

a. Includes all patients with events in that body system.

Potential adverse effects of Zemplar Capsules are, in general, similar to those encountered with excessive vitamin D intake. The early and late signs and symptoms of hypercalcemia associated with vitamin D overdoses include:

Early: Weakness, headache, somnolence, nausea, vomiting, dry mouth, constipation, muscle pain, bone pain, and metallic taste.

Late: Anorexia, weight loss, conjunctivitis (calcific), pancreatitis, photophobia, rhinorrhea, pruritus, hyperthermia, decreased libido, elevated BUN, hypercholesterolemia, elevated AST and ALT, ectopic calcification, hypertension, cardiac arrhythmias, somnolence, death, and, rarely, overt psychosis.

OVERDOSAGE

Excessive administration of Zemplar Capsules can cause hypercalcemia, hypercalciuria, and hyperphosphatemia, and over suppression of PTH (see **WARNINGS**).

Treatment of Overdosage

The treatment of acute overdosage of Zemplar Capsules should consist of general supportive measures. If drug ingestion is discovered within a relatively short time, induction of emesis or gastric lavage may be of benefit in preventing further absorption. If the drug has passed through the stomach, the administration of mineral oil may promote its fecal elimination. Serial serum electrolyte determinations (especially calcium), rate of urinary calcium excretion, and assessment of electrocardiographic abnormalities due to hypercalcemia should be obtained. Such monitoring is critical in patients receiving digitalis. Discontinuation of supplemental calcium and institution of a low-calcium diet are also indicated in accidental overdosage. Due to the relatively short duration of the pharmacological action of paricalcitol, further measures are probably unnecessary. If persistent and markedly elevated serum calcium levels occur, there are a variety of therapeutic alternatives that may be considered depending on the patient's underlying condition. These include the use of drugs such as phosphates and corticosteroids, as well as measures to induce an appropriate forced diuresis.

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Revised: May, 2005

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