

**National Health and Nutrition Examination Survey
(NHANES) Oral Health Component**

2007—Periodontal Feasibility Study

Procedures and Protocols

Field Operation: April-June 2007

| <u>Table of Contents</u> | <u>Page</u> |
|--|--------------------|
| Overview to the Periodontal Examination Pilot | |
| 1.0 Introduction | 3 |
| 1.1 Goals | 3 |
| 1.2 Background and Rationale | 3 |
| 1.3 Preliminary Studies | 5 |
| 1.4 Specific Aims | 6 |
| 1.5 Significance | 7 |
| Overview of Data Collection and Selection of Volunteers | |
| 2.0 Selection of Volunteers | 8 |
| 2.1 Conducting the Pilot | 8 |
| 2.2 Eligibility Criteria | 8 |
| 2.3 Telephone Interview | 9 |
| 2.4 Mobile Examination Center | 9 |
| 2.5 Pre-examination Procedures | 9 |
| 2.6 Recruitment | 10 |
| 2.7 Staff | 10 |
| Self-reported Questionnaire | |
| 3.0 Background | 12 |
| Periodontal Question Set “A” | 12 |
| Periodontal Question Set “B” | 13 |
| 3.1 Telephone and Interview Procedures | 14 |
| 3.2 MEC Interview Procedures | 19 |
| 3.3 Recruitment / Screening Scripts | 22 |
| 3.3 Scoring Codes | 23 |
| Periodontal Examination | |
| 4.0 Description | 24 |
| 4.1 Examination Procedures | 24 |
| 4.2 Guidelines for Scoring | 26 |
| 4.3 Recording Procedures | 27 |
| 4.4 Post-Examination Procedures | 27 |
| 4.5 Examination Screen Shot | 28 |
| Report of Findings | |
| 5.0 Description | 29 |
| 5.1 Recommendation of Care | 29 |

Quality Control

| | |
|------------------------|-----------|
| 6.0 Description | 31 |
| 6.1 Training | 31 |
| 6.2 Evaluation | 31 |

Data Warehousing and Analytical Plan

| | |
|-----------------------------|-----------|
| 7.0 Data Warehousing | 32 |
| 7.1 Analytical Plan | 32 |

| | |
|-------------------|-----------|
| References | 36 |
|-------------------|-----------|

| | |
|-------------------|-----------|
| Appendices | 38 |
|-------------------|-----------|

OVERVIEW TO THE PERIODONTAL EXAMINATION PILOT

1.0 Introduction

This Periodontal Examination Pilot is sponsored by the following organizations:

- 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 Periodontal Examination Pilot was developed by the DOH and the NCHS.

1.1 Goals

There are two goals of this proposed pilot study. The first goal is to assess the validity of the questionnaire items by determining the extent to which the items provide an accurate basis for estimating prevalence of clinically-measured periodontitis. This assessment of validity will be conducted by statistical analysis of the data collected during the pilot study. The second goal is to assess the operational attributes of a new clinical periodontal assessment module and the feasibility for use in larger population based studies. Both of these goals will contribute to a long term objective of estimating prevalence of periodontal disease in the U.S. population by using self-report measures.

1.2 Background and Rationale

Gingivitis and periodontitis, the two most prevalent forms of periodontal diseases, are common chronic diseases in the U.S. population. In some cases, gingivitis, when untreated, can progress to periodontitis in susceptible individuals. Severe periodontitis is a major cause of tooth loss that results in diminished oral function and quality of life in adults. A growing body of evidence now supports important associations between periodontitis and several systemic diseases or conditions (USDHHS 2000; Eke, 2005), including coronary heart disease, cerebral vascular disease, and peripheral arterial disease (Offenbacher et al., 2005; Paquette, 2004; Beck and Offenbacher, 2001; Joshipura et al., 2003); adverse pregnancy outcomes (Scannapieco et al., 2003; Offenbacher, 2005); glycemic control in diabetes (Taylor, 2003); and pneumonia in older adults (Terpenning et al., 2001; Yoneyama et al., 2002). The importance of periodontitis to public health was highlighted in the 2004 Surgeon General's

Report on the health consequences of smoking, in which periodontitis was one of nine conditions reported to be caused by smoking that were not previously causally linked with smoking (USDHHS 2000). Additionally, there is emerging evidence to support an association between periodontitis and biomarkers considered risk factors for several systemic diseases/conditions now recognized to have an inflammatory component to their pathogenesis (Offenbacher et al., 2005; Joshipura et al., 2004, Slade, 2003)). It is well recognized that almost all cases of gingivitis and very large proportion of cases of periodontitis can be treated and maintained with routine professional and self oral care; hence, it is possible to reduce the prevalence of gingivitis and active periodontitis and their sequelae.

The importance of assessing periodontal health in the U.S. adult population is well recognized as an objective for *Healthy People 2010* (Objective 21-5). Historically, clinical periodontal examination has been included in National Health and Nutrition Examination Survey (NHANES) for the past four decades and in the National Institute for Dental Research (NIDR) survey of employee adults and seniors. However, starting in 2005, periodontal examinations are no longer included in NHANES. The major impediments to surveillance of periodontal diseases are the cost and other resources required to collect clinical data which are the “reference” standard for determining periodontal diseases prevalence. The intensity of resources required to conduct thorough clinical periodontal examinations also is recognized by NHANES and reflected in its previous protocol used through 2004 to perform random half-mouth periodontal examinations (rather than full mouth examinations) and to limit the examination to probing 2 or 3 sites per tooth for gingival bleeding, pocket depth, and attachment level.

The prevalence and severity of periodontal diseases, and the growing body of evidence associating periodontal diseases with other systemic diseases and conditions supports the need for continued surveillance of periodontal disease. The lack of surveillance for periodontal diseases will threaten our capacity for developing public health policy, identifying target groups, developing intervention, and evaluating programs for effectiveness. Maintaining continued

surveillance of periodontal disease requires development and evaluation of alternative, inexpensive, valid, and reliable ways to conduct surveillance of periodontal health in U.S. populations at the national, state, and local levels. Therefore, achieving the goals of this project will improve the repertoire of methods for periodontal surveillance.

1.3 Preliminary studies

For the past three years, a workgroup convened by the Centers for Disease Control and Prevention and in collaboration with the American Academy of Periodontology (CDC-AAP) has been working on alternative methods for monitoring periodontitis within the US population. The workgroup has generated five principal findings that provide the bases for this proposed pilot study.

- (1) A review of published studies suggested, contrary to prevailing belief, that some self-report and history of periodontitis may be valid predictors of clinically-assessed periodontitis.
- (2) Cutoff points were agreed upon for probing depth and attachment loss to permit calculation of prevalence of moderate and severe periodontitis in populations using standard clinical measurements made at multiple sites on all examined teeth.
- (3) Re-analyses of existing data selected six candidate questions that achieved promising levels of validity in predicting prevalence of periodontitis, particularly when responses to those questions were combined with information about demographics and health history that is usually collected in health interview surveys.
- (4) Field testing of the panel's selected set of questions was undertaken in the Australian National Survey of Adult Oral Health where examination methods were similar to those used in NHANES oral assessments. Interim results suggest that six screening questions and five conventional risk indicators can be used readily in large population surveys, yielding useful levels of validity in predicting prevalence of periodontitis.
- (5) Cognitive testing of the six screening questions within a small group of US adults led to recommendations for changes in phrasing, hence

creating an alternative set of screening questions that have yet to be evaluated for validity.

Taken together, the evidence from these preliminary studies provides good grounds to believe that periodontitis can be measured with sufficient accuracy for population surveillance through health interview surveys where no clinical examinations are conducted. However, there are two critical additional steps that need to be undertaken to achieve that goal and which warrant this proposed pilot study. First, the validity of the screening questions tested so far and of the alternative set of questions needs to be investigated within a group of US adults. Second, the methods used in studies reviewed by the panel and in the Australian field test need to be evaluated for feasibility of use within NHANES. The intention is to demonstrate both feasibility and validity in this pilot study, furnishing evidence needed to implement the new questions and examination procedures in NHANES 2009/10.

1.4 Specific Aims

There are five specific aims for this project.

- (1) To determine if there is a difference in the accuracy of two sets of self-reported questions that have been developed to predict levels of periodontitis. "Accuracy" will be measured as the degree to which each person's questionnaire responses is in concordance with clinical periodontal assessment of the same person.
- (2) To determine if the best set of self-report questions has sufficient validity for use in population surveys. "Sufficient" accuracy will be judged by comparing the same measure of concordance assessed in aim 1 with benchmark levels of concordance observed for other self-reported health conditions such as diabetes and obesity.
- (3) To determine if rates of non-response to these questions differ among three racial/ethnic groups: whites, African Americans and hispanics. "Non-response" will be defined as questions that are not answered or where the person replies "don't know".

(4) To determine if clinical recording of information from a reduced number of teeth and/or tooth sites yields valid estimate of periodontitis. "Validity" will be measured as the extent to which disease prevalence measured using a subset of teeth and/or sites is equivalent to disease prevalence measured using all sites on all available teeth.

(5) To assess the logistics aspects of conducting the pilot study in order to answer questions related to the operational feasibility of conducting an expanded periodontal examination within the NHANES 2009-10 examinations if this pilot is successful.

1.5 Significance

If these questions prove accurate in assessing clinical disease, our long-term goal is to use these questions in a surveillance system that is capable of generating estimates for periodontal disease at the national, state and local levels where clinical periodontal examinations are not feasible. Achieving these aims also could be valuable for etiologic and other epidemiological studies relating periodontal and systemic health. In addition, these questions could be an important screening tool for health professionals to screen individuals at high risk for periodontal diseases and their sequelae. Achievement of the stated aims will lay important groundwork in preparation for incorporating the tested questions in the full NHANES survey for 2009—2010.

OVERVIEW OF DATA COLLECTION AND SELECTION OF VOLUNTEERS

2.0 Selection of Volunteers

A convenience sample of subjects will be selected from among people living in and around the Washington DC area. Because the intention is to test feasibility and validity, it is not critical to use a representative sample. Furthermore the costs of such a sampling method would be prohibitive. For those reasons, this pilot study will select volunteers who respond to advertisements. They will be selected using a quota sampling method to yield a target of 218 whites, 109 African Americans and 109 Hispanics. These numbers are the minimal sample size calculated for this study.

This study is limited to the three most numerous racial/ethnicity groups within the US population: whites, African Americans and Hispanics. Other racial/ethnic groups will not be recruited. This decision was made to insure that sufficient numbers of these three groups are recruited to permit analysis of study aim 3. Funding for this pilot study did not permit recruitment of similar numbers of additional racial/ethnic groups. However, all of the methods described in this proposal are intended for use among all racial/ethnic groups in the US population. Consequently, if this pilot study proves successful, it is intended that all racial/ethnic groups be included in the next, large-scale study in NHANES 09-10.

2.1 Conducting the Pilot

The telephone interview and examination components of the Pilot will be conducted in Montgomery County, Maryland. A NHANES community Mobile Examination Center (mini-MEC) will be used for the periodontal clinical examination component. Direct data entry will be done using a stand-alone application to the NHANES Integrated Survey and Information System (ISIS).

2.2 Eligibility Criteria

- People 35 years of age or older

- Presence of one or more natural teeth
- Races/Ethnic Groups: Hispanic (109 needed), African American (109 needed), White (218 needed)
- Willingness to have dental examination and answer questions about oral health status

2.3 Telephone Interview

The first introduction to the study for potential participants will be with Westat telephone interviewers. In summary, the telephone interviewers will:

- (1) Provide information about the study to callers
- (2) Answer questions about the study
- (3) Assess eligibility and history of antibiotic prophylaxis
- (4) Obtain contact information
- (5) Ask a series of periodontal questions (Set A questions)
- (6) Ask 4 questions (sex, education level, diabetes status, smoking status)
- (7) Schedule examination appointment

Full details are provided in Section 3.

2.4 Mobile Examination Center

Project staff will obtain informed consent and interviewer will ask an additional series of periodontal Questions (Set B questions). Details are provided in Section 3. Periodontal Examination will be conducted by a licensed dentist with experience in survey research. Details are provided in Section 4.

2.5 Pre-examination Procedures

All prescribed procedures as outlined in the *NHANES Dental Examiners Procedures Manual* will be followed unless otherwise noted. The dental examiner will explain the Pilot process to the volunteer in his/her own words and will include the following facts:

- This Pilot dental exam and questionnaire is a test to determine the feasibility of introducing these new items to the regular Oral Health Exam in NHANES
- Numbers and letters may be mentioned by the examiner that only has meaning for this research project.
- Any questions that the SP may have will be answered after the Pilot assessment and questionnaire is completed.

2.6 Recruitment

Advertisements will be placed by Westat (NCHS contractor for this study) in media and at venues that have proven successful for recruitment of other convenience samples in the Washington DC area. Advertisements will be published in English and Spanish, and they will be targeted to areas and community groups to achieve the target ratio of racial/ethnic groups.

All participants will be recruited from Washington, DC metropolitan area, primarily from Montgomery County, Maryland. Advertisements will be placed in the following media outlets WesInfo, Montgomery County Gazette, and outreach will be conducted with local organizations such as churches, etc. to maximize the study's selection criteria. The advertisement script to be used is:

“The National Health and Nutrition Examination Survey (NHANES) is seeking volunteers to participate in an oral health periodontal examination study. The study will consist of a short health questionnaire and a full periodontal examination conducted by a dentist. The exam sessions will be held in Rockville, MD from Wednesday to Saturday in the mornings and late afternoons during the month of May. Participants will be asked for 1 hour of their time and will receive \$50 for their effort. Those interested must be 35 years of age or older, have natural teeth, not have had any of the following conditions: congenital heart murmurs, bacterial endocarditis, rheumatic fever; and meet additional examination criteria. If you are interested please contact (TBD) at (TBD).”

2.7 Staff

The NHANES oral health reference examiner (a licensed dentist) will conduct the periodontal examination. Additional staff include Westat permanent and temporary staff to recruit volunteers, administer the screening and telephone

interview, to provide volunteer coordination, to conduct the MEC interview, and provide information technology and computer support.

SELF-REPORTED QUESTIONNAIRE

3.0 Background

Two sets of periodontal questions will be evaluated in this pilot study, Set A and Set B. Set A are questions initially identified as most promising in predicting periodontal disease based on analysis of various datasets. Set A questions were field tested in the Australian National Survey of Adult Oral Health. Set B questions were modified from the Set A questions based on changes recommended (by the NCHS Cognitive Testing Lab) after cognitive testing of Set A questions in U.S. subjects. Set A questions were evaluated in English and Spanish. The Spanish translation of the periodontal questions are in Appendix 3-1.

Set A Questions to be administered by telephone interview

Preamble: A common problem with the mouth is gum disease. By gum disease we mean any kind of problem with the gums around your teeth that lasts for at least two weeks – except for problems caused by injury or problems caused by partials or dentures.

1. Do you think you have gum disease?

Yes/No/Refused/DK

2. Has a dental professional ever told you that you have lost bone around your teeth?

Yes/No/Refused/DK

3. Have you ever had scaling, root planing, surgery or other treatment for gum disease?

Yes/No/Refused/DK

4. Have you ever had any teeth that have become loose by themselves without some injury (not baby teeth)?

Yes/No/Refused/DK

5. How often during the last seven days did you use mouthwash or any dental rinse product?

[number of days]

6. How often during the last seven days did you use dental floss, tape or interdental brush to clean between your teeth, other than just to remove food particles stuck between your teeth?

[number of days]

7. How would you rate the health of your gums?

Excellent/Very good/Good/Fair/Poor

8. During the past three months, have you noticed that you have a tooth that does not look right?

Yes/No/Refused/DK

Set B Questions to be administered at Mobile Examination Center

Preamble: Gum disease is a common problem with the mouth. People with gum disease might have swollen gums, receding gums, sore or infected gums or loose teeth.

1. Do you think you might have gum disease?

Yes/No/Refused/DK

2. Overall, how would you rate the health of your teeth and gums?

Excellent/Very good/Good/Fair/Poor/Refused/DK

3. Have ever had treatment for gum disease such as scaling and root planning, sometimes called “deep cleaning?”

Yes/No/Refused/DK

4. Have you ever had any teeth become loose on their own, without an injury?

Yes/No/Refused/DK

5. Have you ever been told by a dental professional that you lost bone around your teeth?
Yes/No/Refused/DK

6. During the past three months, have you noticed a tooth that doesn't look right?
Yes/No/Refused/DK

7. Aside from brushing your teeth with a toothbrush, in the last seven days, how many times did you use dental floss or any other device to clean between your teeth?
[number of days]

8. Aside from brushing your teeth with a toothbrush, in the last seven days, how many times did you use mouthwash or other dental rinse product that you use to treat dental disease or dental problems?
[number of days]

3.1 Screening and Telephone Interview Procedures

Questionnaire Set A will be administered on the phone during the screening by an interviewer following the determination of eligibility for the volunteer. The interviewer will read the questions to the volunteer and record the appropriate responses. The sequence of periodontal questions will be as listed above in Section 3.0 and will conclude the telephone interview session. The overall sequence of questions are:

Screening and related study Questions from NHANES

1. **What is your age?**
Variable Name: RIDAGEYR
__ __=Code age in years
7-Refused
[If <35 years, NOT eligible and END]

2. **Do you consider yourself to be Hispanic or Latino?**

YES 1
NO 2
DK 9
RF 7

3. **What race do you consider yourself to be? Please select one or more.**

CHECK ALL THAT APPLY.

AMERICAN INDIAN OR ALASKAN NATIVE 1
ASIAN 2
BLACK OR AFRICAN AMERICAN 3
NATIVE HAWAIIAN OR PACIFIC ISLANDER 4
WHITE 5
OTHER 6
DK 9
RF 7

4. **NHANES 2003-04 Medical Exclusion Questions**

OHQ010. Has the doctor or dentist ever told you that you must take antibiotics (e.g. penicillin) before you get a dental check up or care?

1 = yes
2 = no

“I am going to read you a list of health conditions that some people have. As I read off each condition, please tell me whether or not a doctor has ever told you that you have the condition. Has a doctor ever told you that you have:”

OHQ020. A heart problem?

1 = yes
2 = no (go to OHQ070)

Was the heart problem due to:

OHQ030. Congenital heart murmurs?

1 = yes
2 = no

OHQ040. A heart valve problem?

1 = yes
2 = no

OHQ050. Congenital heart disease?

1 = yes

2 = no

OHQ060. Bacterial endocarditis?

1 = yes

2 = no

Has a doctor ever told you that you have:

OHQ070. Rheumatic fever?

1 = yes

2 = no

OHQ080. Kidney disease requiring renal dialysis?

1 = yes

2 = no

OHQ100. A pacemaker or other artificial material in your heart, veins, or arteries?

1 = yes

2 = no

OHQ110. A hip bone or joint replacement?

1 = yes

2 = no

[For this section, if YES to any question EXCEPT OHQ020 then NOT eligible and END]

The volunteer is eligible and the Interviewer reads the following script:
“Before we continue, I’d like you to know that taking part in this research is voluntary. You may choose not to answer any questions you don’t want to answer and you may choose to end the interview at any time. We are required by Federal law to keep your answers to government studies strictly confidential. I can describe these laws if you want. They guarantee that your answers will be used only for statistical research. I’d like to continue now unless you have any questions.”

5. **Indicate sex of respondent.**

Variable Name: RIAGENDR

1=Male

2=Female

6. **What is the highest grade or year of school you completed?**

Variable Name: DMDEDUC

1=Less than High School

2=High School Diploma (including GED)

3=More than High School
7=Refused
9=Don't Know

7. **Have you smoked at least 100 cigarettes in your entire life?**

Variable Name: SMQ020

1=Yes
2=No
7= Refused
9=Don't Know

8. **Do you now smoke cigarettes . . .**

Variable Name: SMQ040

1=every day
2=some days
3=not al all
7=Refused
9=Don't know

9. **{Other than during pregnancy,} have you ever been told by a doctor or other health professional that you have diabetes or sugar diabetes?**

Variable Name: DIQ010

1=Yes
2=No
3=Borderline or PreDiabetes
7=Refused
9=Don't know

10. **Are you now taking insulin?**

Variable Name: DIQ050

1=Yes
2=No
7=Refused
9=Don't Know

11. **Are you now taking diabetic pills to lower your blood sugar? These are sometimes called oral agents or oral hypoglycemic agents.**

Variable name: DIQ070

1=Yes
2=No
7=Refused
9=Don't Know

12. **Set "A" Periodontal Questions**

"A common problem with the mouth is gum disease. By gum disease we mean any kind of problem with the gums around your teeth that lasts for at least two weeks – except for problems caused by injury or problems caused by partials or dentures."

PA1: Do you think you have gum disease?

- 1=Yes
- 2=No
- 7=Refused
- 9=Don't Know

PA2: Has a dental professional ever told you that you have lost bone around your teeth?

- 1=Yes
- 2=No
- 7=Refused
- 9=Don't Know

PA3: Have you ever had scaling, root planing, surgery or other treatment for gum disease?

- 1=Yes
- 2=No
- 7=Refused
- 9=Don't Know

PA4: Have you ever had any teeth that have become loose by themselves without some injury (not baby teeth)?

- 1=Yes
- 2=No
- 7=Refused
- 9=Don't Know

PA5: How often during the last seven days did you use mouthwash or any dental rinse product?

- ___: Number of days
- 77=Refused

PA6: How often during the last seven days did you use dental floss, tape or interdental brush to clean between your teeth, other than just to remove food particles stuck between your teeth?

- ___: Number of days
- 77=Refused

PA7: How would you rate the health of your gums?

- 1=Excellent
- 2=Very good
- 3=Good
- 4=Fair
- 5=Poor
- 7=Refused
- 9=Don't Know

PA8: During the past three months, have you noticed that you have a tooth that

does not look right?

1=Yes

2=No

7=Refused

9=Don't Know

3.2 MEC Interview Procedures

Periodontal Questionnaire Set B will be administered by an interviewer before the volunteer undergoes the periodontal examination. The interviewer will read the questions to the volunteer and record the appropriate responses. The sequence of periodontal questions (listed above in Section 3.0) is:

1. Confirm participant's name and age

2. Set "B" Periodontal Questions

"Gum disease is a common problem with the mouth. People with gum disease might have swollen gums, receding gums, sore or infected gums or loose teeth."

PB1: Do you think you might have gum disease?

1=Yes

2=No

7=Refused

9=Don't Know

PB2: Overall, how would you rate the health of your teeth and gums?

1=Excellent

2=Very good

3=Good

4=Fair

5=Poor

7=Refused

9=Don't Know

PB3: Have you ever had treatment for gum disease such as scaling and root planning, sometimes called "deep cleaning?"

1=Yes

2=No

7=Refused

9=Don't Know

PB4: Have you ever had any teeth become loose on their own, without an injury?

1=Yes

2=No

7=Refused

9=Don't Know

PB5: Have you ever been told by a dental professional that you lost bone around your teeth?

1=Yes
2=No
7=Refused
9=Don't Know

PB6: During the past three months, have you noticed a tooth that doesn't look right?

1=Yes
2=No
7=Refused
9=Don't Know

PB7: Aside from brushing your teeth with a toothbrush, in the last seven days, how many times did you use dental floss or any other device to clean between your teeth?

___: Number of days
77=Refused

PB8: Aside from brushing your teeth with a toothbrush, in the last seven days, how many times did you use mouthwash or other dental rinse product that you use to treat dental disease or dental problems?

___: Number of days
77=Refused

3.3 Recruitment / screening scripts

When a volunteer calls in response to a recruitment advertisement, the interviewer will initiate conversation and administer the screening questions as follows:

“Hello, thanks for calling the NHANES oral health study recruitment line. We are recruiting volunteers to participate in the oral health study. The study will help us determine the prevalence of periodontitis as well as validate a health questionnaire. The study will consist of a short questionnaire followed by a full periodontal examination conducted by a dentist. You will be compensated \$50 for about 1 hour of your time. Before I go on, I need to ask you a few questions to see if you will be eligible for the study.”

The interviewer will begin the screening questionnaire as described in Section 3.1

IF the volunteer is less than 35 years of age, or does not answer as either being Hispanic, African American, or White, or answers YES to any medical exclusion questions (items 1-3), they will not be eligible for the study, and the interview will state the following:

“Based on your answers, you are not eligible to participate in the study. Thank you very much for your interest.”

Otherwise, the interviewer will continue and they will be ELIGIBLE for the study.

“Based on your answers, you are eligible to participate in our study. Do I have your permission to continue asking you a few more questions?”

No- this will end the call.
Yes – Ok.

Following the end of questions (i.e., Periodontal Set “A” questions) as described in section 3.1, the interviewer will state the following:

“Thanks for answering these questions. Now, I would like to schedule an appointment for the periodontal exam. We have the following dates and times available, Wednesdays-Fridays from 10-2p or 3-7 pm and Saturdays from 9-1pm. When would you like to schedule your appointment?”

(Confirm appointment date and time).

“The exam will take place in (provide address -TBD -and directions).We ask you to arrive on time for your appointment. We will call you before your appointment

time to remind you, can you provide us with a phone number? (Confirm the phone number with volunteer) If you need to call us to re-schedule your appointment, please call us at (TBD)”

“Do you have any questions?” (Answer any questions they might have)

“Thanks for your interest and we will see you on (repeat appointment date and time).”

3.4 Scoring Codes

The code for Periodontal Question Sets A and B are one of the following:

1=Yes
2=No
7=Refused
9=Don't Know

1=Excellent
2=Very good
3=Good
4=Fair
5=Poor
7=Refused
9=Don't Know

0-7 = [number of days] WHOLE NUMBERS
77=Refused
99=Don't Know

PERIODONTAL EXAMINATION

4.0 Description

Measurements will be made of gingival recession and pocket depth. An algorithm is subsequently used to calculate loss of attachment. Clinical measurements made at multiple sites on all teeth will be recorded in the mini-MEC. Later, the data will be analyzed to determine cases of moderate and severe periodontitis. For this Pilot, diagnostic criteria used in the 2003-04 NHANES will be expanded to include a full-mouth periodontal exam.

4.1 Examination Procedures

The dental examiner will verbally confirm that the volunteer would not be excluded from the examination because of specific health history concerns.

Periodontal assessments are conducted from posterior to anterior, beginning with the most distal tooth in a quadrant (including third molars) and proceeding toward the midline. Each quadrant is dried with air and then each site in the quadrant is examined with a surface reflecting mirror and a periodontal probe. The periodontal probe is used to measure the distal-facial interproximal (DF), mid-facial (BF), and mesio-facial interproximal (MF) sites. This is followed by measuring the distal-lingual (DL), mid-lingual (BL), and mesio-lingual (ML) sites. For each site, the distance from the free gingival margin (FGM) to the cemento-enamel junction (CEJ) is measured first, and then the distance from the FGM to the bottom of the pocket is measured. Where the gingival margin has receded and the CEJ is exposed, the distance from the CEJ to the gingival margin is assigned a negative value. The computer program calculates loss of attachment. The examiner takes two measurements per site for use in this calculation.

The periodontal probe is color coded and graduated at 2, 4, 6, 8, 10, and 12 millimeters. The periodontal probe is to be held with a light grasp and pointed toward the apex of the tooth parallel to the long axis of the tooth. Each measurement is rounded to the lowest whole millimeter. The probe is inserted

from the facial aspect to measure all three facial sites – the distal interproximal, the mid-facial, and the mesial interproximal. The probe is inserted from the lingual aspect to measure all three lingual sites – the distal interproximal, the mid-lingual, and the mesial interproximal.

For the interproximal sites, (ML), (DL), (MF), and (DF), the probe should be placed parallel to the long axis of the tooth and facially adjacent to the dental contact area. Angulating the probe into the interproximal area under the dental contact is not permitted. For the maxillary and mandibular molars the mid-facial assessment is always made mid-buccally at the location of mid-facial furcation area, keeping the probe parallel to the long axis of the tooth. Similarly, the mid-lingual measurement of these teeth is made at the location of the mid-lingual furcation area

The allowable range for the FGM to CEJ measurement is:

| | | |
|---------|---|-------------------------------------|
| -9 to 9 | = | Measurement in millimeters |
| $\pm A$ | = | Measurement is ± 10 millimeters |
| $\pm B$ | = | Measurement is ± 11 millimeters |
| $\pm C$ | = | Measurement is ± 12 millimeters |
| Y | = | Cannot be assessed |

The allowable range for the FGM to sulcus base measurement (pocket depth) is:

| | | |
|-------|---|-------------------------------|
| 0 - 9 | = | Measurement in millimeters |
| A | = | Measurement is 10 millimeters |
| B | = | Measurement is 11 millimeters |
| C | = | Measurement is 12 millimeters |
| Y | = | Cannot be assessed |

The periodontal assessment is conducted in the following order:

- The examiner will identify the most distal tooth that is eligible in the upper right quadrant (URQ) and proceed tooth-by-tooth in a posterior to anterior direction. The examiner will make the distal FGM-CEJ measurement first followed by the distal FGM-pocket depth measurement. The examiner will proceed to the mid-facial aspect of the tooth and will make the FGM-CEJ measurement followed by the FGM-pocket depth measurement. The

examiner will proceed to the mesial site of the same tooth and measure accordingly. The examiner will then repeat for the lingual measurements.

- The examiner will then proceed to the next tooth toward the anterior and repeat the same measures for attachment loss. This process continues until measurements are made and recorded for all teeth in the quadrant.
- The examiner will then repeat the measuring process for the upper left quadrant (ULQ).
- Once the ULQ is completed, the examiner will proceed to the lower left quadrant (LLQ) and repeat the measuring sequence; and then to the lower right quadrant (LRQ) and repeat the measuring sequence. This now completes the periodontal assessment.

4.2 Guidelines for Scoring

1. Calculus at the sites that obscures the CEJ or interferes with the correct placement of the probe is removed (using a curette, if necessary).
2. When the margin of a restoration is below the CEJ, the position of the CEJ will be estimated using adjacent landmarks and dental anatomy.
3. When the CEJ cannot be estimated, the examiner codes “Y” to exclude the site.
4. When the natural tooth is missing, (i.e., space maintainers, implants, partial denture, or pontics), the tooth sites are automatically scored “Y” by the ISIS program.
5. Mobile teeth should be examined with care. The CEJ should be estimated if possible.
6. Orthodontically banded teeth, splinted teeth, and hemisected teeth will be considered on an individual basis and should be examined if possible.

7. Partially erupted teeth are excluded from all periodontal assessments. Retained roots are also excluded if the CEJ and part of the clinical crown are not present. The code of “Y” should be used for the periodontal sites of the excluded tooth. If the entire quadrant cannot be scored, the single code of “NS” (no score) should be called and the recorder will enter “Y” for each tooth present in that quadrant.

4.3 Recording Procedures

Findings for the periodontal assessment are recorded on the Periodontal Assessment screens. Each screen view is reserved for one quadrant. The examiner “calls-out” the assessment codes to a dental recorder for direct data entry.

4.4 Post-examination Procedures

Following completion of the periodontal assessment, the examiner provides a brief summary (report of findings) to the volunteer. The dental examiner provides an overall recommendation of care for the volunteer using his/her clinical judgment. The volunteer is escorted from the examination room back to the reception area and the volunteer receives compensation for time according to current CDC study ethnic guidelines.

4.5 Periodontal Examination Screen Shots:

Dental: Stand:107 Session:107011 07/06/1999 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

Dental: Stand:107 Session:107011 07/06/1999 01:30 pm - 05:30 pm

SP ID: Name: Age: 35 years Gender: Female Date: 11/07/2000 Time: 03:17 PM

Periodontal Assessment - Upper

| | | | | | | | | | | | | | | | | | |
|----|----|----|----|----|----|---|----|----|--|----|----|---|----|----|----|----|----|
| | 3M | 2M | 1M | 2B | 1B | C | LI | CI | | CI | LI | C | 1B | 2B | 1M | 2M | 3M |
| UR | | | | | | | | | | | | | | | | | |
| LR | | | | | | | | | | | | | | | | | |

Loss of Attachment - UR

| | | | |
|----------------------|----------------------|----------------------|----------------------|
| 2M | 1M | 2B | 1B |
| Dis Mid Mesio | Dis Mid Mesio | Dis Mid Mesio | Dis Mid Mesio |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

| | | |
|----------------------|----------------------|----------------------|
| C | LI | CI |
| Dis Mid Mesio | Dis Mid Mesio | Dis Mid Mesio |
| <input type="text"/> | <input type="text"/> | <input type="text"/> |

Bleeding on Probing

| | | | |
|----------------------|----------------------|----------------------|----------------------|
| 2M | 1M | 2B | 1B |
| Dis Mid Mesio | Dis Mid Mesio | Dis Mid Mesio | Dis Mid Mesio |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

| | | |
|----------------------|----------------------|----------------------|
| C | LI | CI |
| Dis Mid Mesio | Dis Mid Mesio | Dis Mid Mesio |
| <input type="text"/> | <input type="text"/> | <input type="text"/> |

1 of 3 End of Section Close Exam Finish

Go to the Section Status Screen MEC Layer: 9/21/00 Application: Ver 8.10.23B No Safety Exclusion Not connected to Coordinator 03:19 PM

Dental: Stand:107 Session:107011 07/06/1999 01:30 pm - 05:30 pm

File View Utilities Reports Window Help

Dental: Stand:107 Session:107011 07/06/1999 01:30 pm - 05:30 pm

SP ID: Name: Age: 35 years Gender: Female Date: 11/07/2000 Time: 03:17 PM

Periodontal Assessment - Lower

| | | | | | | | | | | | | | | | | | |
|----|----|----|----|----|----|---|----|----|--|----|----|---|----|----|----|----|----|
| | 3M | 2M | 1M | 2B | 1B | C | LI | CI | | CI | LI | C | 1B | 2B | 1M | 2M | 3M |
| UR | | | | | | | | | | | | | | | | | |
| LR | | | | | | | | | | | | | | | | | |

Loss of Attachment - LR

| | | | |
|----------------------|----------------------|----------------------|----------------------|
| 2M | 1M | 2B | 1B |
| Dis Mid Mesio | Dis Mid Mesio | Dis Mid Mesio | Dis Mid Mesio |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

| | | |
|----------------------|----------------------|----------------------|
| C | LI | CI |
| Dis Mid Mesio | Dis Mid Mesio | Dis Mid Mesio |
| <input type="text"/> | <input type="text"/> | <input type="text"/> |

Bleeding on Probing

| | | | |
|----------------------|----------------------|----------------------|----------------------|
| 2M | 1M | 2B | 1B |
| Dis Mid Mesio | Dis Mid Mesio | Dis Mid Mesio | Dis Mid Mesio |
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |

| | | |
|----------------------|----------------------|----------------------|
| C | LI | CI |
| Dis Mid Mesio | Dis Mid Mesio | Dis Mid Mesio |
| <input type="text"/> | <input type="text"/> | <input type="text"/> |

2 of 3 End of Section Close Exam Finish

Ready MEC Layer: 9/21/00 Application: Ver 8.10.23B No Safety Exclusion Not connected to Coordinator 03:24 PM

REPORT OF FINDINGS, RECOMMENDATION FOR CARE, AND REFERRALS

5.0 Description

Each volunteer will receive some general results about the dental examination he/she received during this study. A report of overall oral health finding will be provided to the volunteer in writing and a more detailed finding of periodontal health status will be conveyed by the examining dentist. Participants will receive a form resembling a checklist used during NHANES 2003-04 oral health examination highlighting their oral health status. Participants may also receive patient information pamphlets provided by the American Academy of Periodontology describing periodontal disease and care (Appendix 5-1). When asked, if a volunteer does not have a dentist of record and requests a referral option, information will be provided of a dentist or clinic willing to accept participants of this study. **A duplicate referral form will be kept for study records.**

5.1 Completing the Recommendations for Dental Care

The oral examination included in this study does not take the place of a dental checkup, treatment by the participant's own dentist, or routine dental care since no radiographs are taken and the participant's history is not available to the examiner. Rather, the exam is designed to achieve specific research objectives. Therefore, a procedure has been developed for alerting participants to the need for follow-up care or the need to continue regular routine dental care that takes the limits of the exam into consideration.

The report of dental findings called Recommendation for Care (Appendix 5-2) will be completed for each volunteer. This report makes recommendations about the volunteers need for dental care. At the conclusion of the examination, the examiner determines which of four levels should be recorded on the Recommendations for Care form. This form is nearly identical to the electronic form used on NHANES 2003-04. These boxes indicate whether the volunteer should:

1. See a dentist immediately;
2. See his/her dentist within 2 weeks;
3. See his/her dentist at the earliest convenience; or
4. Continue his/her regular routine dental care.

When the volunteer requires dental care beyond “regular or routine care,” the examiner will indicate the main reason(s) for the referral and will select from the approved descriptions and/or include a brief comment in the space allocated. The comments should not provide a detailed diagnosis. Avoid descriptions which are references to specific tooth surface, specific treatment needs, or statements indicating a specific diagnostic classification. The approved descriptions include:

- A. Decayed teeth (this is listed as cavities on the Report of Findings);
- B. Gum problem/disease;
- C. Oral hygiene problem;
- D. Clinical impression of soft tissue conditions;
- E. Denture/Partial Denture/Plates
- F. No significant findings, and
- G. Some other finding.

QUALITY CONTROL

6.0 Description

The dental examiner and support staff are responsible for protecting the accuracy and precision of the data collected. Moreover, activities that may diminish the analytical value of the data collected from this Pilot should be minimized.

Staff will be exposed to and instructed in procedures for the pilot prior to implementing the pilot in the mini-MEC (Mobile Examination Clinic). The NHANES Reference Examiner will provide training. Time for Pilot administration will be collected and compartmentalized into the following modules: Questionnaire and Periodontal Exam. Furthermore, an overall Pilot exam time will be computed.

The NHANES Reference Examiner may record on a separate hard copy various activities as observed during the conduct of the Pilot. This information will be essential in reviewing the outcomes of the Pilot and modifying the exam assessments and questionnaires for inclusion into a future NHANES Oral Health Component.

6.1 Training

The contractor, Westat will train all interviewers for this feasibility study.

6.2 Evaluation

The DOH Project Officer will conduct a site visit during the Pilot to observe staff and operational procedures.

Data Warehousing and Analytical Plan

7.0 Description

For this study, computer templates will be created for both the interview items and the clinical examinations. With each interview, the responses are recorded on computer and saved to the individual computer. Clinical examination findings also are recorded on the chair side computer and saved. Both interview and clinical data are periodically backed up. The data is collected by the contractor (Westat) and stored on their server with appropriate backup. At the completion of the study, the contractor will send NCHS a flat SAS data file containing all of the interview and clinical information for each study participant. NCHS then will create appropriate summary statistics for the clinical variables that are collected at the site level with the assistance of the CDC Division of Oral Health for analytical purposes. Data collected will be stored at NCHS following existing storage and use guidelines.

Westat will provide an earlier data file to NCHS to permit basic analyses to determine if the study's quota sample is identifying periodontal cases and if adjustments will be needed in the recruitment targets.

7.1 Analytical Plan

There are five specific aims that drive the primary analyses for this study.

Aim 1) To determine if there is a difference in the accuracy of two sets of screening questions that have been developed to predict levels of periodontitis. "Accuracy" will be measured as the degree to which each person's questionnaire responses is in concordance with clinical periodontal assessment of the same person.

These analyses would be accomplished using logistic regression models with periodontal disease as the outcome variable and the questions as the predictor variables. Sensitivity and Specificity of the predictive ability of the models would be calculated and the decisions would be based on the c-statistic option of the SAS PROC logistic, which provides information on predictive ability of Sensitivity values plotted against 1-Specificity values for all thresholds of logistic regression model (equivalent to the Area Under the Receiver Operating Curve).

Aim 2) To compare the best set of screening questions has sufficient accuracy for use in population surveys. "Sufficient" accuracy will be judged by comparing the same measures of concordance assessed in aim 1 with benchmark levels of concordance observed for other reported self-reported health conditions such as diabetes and obesity, as reported, for example by BRFSS.

Aim 3) To determine if rates of non-response to screening questions differ among three racial/ethnic groups: Whites, African Americans and Hispanics. "Non-response" will be defined as questions that are not answered or where the person replies "don't know".

Non-response rates will be calculated for whites, African Americans, and Hispanics and calculated as proportion of non-response items for each group. Statistical significance will be determined using Chi-squared tests. Additionally, we would calculate 95% confidence intervals for comparing African-Americans, Hispanics, with Whites.

Aim 4) To determine if clinical recording of information from a reduced number of teeth and/or tooth sites yields valid estimate of periodontitis.

"Validity" will be measured as the extent to which disease prevalence measured using a subset of teeth and/or sites is equivalent to disease prevalence measured using all sites on all available teeth.

The analysis will be based upon summary statistics that are averages of PD or CAL for each subject. Evaluation of bias and precision of the various partial sampling methods relative to the full mouth method is based upon means and standard deviations of these summary measures across all subjects in the sample.

Bias is defined as the mean score of the summary statistics based upon the partial sampling method minus the mean score based upon the full mouth method. To evaluate bias we calculated the "percent relative bias:

$$\% \text{ relative bias} = 100 * (M_p - M_f) / M_f$$

where: M_p = mean score based on partial method
 M_f = mean score based on full mouth method

The **precision** of a partial method is defined as the mean squared error (MSE) of the measure. The MSE quantifies the variability of the measure around M_f :

$$MSE = \sum (p - M_f)^2 / N = (M_p - M_f)^2 + \sum (p - M_p)^2 / N = \text{bias}^2 + [(N-1)/N] SD^2$$

where p is the score for an individual based on the partial method and summation (\sum) is over the $N=6793$ individuals.

An additional approach would be to use the partial mouth score as the predictor and the full mouth score as the “standard” or “truth”.

Sensitivity and Specificity of the prediction can be calculated using Logistic Regression Analyses and the validity can be assessed using the c-statistic as described in Aim 1.

Finally, we will compare estimates from partial mouth recording of periodontal sites with estimates of prevalence from all sites to derive the percent of under-representation of disease prevalence due to partial mouth measurements.

Aim 5) To assess the logistics aspects of conducting the pilot study in order to answer questions related to the operational feasibility of conducting an expanded periodontal examination within the NHANES 2009-10 examination.

These analyses will be conducted within NCHS and involve issues such as length of the examination, acceptance by the respondents, and other related aspects.

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Appendix 3-1

Periodontal Set “A” Questions

La enfermedad de las encías es un problema común en la boca. Las personas que sufren de la enfermedad de las encías pueden sangrar en las encías alrededor de los dientes, tener inflamación en las encías, retracción de las encías, encías adoloridas o infectadas por lo menos durante dos semanas y sin que haya una lesión, o pueden tener problemas con dentaduras postizas parciales o completas.

- | | | | |
|----|----|---------|-------------|
| Sí | No | No Sabe | No contesta |
|----|----|---------|-------------|
1. ¿Piensa usted que tal vez sufra de la enfermedad de las encías?
-
- | | | | |
|----|----|---------|-------------|
| Sí | No | No Sabe | No contesta |
|----|----|---------|-------------|
2. ¿Alguna vez le ha dicho un profesional de la salud dental que usted ha perdido hueso alrededor de los dientes?
-
- | | | | |
|----|----|---------|-------------|
| Sí | No | No Sabe | No contesta |
|----|----|---------|-------------|
3. ¿Alguna vez le han hecho un raspado o un alisado de las raíces de los dientes que a veces se conoce como limpieza “profunda”?
-
- | | | | |
|----|----|---------|-------------|
| Sí | No | No Sabe | No contesta |
|----|----|---------|-------------|
4. ¿Alguna vez se le ha aflojado algún diente por sí solo sin haber tenido una lesión?
-
- | | | | |
|----|----|---------|-------------|
| Sí | No | No Sabe | No contesta |
|----|----|---------|-------------|
5. ¿Durante los últimos siete días, ¿cuántas veces usó enjuague bucal u otro producto de enjuague dental?
- _____Número de veces
6. ¿Durante los últimos siete días, ¿cuántas veces usó hilo dental o cinta dental?
- _____Número de veces
7. ¿En general, ¿cómo diría que es el estado de salud de sus encías?
- Excelente
Muy bueno
Bueno
Regular
Malo
No sabe
No contesta
-
- | | | | |
|----|----|---------|-------------|
| Sí | No | No Sabe | No contesta |
|----|----|---------|-------------|
8. ¿En los últimos tres meses, ha notado que alguno de sus dientes no parece verse bien?

Periodontal Set “B” Questions

Preámbulo: La enfermedad de las encías es un problema común en la boca. Las personas que sufren de la enfermedad de las encías pueden tener encías inflamadas, encías retraídas, adoloridas, infectadas y pueden llegar a dientes que se mueven.

1. Piensa usted que tal vez sufra de la enfermedad de las encías?
Sí No No Sabe No contesta

2. En general, ¿cómo diría que es el estado de salud de sus dientes y encías?
Excelente
Muy bueno
Bueno
Regular
Malo
No sabe
No contesta

3. Alguna vez ha tenido usted tratamiento de las encías tipo raspado o alisado de las raíces, que a veces se conoce como limpieza “profunda”.
Sí No No sabe No contesta

4. Alguna vez se le ha aflojado algún diente por sí solo sin haber tenido una lesión?
Sí No No sabe No contesta

5. Alguna vez le ha dicho un profesional de la salud dental que usted ha perdido hueso alrededor de los dientes?
Sí No No sabe No contesta

6. En los últimos tres meses, ha notado usted un diente que no parece verse bien?
Sí No No sabe No contesta

7. Aparte del cepillado de sus dientes, cuantas veces ha usado la seda/hilo dental o algún otro medio o utensilio para limpiarse entre los dientes en los últimos siete días?
_____Número de veces

8. Aparte del cepillado de sus dientes, cuantas veces a usado un enjuague bucal u otro producto liquido para el tratamiento de enfermedades dentales en los últimos siete días?
_____Número de veces

Appendix 5-1

American Academy of Periodontology pamphlets:

“Periodontal Diseases: what you need to know”

“Periodontal care is for everyone”

Study Participant ID Label

Appendix 5-2

Recommendation for Care

NHANES-OH 2007 Periodontal Feasibility Study

Recommended Level of Referral:

(circle only one number as appropriate)

- Individual should see a dentist immediately.....1
- Individual should see a dentist within the next 2 weeks.....2
- Individual should see a dentist at his/her earliest convenience.....3
- Individual should continue with his/her regular routine dental care.....4

Recommended Level of Care:

(circle any letter as appropriate)

| | Decayed Teeth | Periodontal Disease/Problem | Oral Hygiene | Soft Tissue Problem | Denture/RPD Problem | No Significant Findings | Other Finding |
|-----------|------------------|--------------------------------|-----------------|------------------------|------------------------|----------------------------|------------------|
| Condition | A | B | C | D | E | F | G |

If “Other Finding” (G), please specify:
