Generic Clearance
National Health and Nutrition Examination Survey

OMB No. 0920-0237
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Thai Fluorosis Methodology Pilot Study in NHANES

Contact Information

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This is a request for a non-substantive/generic change to the approval of the National Health and Nutrition Examination Survey (NHANES) (OMB No. 0920-0237, exp. December 31, 2011), 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 2011-12 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 studies should be conducted without receipt of approval from OMB."

The methodological study planned is a study of fluorosis collection methodology on respondents 9 to 15 years and older. The study will take place in Chiang Mai, Thailand. There is no change to burden.

A. Justification

1. Circumstances Making the Collection of Information Necessary.

NHANES is a continuous survey, meaning survey data are collected every year. A major advantage of continuous NHANES data collection is the ability to address emerging public health issues and provide objective data on more health conditions and issues. Because of the NHANES sample design, data are released in two year cycles. Some of the survey information gathered may change at the beginning of each two year cycle. In some cases, this means new content will be added. In other cases, this means that existing content may be modified.

New methodology must be tested, before being implemented. There are many reasons for this. This allows us to find out how long the procedure being tested will take or how well received the procedure will be among our participants. The results of such testing also allow the NHANES program to make changes or adjustments to improve the methodology. It also provides hands on training opportunities for NHANES survey staff responsible for collecting the data. Testing is a vital step in making sure NHANES is effective and efficient in its use of resources. Such measures promote improved data quality once the data is collected in an actual survey.

The 2009 Thai Fluorosis Study is sponsored by the following organizations:

- The National Institutes of Health (NIH) / National Institute for Dental and Craniofacial Research (NIDCR);
- The Centers for Disease Control and Prevention (CDC) / National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) / Division of Oral Health (DOH); and

- The CDC / National Center for Health Statistics (NCHS).

This protocol was developed by NIDCR, DOH and the NCHS. A portion of this study was developed in collaboration with oral health researchers from the University of Manchester Dental School, United Kingdom and the University of Chiang Mai Dental School, Thailand. Conducting this project in conjunction with an existing survey vehicle is more efficient than designing and launching entirely new special study here in the United States.

2. Purpose and Use of the Information Collection

The purposes and uses of this methodological study are detailed below. All tests will include only children aged 9 to 15 years. No identifying information is being collected. Participation is voluntary.

The NHANES program routinely assesses new methods for collecting biomedical data in the household and the mobile examination center. New methods ensure that NHANES continues to establish national standards in health measure data collection. The purpose of this pilot study is to assess the validity of using a quantitative light-induced fluorescence (QLF) imaging device to detect dental fluorosis when measured by the US clinical standard called the Dean's Index assessment. If the study in Thailand shows this method has validity, then a pilot study would also be conducted in the United States. If the U.S. pilot study is successful, then this methodology could be introduced in a future NHANES.

Community water fluoridation has been identified as one of the 10 most significant public health achievements in the United States in the past century. Water fluoridation is a key disease prevention activity for CDC, in particular at the program service levels through interaction with the states. The addition of 0.7mg/L to 1.0 mg/L of fluoride to public drinking water has been proven to be a safe and cost effective dental public health measure. Fluorosis is a recognized side effect of excessive fluoride in the drinking water. It is a condition that affects the dental enamel, resulting in mild, white striations in its mildest form, through to brown pitting or even complete loss of the enamel in its most severe. It has been shown that there is a relationship between water fluoride concentration and the extent of fluorosis. Even at optimal and suboptimal levels of water fluoride concentration, mild fluorosis may occur. The concern for severe Fluorosis is at 4.0mg/L or greater of fluoride added to drinking water. Consequently, CDC has a vested interest in exploring and developing cost effective surveillance measures for dental fluorosis as part of an overall strategy to balance continual caries reduction measures using fluoride in other delivery vehicles such as school rinse programs, fluoridated toothpaste, etc. and the recommended levels of fluoride additive to public drinking water systems in the United States while minimizing the prevalence of dental fluorosis in the US population. There have been two national dental fluorosis exams conducted in the United States: the NIDCR 1986-87 national survey on school children's dental health and NHANES 1999-2004.

A summary of the protocol for the THAI Flurosis Methodology Study Mobile Examination

Center Component is provided in Attachment A.

9. Explanation of any payment or gift to respondents.

In addition to the dental fluorosis exam, study participants will receive a complimentary, simplified dental screening consisting of cursory visual exam of the mouth. This exam is designed to assess the general condition of the mouth and to provide basic information to parents/guardians regarding the oral health of their children. Study participants will also receive a small book bag as a token of appreciation for participating in this study.

12. Estimates of Annualized Burden Hours and Cost.

Burden category	Number of respondents for five days	Number of responses per respondent	Average burden per response (hours)	Total respondent burden (hours)
Follow-up and Special Studies				
THAI_fluorosis study	150	1	15/60	38
				38

THAI Fluorosis Methodology Studies

The Thai fluorosis methodology study has been budgeted for 12-15 minutes. We will test for a total of five days. The maximum number of respondents would be 150 (aged 9-15 years) and the maximum burden 38 hours (150 respondents *15/60 hour = 38 hours).

The total burden is 38 hours. This time was already budgeted and approved in table above (Follow-up and Special Studies). No additional burden is sought.

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

List of attachments:

A. Protocol for THAI Fluorosis Methodology Study