



Analytical methods

“If I didn’t go to the screening at Farmers Market I would not have known about my kidney problems. I am grateful to the whole staff. They were very professional. Thank you.”

KEEP Participant: Screening date, June, 2005



e report only eligible participants as they are defined in the introduction. Most analyses are descriptive. Due to missing data in the survey, we use the following inclusion criteria:

- In the overall analysis, we include all eligible participants.
- In analyses by any participant characteristics we exclude subjects with missing values for the corresponding characteristics. When we report participant distribution by race or by self-reported disease, for example, we exclude participants with missing values for race or self-reported disease.
- For all percent distribution analyses, denominators include only eligible participants without missing data for the specified characteristics.
- For most analyses including race, we divide race into white, black, or other race, and exclude participants with a missing value for race. We divide ethnic groups into Hispanic and non-Hispanic, and treat participants with missing values for ethnicity as non-Hispanic.
- In the age category, we group participants as follows: 18–30, 31–45, 46–60, 61–75, and 75+.
- When we calculate the mean of biochemical measures such as blood pressure, blood glucose, eGFR, BMI, hemoglobin, and so on, we exclude participants with missing values for these measures.

- In any analysis with multiple participant characteristics or biochemical measures, we exclude participants with any missing values for those characteristics or measures.

Laboratory analysis

Data were collected on height, weight, blood pressure, age, family history, plasma glucose, hemoglobin, serum creatinine, and the presence of microalbuminuria, pyuria, and hematuria. Bayer Healthcare's Clinitek reagent strips for urinalysis were used to obtain the microalbumin and albumin to creatinine ratio results (Bayer Diagnostics, Tarrytown NY). Bayer's Multistix PRO Reagent Strip for Urinalysis was used for the blood and leukocyte measures. Plasma glucose testing on venous blood specimens was performed using Lifescan's SureStep Pro test strips (Lifescan, Milpitas, CA). Hemoglobin and serum creatinine testing was performed by Satellite Laboratory Services, (Redwood City, CA), hemoglobins using the Sysmex SE2100 (Sysmex America Inc., Mundelein IL), and creatinines using the Olympus 5431 (Olympus Optical, Tokyo, Japan). Hemoglobin and serum creatinine testing was also performed by Consolidated Laboratory Services, Van Nuys, California, using the Abbott Cell-Dyn 3200 (Abbott Laboratories, Abbott Park, IL) for hemoglobins and the Abbott Architect c8000 (Abbott Laboratories, Abbott Park, IL) for creatinines.

Definitions

BMI groups

- Underweight: BMI <18.5 kg/m²
- Normal: BMI 18.5–24.9 kg/m²
- Overweight: BMI 25–29.9 kg/m²
- Obese: BMI 30–39.9 kg/m²
- Extremely obese: BMI ≥40 kg/m²

Measured hypertension: JNC 7

- Normal: systolic <120 mmHg and diastolic <80 mmHg
- Prehypertension: systolic 120–139 mmHg or diastolic 80–89 mmHg
- Stage 1: systolic 140–159 mmHg or diastolic 90–99 mmHg
- Stage 2: systolic ≥160 mmHg or diastolic ≥100 mmHg

Elevated measured blood pressure

- Diabetes or CKD: systolic ≥130 mmHg or diastolic ≥80 mmHg
- No diabetes or CKD: systolic ≥140 mmHg or diastolic ≥90 mmHg

Elevated blood sugar

- KEEP guideline ≥126 mg/dl fasting and ≥140 mg/dl non-fasting

CKD

- eGFR by K/DOQI MD RD <60 ml/min/1.73 m² or eGFR ≥60 ml/min/1.73 m² and abnormal albumin/creatinine ratio (ACR; ≥30 mg/g)

CKD stages

- Stage 1: eGFR ≥90 ml/min/1.73 m² and abnormal ACR
- Stage 2: eGFR 60–89 and abnormal ACR

- Stage 3: eGFR 30–59
- Stage 4: eGFR 15–29
- Stage 5: eGFR <15 or on dialysis

WHO anemia

- Males: hemoglobin <13 g/dl
- Females: hemoglobin <12 g/dl

K/DOQI anemia

- Males: hemoglobin <12 g/dl
- Females: age >50: hemoglobin <12 g/dl
age ≤50: hemoglobin <11 g/dl

Mean blood pressure

- Diastolic BP + (systolic BP – diastolic BP) / 3

Chapter 2: Participant demographics

Figures 2.1–5 present KEEP participant demographics by NKF affiliate, KEEP program year, U.S. Census division, state, and U.S. Census region. Figure 2.6 shows the distribution of KEEP and NHANES participants by age, gender, and race/ethnicity.

Figures 2.7–9 illustrate the distribution of participants by educational level, grouped as grade school or less, some high school, high school graduate, some college, college graduate, and post-graduate or professional degree. Figure 2.10 shows the distribution of participant's educational level by age and gender. Figure 2.11 shows the distribution of education level by race/ethnicity for KEEP and NHANES, respectively. NHANES data in these figures are grouped by three education levels.

Figure 2.12 presents the distribution of KEEP participants by insurance type, grouped into Medicare only, Medicare and Medicaid, Medicare with other insurance, non-Medicare, and unknown or missing. Figures 2.13–17 show the percentage of participants with health insurance coverage by program year, region, age, gender, and race/ethnicity for KEEP and NHANES, respectively. Figure 2.18–19 present the distribution of KEEP and NHANES participants by education and by education and race.

Figures 2.20–24 illustrate participant access to medical care, measured by whether or not they have a physician. The percent of participants with a physician is presented by KEEP program year, region, age, gender, and race/ethnicity (Figures 2.20, 2.21, and 2.23). Figure 2.22 presents the percent of participants with a physician by race and region. In Figure 2.24 we show the percentage of participants with a physician by education and insurance status.

Chapter 3: Health history

Figures 3.1–6 examine the history of diabetes in KEEP and NHANES participants. Figure 3.1 presents the percent with self-reported diabetes, by age, gender, and race/ethnicity; Figure 3.2 the distribution of participants by measured blood pressure (JNC 7), stratified on self-reported diabetic status; Figure 3.3 the percent with elevated blood pressure (JNC 7)

by gender and race/ethnicity, stratified on self-reported diabetic status; Figure 3.4 the percent with self-reported diabetes by measured blood pressure (JNC 7); and Figure 3.5 the percent with a glucose greater than the normal limit, by age, gender, and race, and stratified on self-reported diabetic status. Figure 3.6 shows the percent of participants with self-reported diabetes by education and insurance status.

Figures 3.7–12 examine the history of hypertension in KEEP and NHANES participants. Figure 3.7 presents data on participants' self-reported hypertension, by age, gender, and race/ethnicity. Figures 3.8–9 show the percent distribution of participants with measured blood sugar, by self-reported hypertension and by gender and race/ethnicity, respectively. Figure 3.10 presents the percent with self-reported hypertension by glucose level; Figure 3.11 the percent with elevated measured blood pressure, by age, gender, and race/ethnicity, stratified on self-reported hypertension; and Figure 3.12 the percent distribution of self-reported hypertension, by education and insurance status.

Figures 3.13–16 examine participants' history of cardiovascular disease, defined by the occurrence of a heart attack, PVD, a stroke, heart bypass surgery, heart failure, heart angioplasty, or abnormal heart rhythm. Figure 3.13 presents the percent distribution with cardiovascular disease by age, gender, and race/ethnicity, while Figure 3.14 shows the same distribution stratifying on CKD status. Figure 3.15 examines the risk factors for cardiovascular disease among participants with any cardiac event by age, gender, race/ethnicity, and CKD status, and Figure 3.16 shows the percent with cardiovascular disease by education and insurance status.

Figures 3.17–23 present KEEP and NHANES participant characteristics by the presence of obesity, defined by body mass index (BMI). Percent distribution by BMI is shown in Figure 3.17. Participant obesity is also examined by gender, race/ethnicity, region, self-reported disease, measured blood pressure (JNC 7), and educational and insurance status.

Figures 3.24–29 present information on KEEP and NHANES participant smoking status. Figures 3.24–25 present smoking status overall and by race/ethnicity. Figures 3.26–28 examine the percent with self-reported diabetes, self-reported hypertension, and CKD by smoking status. And Figure 3.29 shows the percent with a history of smoking by education and insurance status, stratified on age and race/ethnicity.

Figures 3.30–35 examine KEEP and NHANES participant characteristics by the presence of kidney disease. Figures 3.30–33 present KEEP participant self-reported kidney problems overall, by gender, by race/ethnicity, and by region. Figure 3.34 presents KEEP/NHANES participant distribution by CKD stage and race/ethnicity. Figure 3.35 shows the percent of participants with CKD by education and insurance status, stratified on age and race/ethnicity.

Figure 3.36 examines risk factors by region. These risk factors include the presence of CKD, self-reported diabetes or

hypertension, obesity, and smoking history. Figures 3.37–40 show risk factors and family history of comorbidities (diabetes, hypertension, CKD, and cardiac events).

Figures 3.41–47 present data on medical intervention from the KEEP program follow-up survey. We look here only at participants who returned the survey follow-up forms. Figure 3.41 looks at the percent of patients completing their followup forms, and Figure 3.42 presents data on participants who have seen a doctor about their test results. Figure 3.43 lists the reasons why KEEP participants saw a physician after completing their followup forms and figure 3.44 shows reasons why participants did not see a physician after receiving abnormal test results. Figures 3.45–47 show the percent of participants who learned they have anemia, diabetes, and hypertension, respectively, and who received medical intervention for that condition.

Chapter 4: Diabetes and hypertension

In Chapter 4 we examine diabetes and hypertension in KEEP and NHANES participants, as well as the risk factors for these diseases. Figures 4.1–4 present the percent of KEEP and NHANES participants with diabetes by age, gender, and race/ethnicity; by cohort year; by region; and by education and insurance status. Figure 4.5 illustrates the percent with a positive microalbuminuria test or an abnormal albumin creatinine ratio, and the mean microalbuminuria values by diabetic status. Diabetes is defined here as either self-reported or measured by a glucose value greater than the normal level (126 mg/dl fasting, and 139 mg/dl non-fasting). In Figures 4.6–11 we examine mean blood pressure, elevated blood pressure, mean eGFR, CKD status, mean BMI, and percent with a BMI equal to or greater than 30 kg/m² by self-reported diabetes and family history of diabetes.

Figures 4.12–19 and Tables 4.a–b examine glycemic control in KEEP participants. Figure 4.12 presents the mean blood sugar level in KEEP participants with or without self-reported diabetes by hypertensive stage (JNC7). Figures 4.13–15 present KEEP participants with or without self-reported diabetes who meet the target blood sugar level, by hypertensive stage (JNC7), cohort year, and U.S. Census region. Figures 4.16–17 examine mean and elevated blood sugars by whether participants have seen a physician. Figure 4.18 and Table 4.a examine the association of risk factors with an elevated blood sugar level in self-reported non-diabetic KEEP participants, and Figure 4.19 and Table 4.b show the association of risk factors with a target blood sugar level in self-reported diabetic KEEP participants.

Figures 4.20–22 present the percent of KEEP participants with hypertension by age, gender, and race/ethnicity; cohort years; and U.S. Census region. Figure 4.23 presents hypertension status by education and insurance status for KEEP and NHANES participants, respectively. Figure 4.24 shows the percent with a positive microalbuminuria test by hypertension status. Hypertension is defined either as self-reported or through an elevated measured blood pressure (JNC 7).

In Figures 4.25–31 we examine participant blood pressure parameters, mean blood pressure, percent with elevated blood pressure, mean eGFR, percent with CKD, mean BMI, and percent with a BMI equal to or above 30 kg/m², by self-reported hypertension and family history of hypertension.

Figures 4.32–33 present the mean blood pressure and target blood pressure in KEEP participants with self-reported hypertension by BMI group. Figures 4.34–35 include data on blood pressure control and physician interaction in KEEP participants. Figures 4.36 and 4.37 examine the type and number of risk factors for hypertension in KEEP participants by family history of peripheral vascular disease. Figure 4.38 and Table 4.c examine the odds ratios of self-reported non-hypertensive KEEP participants having and elevated blood pressure (JNC7), by risk factor, while Figure 4.39 and Table 4.d examine the odds of meeting the target blood pressure in KEEP participants with known hypertension.

Logistic regressions are used to analyze the associations in Tables 4.a–d. The controlled risk factors in the logistic regressions are age, gender, race, smoking history, self-reported diabetes or hypertension, family history of diabetes and hypertension, obesity, participant CKD status, cohort years, and region.

Chapter 5: CKD

Figure 5.1 illustrates the percent of KEEP participants with elevated serum creatinine levels overall and by age, gender, and race. In Figure 5.2 we compare the prevalence of CKD in KEEP participants and NHANES participants; while in Figure 5.3 we compare the distribution of KEEP and NHANES participants by CKD stage. Figure 5.4 examines the interaction of CKD, self-reported diabetes, and elevated blood pressure in KEEP and NHANES participants. Figure 5.5 presents the prevalence of CKD by age and race/ethnicity, stratifying on education and insurance status.

Figures 5.6–8 present the percent of KEEP participants with CKD who have a family history of kidney disease.

Figure 5.9 illustrates the distribution of KEEP and NHANES participants by measured blood pressure (JNC 7), stratifying on CKD status. Figure 5.10 examines the prevalence of self-reported hypertension and elevated blood pressure (JNC 7) by age, gender, and race/ethnicity, stratifying on CKD status. Figure 5.11 presents blood pressure parameters (systolic, diastolic, and mean blood pressure) by CKD stage for KEEP and NHANES participants. Figures 5.12–13 show, by CKD stage, the percent of KEEP and NHANES participants with elevated blood pressure and those meeting target blood pressure levels. Figure 5.14 examines the distribution of KEEP and NHANES participants, with and without CKD, who have elevated blood pressure, by age, gender, and race/ethnicity.

In Figure 5.15 we compare the prevalence of diabetes in KEEP and NHANES participants by CKD status, by age, gender,

and race/ethnicity. Figure 5.16 presents the prevalence of self-reported diabetes in KEEP and NHANES participants with and without CKD, by gender and obesity status. Figure 5.17 examines the distribution of self-reported diabetes in KEEP and NHANES participants by CKD stage.

Figure 5.18 examines the distribution of KEEP and NHANES participants by BMI and CKD stage. Figures 5.19–20 present the percent with a BMI equal to or greater than 30 kg/m², by age, gender, and CKD status and by diabetes, hypertension and CKD status, respectively. Figure 5.21 shows the percent of KEEP participants with a BMI equal to or greater than 30 kg/m² by gender and CKD status, stratified on Hispanic ethnicity. Figure 5.22 presents the percent of KEEP and NHANES participants with a BMI equal to or greater than 30 kg/m² by CKD status and race/ethnicity.

Figures 5.23–25 shows smoking status in KEEP and NHANES participants by age, gender, and CKD status, by CKD stage, and by interaction of CKD status with race/ethnicity.

Figures 5.26–30 examine risk factors for CKD in KEEP and NHANES participants. Figure 5.26 compares the distribution of the number of risk factors (obesity, diabetes, smoking, anemia, and hypertension) in KEEP and NHANES participants with CKD. Figures 5.27–29 present the percent with elevated blood pressure by interactions of obesity and self-reported diabetes, smoking, and anemia, respectively. Figure 5.30 presents the distribution of the number of risk factors for cardiovascular disease by CKD stage.

Figures 5.31–35 present the percent of KEEP and NHANES participants with a positive microalbuminuria test, the mean microalbuminuria level, and the percent with an albumin/creatinine ratio greater than normal limit by serum creatinine level, eGFR stage, eGFR stage and diabetic status, eGFR stage and JNC 7 blood pressure stage, and eGFR stage and smoking history.

Figures 5.36–62, new to the report this year, present PTH, calcium, and phosphorus values in KEEP participants with an eGFR of 15–<60 ml/min/1.73 m². Figures 5.36–44 present mean intact PTH and the percent of participants with abnormal PTH by age, gender, race/ethnicity, self-reported diabetes, hypertension, CVD, eGFR, CKD stage, WHO anemia status, and BMI. Normal intact PTH is defined as a PTH value of 14–72 for Satellite and 10–69 for CLS. Figures 5.45–53 present mean calcium levels and the percent of participants with abnormal calcium by the same factors. A normal calcium is defined as a value of 8.4–10.2 for CLS. Figures 5.54–62 present mean phosphorus levels and the percent of participants with abnormal phosphorus, again by the same factors. A normal phosphorus level is defined as a value of 2.3–4.7 for CLS.

Chapter 6: Anemia and CKD

Figure 6.1 presents the distribution of KEEP and NHANES participants with anemia (WHO and K/DOQI) by age and gender. Figures 6.2 present the percent with anemia by race/

ethnicity, and Figures 6.3–4 show the percent by age, race, education, and insurance status.

Figure 6.5 illustrates the percent of KEEP and NHANES participants with or without anemia (WHO and K/DOQI) who have a positive microalbuminuria test, and the mean microalbuminuria level. The percent with anemia (WHO and K/DOQI) is shown in Figure 6.6 by CKD status, in Figures 6.7–8 by the interactions of CKD status with gender and race, and in Figures 6.9–12 by CKD stage and its interaction with gender, race, and diabetic status, respectively. Figures 6.13–17 and Tables 6.a–b examine the association of risk factors and anemia (WHO and K/DOQI), analyzed by logistic regressions. The controlled risk factors are age, gender, history of smoking, self-reported hypertension, family history of diabetes and hypertension, obesity, eGFR, cohort years, region, and the interaction between race and self-reported diabetes.

Reference Tables

Tables 1–15 present total counts of eligible KEEP participants, and show the prevalence of diabetes, hypertension, CKD, obesity, microalbuminuria, anemia, and risk factors for CVD, overall and by age, gender, race/ethnicity, region, smoking status, education, insurance status, and whether participant have a physician.

Table 16 reports counts of eligible KEEP participants by NKF affiliate. Tables 16.1–10 present total counts, prevalence, and odds ratios for participants with diabetes, hypertension, diabetes and hypertension, obesity, blood pressure control, glycemic control, microalbuminuria, eGFR < 60 ml/min/1.73 m², WHO anemia, and K/DOQI anemia. To calculate the odds ratio, we use a set of logistic regressions with all affiliates as independent variables and Florida as the reference.

NHANES 1999–2002:

Database design, setting, & study participants

The National Health and Nutrition Examination Survey (NHANES) is a series of health examination surveys conducted by the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention in the United States. Begun in 1960, NHANES is designed to monitor the health and nutritional status of the non-institutionalized civilian population in the United States. In 1999, NHANES became a continuous annual survey to allow annual estimates, with release of public-use data files every two years. NHANES 1999–2002 were nationally representative cross-sectional health examination surveys and used a complex, stratified, multistage probability cluster sampling design that included selection of primary sampling units (counties), household segments within the counties, and sample persons from selected households. Survey participants were interviewed in their homes and/or received standardized medical examinations in mobile examination centers. NHANES over-sampled African Americans, Mexican Americans, and individuals age 60 or older to improve the estimates for these population subgroups.

For comparison purposes, all samples analyzed used data collected in NHANES 1999–2002 (11,441 participants age 18 or older).

Measurements

Age, gender, race, and ethnicity

Age was defined as the participant's age at the time of the household interview, and grouped as follows: 18–30, 31–45, 46–60, 61–75, and 75+. Race was defined as white, black and other. Ethnicity was defined as Hispanic (including Mexican-American and other Hispanic) and non-Hispanic only.

Education level

Education level was defined as less than high school, high school diploma (including GED), and more than high school.

Insurance

Participants were defined as insured if they answer yes to “covered by health insurance or some other kind of health care plan? (Include health insurance obtained through employment or purchased directly as well as government programs like Medicare and Medicaid that provide medical care or help pay medical bills.)”

Diabetes

To be classified as having self-reported diabetes, participants had to report being told by a doctor, at any time, that they had diabetes or sugar diabetes other than that related to pregnancy. Participants answering “borderline” to the question were classified as non-diabetic.

Hypertension

Self-reported hypertension was identified by a “yes” answer to the question: “Have you ever been told by a doctor that you had hypertension, also called high blood pressure?”

The definitions of measured hypertension by JNC 7 and an elevated measured blood pressure were the same as those used by KEEP. In NHANES 1999–2002, systolic blood pressure (SBP) / diastolic blood pressure (DBP) for each participant was calculated as mean of all measured SBPs / DBPs.

Obesity

BMI definitions were the same as those used in KEEP.

Smoking status

Smokers were identified by an affirmative answer to the question: “Have you smoked at least 100 cigarettes during your entire life?” They were grouped further based on their answers to the question: “Do you smoke cigarettes now?” If the answer was “No,” the participant was classified as an “ex-smoker.” If the answer was “Yes,” the participant was defined as a “current smoker.” In NHANES 1999–2000, information about smoking status is available only for participants age 20 and above. All NHANES comparison analyses, therefore, include only participants age 20 and older.

Cardiovascular disease

Self-reported cardiovascular disease is defined as having at least one of following self-reported diseases: coronary heart disease, angina/angina pectoris, heart attack, congestive heart failure, or stroke.

Anemia

WHO and K/DOQI anemia definitions are the same as those used in KEEP.

Microalbuminuria

Microalbuminuria was defined by the ratio of urinary albumin (mg/l) to urinary creatinine (mg/dl) (ACR). Participants with a valid ACR were classified as having positive microalbuminuria if this value was not less than 30 mg/g.

Elevated blood sugar

- ≥ 126 mg/dl fasting and ≥ 140 mg/dl non-fasting

Chronic kidney disease (CKD)

Glomerular filtration rate (ml/min/1.73 m²) was estimated by the MDRD method based on adjusted creatinine value for both NHANES 1999–2000 and NHANES 2001–2002, separately.

Estimated GFR = $186.3 * (\text{serum creatinine}) - 1.154 * \text{age} - 0.203 * (0.742 \text{ for women}) * (1.21 \text{ if African American})$.

CKD was defined as an eGFR less than 60 ml/min/1.73 m², or an eGFR greater than or equal to 60 and abnormal albumin/creatinine ratio (ACR ≥ 30 mg/g). NHANES CKD stage definitions were the same as those used in KEEP. For Figures 5.32–35 and Table 6.b, CKD status was classified based on eGFR only.

Calibration of serum creatinine in NHANES 2001–2002

The “fudge factor” here is estimated by an indirect method. We assume that the percentage of participants with an eGFR less than 60 ml/min/1.73 m² is the same in NHANES 1999–2000 and NHANES 2001–2002 when age-adjusted to the 2000 census standard population

Statistical analysis

To obtain national estimates of each statistic in these complex sample surveys, odd ratios, sampling weights, and survey design were implemented by SUDAAN (Research Triangle Institute, Research Triangle Park, NC). Standard errors were estimated with use of the Taylor Series Linearization method for NHANES 1999–2002. Standard 2000 U.S. population estimates were used for comparison of age-adjusted statistics. For ages 18 and above, three age groups were used: 18–39, 40–59, and 60+. For ages 20 and older, three age groups were used: 20–39, 40–59, and 60+, as suggested in the 1999–2000 survey’s analytical guideline.

A weighted logistic regression model was used to examine the relationship between anemia (WHO and K/DOQI) and eGFR. Estimated GFR was grouped as 0–59.9, 60–89.9 and 90+ ml/min/1.73 m². Estimated GFR was examined in the model, and adjusted for risk factors of age, gender, history of smoking, self-reported hypertension, and the interaction between race and self-reported diabetes.