D. Post Primary Exam Components

Home Urine Collection

Public Health Significance:
Microalbuminuria, protein excretion in the urine, is an important indicator of early renal disease. Calculation of the urine albumin/creatinine ratio is recommended by the National Kidney Disease Education Program as the diagnostic test to ascertain early chronic kidney disease. Persistent microalbuminuria is a major prognostic indicator for cardiovascular disease and mortality. The purpose of the addition of the Albumin/Creatinine Ratio Urine Collection is to assess persistent microalbuminuria in the U.S. population. This requires the collection of a second urine specimen.

Eligibility:
Sample persons aged six years or older are eligible for the home urine collection.

Protocol:
A urine specimen is currently collected in the Mobile Examination Center on all examined persons 6 years and older. Specimens are sent to a testing laboratory for urine creatinine and albumin measurements. The laboratory reports the results of the urine analysis to NCHS within 21 days of the MEC examination. A urine collection kit is given to participants before they leave the examination center. A technician reviews instructions on how to collect and mail the urine specimen to the testing laboratory. Instructions can be found at the end of this section. Participants are asked to send the sample to a designated laboratory in a pre-addressed, pre-paid box. Once the second urine is received in the laboratory, a second albumin/creatinine ratio is calculated. This result is also provided along with the first albumin/creatinine ratio in the Final Report of Findings.

Risks:
None

Respondent Burden:
It is estimated that the home urine collection will take approximately 10 minutes to complete.

Justification for Using Vulnerable Populations:
Minors are included in this component because they are an important target population group. Laboratory data are linked to other household interview and health component data and are used to track changes that occur in health over time.

Report of Findings:
The albumin/creatinine ratio (ACR) will be calculated from the albumin and creatinine results of the first urine sample collection and reported to the participant. If the ACR is >300 mg/g, an early report will be sent to the participant with recommendation for follow-up. **(Attachment 31 – Early Reporting – Urine Tests)**

Both the first and second ACR (if done) will be reported to the participant in the **Final Report of Findings** – **Attachment 32**.

Physical Activity Monitor Component

Public Health Objectives:

Physical inactivity is an independent risk factor for coronary heart disease. In the United States, a significant percentage of deaths from coronary heart disease, colon cancer, and type 2 diabetes are attributable to sedentary lifestyle. Americans are encouraged to engage in regular physical activity to maintain good health and to lower their risk of health problems. Physical activity guidelines were published in 2008 to provide information and guidance on the types and amounts of physical activity that benefit health.

NHANES data have been used to examine physical activity levels and compliance with physical activity recommendations. Self-reported physical activity information has been collected in all NHANES using questionnaires. The adult questionnaires that have been used since 1999 include questions about physical activity performed as part of work, transportation, household, and leisure-time. A report based on NHANES 1999–2004 examined self-reported physical activity levels of U.S. adults 60 or more years of age. Leisure-time physical activity levels varied by demographic and health characteristics with more than half of adults 60 or more years of age reported no leisure-time physical activities. Overall, 27 percent of older adults achieved leisure-time physical activity levels of 150 minutes or more per week with walking being the most commonly reported leisure-time activity.

Objective measurements of movement using a physical activity monitor, a.k.a accelerometer, were included in NHANES 2003–2006. Accelerometers are motion sensor devices that measure the intensity and duration of body movement as well as the number of steps traveled. NHANES participants six years of age and over were asked to wear a small accelerometer device on a waist belt for seven days. Results from the NHANES 2003–2004 accelerometry component were published in 2007 and gave a different picture of the activity levels of the U.S. population. Adherence to physical activity recommendations based on accelerometer-measured activity was substantially lower than self-reported levels. The accelerometer results showed that large declines in physical activity levels occur across age groups. Among children and adolescents, 42 percent of children 6–11 years met the recommendation to obtain at least an hour

of physical activity on most days of the week whereas only 8 percent of adolescents 12–19 years achieved this goal. Among adults, only 5 percent adhered to recommendations to obtain 30 minutes of moderate physical activity per day.

Protocol:

Methods

The activity monitor is programmed to record data at the MEC. A health technician provides the respondent with a monitor affixed to a wristband that closes around the wrist with Velcro. Respondents are instructed to wear the monitor during normal waking hours for seven days including when sleeping, bathing and swimming. The activity monitors are returned in postage-paid padded envelopes; instructions and a toll-free phone number are provided if other questions or problems arise. A remuneration check for $40 is mailed to each survey participant when the monitor is returned.

Time Allotment:

The time in the mobile examination center to give the participant the monitor and instructions is less than 5 minutes.

Target Sample:
Examined persons six years and older.

Eligibility:
Examined persons six years and older who are able to walk (either assisted or unassisted).

Exclusion Criteria:
Individuals who are missing arms bilaterally will be excluded because it will not be possible to attach the monitor to the participant in the desired location. Survey participants who use a wheelchair exclusively are also excluded from the component.

Justification for Using Vulnerable Populations:
Minors are included in this component because they are an important target population group. There is no reason to exclude mentally impaired or handicapped individuals as long as there is a parent or guardian who can assist the respondent.

Risks:
None

Report of Findings:
No reporting is involved with this component.

Hepatitis C Phone Follow-up Questionnaire

Public Health Objectives:
To determine:

- What proportion of NHANES participants testing positive for infection with hepatitis C virus (HCV) already knew of their infection status;
- What participants know about hepatitis C; and
- Actions taken after becoming aware of their infection status.

Hepatitis C virus (HCV) infection is the most common chronic blood borne infection in the United States. It is estimated to be the cause of 40% to 60% of cases of chronic liver disease and 8,000 to 10,000 deaths annually in the United States. The highest infection incidence occurs in young adults, ages 20 to 39. African-American and Hispanic populations have a higher prevalence of HCV infection than non-Hispanic white populations. Although an estimated 3.2 million Americans have chronic HCV infection, because many are asymptomatic, it is likely that few are aware of their infection status. However, with increasing publicity regarding HCV infection through CDC, other health agencies, advocacy groups, and the media, as well as educational efforts targeting health professionals, it is hoped that more people with known risk factors will be identified and be offered HCV counseling and testing. Information collected may be used to guide allocation of public health resources, policy development, and development of education efforts for prevention and control of HCV infection and related chronic disease

NHANES is the only population-based study from which prevalence data are available on HCV infection. This study provides a unique opportunity to follow up persons receiving test results to see whether health messages are reaching those that need to know. No such population-based follow-up study on participants with HCV infection has been done before. In addition, no such study has been done for a specific group of persons testing positive for a chronic blood born infectious disease of the public health magnitude of HCV infection. Health resources, both private and public, are currently being challenged, and this survey could provide important data to help guide allocation of public health resources, policy development, and development of education efforts for prevention and control of HCV infection and related chronic disease.

Staff:
Trained interviewers

Protocol:
The hepatitis C follow-up study is mentioned in the NHANES informed consent brochure and in the notification letter for hepatitis C. Trained interviewers contact participants with positive hepatitis C test results by telephone for an interview six months after the examination. In order to determine what actions persons take with the information that they are infected (and for many, the NHANES test is expected to be the first time they are tested for, and determined to be infected with, HCV), it is necessary to allow time to have initiated or implemented such actions after notification of infection. Thus, a telephone survey for this purpose would need to occur at least a few months after notification. The questionnaire can be found in **Instruments – Hep C Follow-up**. A system for managing the calls, i.e., setting up appointments, tracking the calls to contact the participant, and reasons for refusal, is maintained in the Field Follow-up Management System (FFMS). Responses to interview questions are keyed directly into the FFMS, a web based application of the Integrated Survey Information System (ISIS) software used for all NHANES data collection. Parents or guardians are interviewed for participants with hepatitis C who are under the age of 18 years or adults who cannot respond for themselves. Interviewers are trained to answer questions about hepatitis C, should participants want more information. The Hep C follow-up study has been in the field since January 2001.

Participants with positive hepatitis C results who live in households with no telephones (or disconnected/non-working telephones) will be sent an additional letter (**Attachment 49 – Hep C Follow-up Reminder Letter**) asking them to call a toll free number to answer a few questions about their test results.

Time Allotment:
20 minutes

Eligibility:
NHANES participants six years of age and older testing positive for antibody to hepatitis C virus (anti-HCV).

Exclusion Criteria:

Circumstances when communication or cognitive difficulties make it impossible for the participant to respond to questionnaire and a parent or guardian is not available to complete the interview would result in exclusion.

Justification for Using Vulnerable Populations:
Minors under age 18 are included in the questionnaire because there is no contraindication. There is no reason to exclude mentally impaired or handicapped individuals because there is no contraindication.

Risks:
There is no greater than minimal risk associated with this component.

Report of Findings:
No findings are reported to respondents.