National Health and Nutrition Examination Survey

OMB No. 0920-0237
(Expires November 30, 2009)

Change to Conduct Pilot Testing on New NHANES 2009-10 Content

Contact Information

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Supporting Statement (Change)
National Health and Nutrition Examination Survey (0920-0237)

This is a request for a non-substantive change to the approval of the National Health and Nutrition Examination Survey (NHANES) (OMB No. 0920-0237, exp. November 30, 2009), conducted by the National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention, to conduct methodological studies and pilot tests for content planned for the 2009-10 NHANES. Burden for these projects has already been approved; thus, no change to the burden is requested.

The NHANES Conditions of Approval stated the following: "With respect to conducting any pilot or nonresponse studies, OMB should be provided with a formal request that describes the specific study design, need for the information, and response burden. OMB will respond within three weeks indicating approval, disapproval, or passback exchanges seeking further information. No pilot or nonresponse studies should be conducted without receipt of approval from OMB."

The methodological studies planned include the following:

1) Pilot tests of 2009 Examination Center Components
   a) Urinary flow rate (ages 6+)
   b) Oral Human Papillomavirus (ages 14+)

2) Post examination data collection
   a) Urine specimen collection pilot (ages 6+)

A. Justification

1. Circumstances Making the Collection of Information Necessary.

In section B, page 57 of the approved supporting statement we said the following about these methodological studies under the subheading 'Pilot Testing for 2009-2010'.
"All pilot/feasibility testing must be concurrent to the ongoing data collection within the framework of the survey." DHANES started piloting and developing methods for NHANES 2009-10 in the spring of 2007 and proposes to continue pilot testing in 2008.

2. Purpose and Use of the Information Collection

The purposes and uses of each methodological/pilot study are detailed below.

a. Pilot test of 2009 Examination Center Components

All pilot tests will include only NHANES participants.

i. Urinary Flow Rate Pilot (ages 6+)

The NHANES protocol includes many measures of environmental toxicants or their metabolites in urine. It is difficult to quantify the level of exposure based on measurements in urine because concentrations will vary by the amount of urine produced. Currently, NHANES urine measurements are adjusted by the urinary creatinine concentration to account for variations in urinary dilution. However, creatinine excretion into the urine varies by many factors other than the urinary dilution (e.g., age, gender, muscle mass and diet). Also, information on the amount of toxicant excreted in a 24 hour period is often needed to quantify exposures for risk and exposure assessment purposes. Ideally, this requires 24 hour urine collections, but this is impractical in NHANES for logistical reasons. However, it is possible to estimate the mass of analyte excreted in the urine in a 24 hour period by estimating the urine flow from the urine specimen collection.

In past NHANES, we obtained a mid-stream collection. Now we will collect a full void. The protocol for the urinary flow rate pilot study is provided in Attachment A.

ii. Oral Human Papillomavirus (ages 14+)

Head and neck squamous cell carcinoma (HNSCC) is a major cause of morbidity and mortality worldwide, with over 560,000 new cancers diagnosed annually. In 2007, 42,000 Americans were diagnosed with HNSCC.

HNSCCs are etiologically heterogeneous, with one major subset attributable to tobacco, alcohol use and poor oral hygiene and another to oral, high-risk, human papillomavirus (HPV) infection. Despite the strong and consistent association between oral HPV infection and a type of HNSCC that has nearly doubled in incidence in the US over the last 30 years, very little is known about the epidemiology of oral HPV infection in the U.S. population or in any other population worldwide.

The purpose of this component is to perform the first population-based study of oral HPV infection to determine the prevalence and type distribution of infection and to investigate the demographic and behavioral factors associated with infection.

The protocol for the oral HPV component is provided in Attachment B.

b. Post examination data collection

iii. Urine specimen collection pilot (ages 6+)

Chronic kidney disease (CKD) is a serious condition associated with premature mortality, decreased quality of life, and increased health-care expenditures. Untreated CKD can result in end-stage renal disease and necessitate dialysis or kidney transplantation. Risk factors for CKD include cardiovascular disease, diabetes, hypertension, and obesity. Persistent albuminuria is used to determine kidney damage for categorizing persons as having stage 1 and stage 2 CKD. Two urine samples are needed to assess persistent albuminuria and confirm the presence of kidney damage.

The protocol for post-examination urine collection on a subset of examined persons whose first urinalysis results were indicative of CKD is provided in Attachment C.

9. Explanation of any payment or gift to respondents.

The examination center pilot tests will not involve any additional remuneration to the NHANES participants.

Post examination urine specimen: Participants will be paid twenty dollars. This will be mailed to participants after the urine sample is collected at home and participants have mailed the specimens directly to the laboratory.

12. Estimates of Annualized Burden Hours and Cost.

Burden category	Number of respondents for four weeks	Number of responses per respondent	Average burden per response (hours)	Total respondent burden (hours)
7. Follow-up and Special Studies				
Urinary Flow Rate	360	1	1/60	6
Oral HPV	250	1	2.5/60	10
Second (post examination) Urine Collection	116	1	10/60	19
				35

Pilot tests of 2009-10 Examination Content Components

Three attachments are provided describing the details of the studies.

The Urinary Flow Rate pilot has been budgeted for 1 minute. We will pilot test for four weeks, at one NHANES PSU. The maximum number of respondents would be 360 (ages 6+) and the maximum burden 6.0 hours (360 respondents *1/60 hour = 6 hours).

The Oral Human Papillomavirus pilot has been budgeted for 2.5 minutes. We will pilot test at one NHANES PSU. The maximum number of respondents would be 250 (ages 14+) and the maximum burden 10.4 hours (250 respondents*(2.5/60 hour) = 10 hours).

The Second Urine Collection pilot has been budgeted for 10 minutes. We will pilot test at one NHANES survey location. The maximum number of respondents would be 116 (ages 6+) and the maximum burden 19 hours (116 respondents*(10/60 hour) = 19 hours).

The total burden is 35 hours. This time was already budgeted and approved in line 7. Follow-up and Special Studies, of the original submission. No additional burden is sought.

15. Explanation for Program Changes and Adjustments. There are no changes in this package from the previous-approved clearance. The burden hours were approved by OMB in the full clearance.

List of attachments:
A. Oral health examination protocol
B. Urinary flow rate protocol
C. Second (post examination) urine specimen collection protocol