

## Manual 10 Oral Health Assessment

March 30, 2009 - Version 2.00

Study website - http://www.cscc.unc.edu/hchs/

## Tracking of Revisions to HCHS/SOL Protocol Manuals

| [Manual, Date, Version]  Manual 10, Ver 1.02, dated July 10, 2008 | Date(s) of<br>Revisions;<br>source | Approved by,<br>Date               | Revisions  | Page #s changed etc. | Distribution;<br>Date    |
|---|------------------------------------|------------------------------------|--|----------------------|--------------------------|
| Section 7.3.3.2.  | March 23, 2009                     | Clarification of original protocol | Added 3 new bullets to scoring rules   | 14-15                | v2.00;<br>March 30, 2008 |
| Section 7.5.2.  | March 23, 2009                     | и                                  | Fixed Examination Sequence table. Order of sequence was incorrect.   | 20                   | -                        |
| Various sections  | December 4, 2008                   | Clarification of original protocol | Moved code information to tables   | various              | -                        |
| Section 7.6.1   | October 30, 2008                   | Clarification of original protocol | Moved code information to table  | 23                   | -                        |
| Section 7.5.2 Examination Procedure                               | October 30, 2008                   | u                                  | Change to read that the examiner calls a "=" instead of a "9" when a site cannot be accessed.  | 21                   | -                        |
| Section 5. Clinic Room<br>Preparation for Oral Exams              | October 5, 2008                    | Clarification of original protocol | Deleted sentence that says: Examiners are provided with lab jackets or disposable gowns which should be disposed after teach subject exam. | 4                    | -                        |
| Section 7.1.1. Examination Procedures                             | October 5, 2008                    | и                                  | Deleted sentence: The maximum number of primary tooth spaces that can be indicated is 20.  | 5                    | -                        |
| Section 7.3.1. Examination Procedures                             | October 5, 2008                    | и                                  | Deleted this section. Duplicated further in document.  | 8-9                  | -                        |
| Section 7.1.1.  | October 5, 2008                    | и                                  | Deleted sentence: the recorder cannot proceed if the box is checked and there is not at least one "3"                                      | 7                    | -                        |
| Section 7.4 Root Caries<br>Assessment                             | October 5, 2008                    | и                                  | All dentate participants receive this assessment to determine the prevalence of root caries and root restorations.                         | 17                   | -                        |
| Section 7.4.4 Guide for Referral and Follow-up                    | October 5, 2008                    | и                                  | A root caries was changed from a Level 3 to a Level 2 recommendation   | 20                   | -                        |

Updated 4/1 uccmxk

# Oral Health Assessment TABLE OF CONTENTS

| 1. | PURPOSE  | 3  |
|----|--|----|
| 2. | TIMING / SCHEDULING OF THE BASELINE DENTAL EXAMINATION   | 3  |
| 3. | DENTAL EXAMINER  | 3  |
| 4. | SEQUENCE OF PROCEDURES   | 3  |
| 5. | CLINIC ROOM PREPARATION FOR ORAL EXAMS   | 4  |
| 6. | VITAL SIGNS AND PERIODONTAL EXAM EXCLUSION   | 4  |
| 7. |  |    |
|    | 7.1. Tooth Count   | 5  |
|    | 7.1.1. Examination Procedures  |    |
|    | 7.1.1.1. Surgical Implants   |    |
|    | 7.1.2. Guidelines for Scoring  | 6  |
|    | 7.1.3. Recording Procedures  | 7  |
|    | 7.2. Restorative Materials Component   | 7  |
|    | 7.2.1. Objective   |    |
|    | 7.2.2. Examination Procedures  | 7  |
|    | 7.2.3. Scoring Codes   | 7  |
|    | 7.3. Coronal Caries Assessment   | 8  |
|    | 7.3.1. Examination Procedures  | 8  |
|    | 7.3.2. Assessment Diagnostic Criteria: Decayed, Missing, and Filled                              |    |
|    | 7.3.2.1. Decayed Tooth Surfaces (D Component of the DMFS Index)                                  |    |
|    | 7.3.2.2. Missing Teeth (the M Component of the DMFS Index)                                       |    |
|    | 7.3.2.3. Filled Tooth Surfaces (the F Component of the DMFS Index)                               |    |
|    | 7.3.3. Scoring Permanent Teeth   |    |
|    | <ul><li>7.3.3.1. Scoring Primary Teeth</li><li>7.3.3.2. General Guidelines for Scoring</li></ul> |    |
|    | S  |    |
|    |  | 15 |
|    | 7.4.1. Examination Procedures  |    |
|    | 7.4.2. Scoring Codes   |    |
|    | 7.4.3. Diagnostic Criteria   |    |
|    | 7.4.4. Guide for Referral and Follow-up  |    |
|    |  |    |
|    | 7.5. Periodontal Assessments   |    |
|    | 7.5.1. Participant Eligibility for the Periodontal Assessment                                    |    |
|    | 7.5.2. Examination Procedure   |    |
|    |  | ∠∪ |

|    | 7.5    | 5.4. Guide to Referral and Follow-up  | 21 |
|----|--------|---|----|
|    | 7.6. I | Recommendation for Care Recording Procedure   | 21 |
|    | 7.6    | 5.1. Recommendation for Care (END) Screen   | 21 |
|    |        | 5.2. Guidelines for Assigning Condition Codes   |    |
| 8. | POS    | T-EXAMINATION PROCEDURES  | 24 |
|    | 8.1.   | Infection Control after Each Examination  | 24 |
|    | 8.1    | .1. Instruments   | 24 |
| 9. | Denta  | al Examiner Certification   | 24 |
|    |        | Credential Requirements, Training, Certification & Recertification of Examiners  1. Certification |    |
|    |        | .2. Re-certification and re-training.   |    |
|    | 9.2.   | Training and Certification Requirements for Dental Data Entry System (DDES)                       | 26 |

#### 1. PURPOSE

The purpose of the Baseline Dental Examination is to assess the dental and periodontal status of each eligible study participant in order to estimate the prevalence of oral diseases and to conduct analytic investigations of associations of a variety of social, behavioral, contextual, medical, genetic and biological phenotypic characteristics with oral disease prevalence. The examination will include an assessment of the need for prophylactic antibiotics prior to periodontal probing, measures of coronal and root caries, restoration materials, and periodontal disease. In addition study participants will receive feedback on examination findings.

## 2. TIMING / SCHEDULING OF THE BASELINE DENTAL EXAMINATION

The Baseline Dental Examination occurs after a participant has been enrolled and complete eligibility has been determined. The examination is one component of the full HCHS/SOL clinical examination and will occur following other examination components that require the participant to be fasting. This visit will require approximately 25 minutes. The visit exam and data collection will be performed in a fixed examination area in each field center by a study trained and certified Dental Examiner.

#### 3. DENTAL EXAMINER

Clinical baseline examinations will be attended by a study Dental Examiner, who is either a dental hygienist or dentist. All examiners will be trained in examination procedures and certified prior to commencement of the study. Examiners will be documented to have achieved acceptable proficiency as determined by good agreement with the Reference Examiner and other examiners (i.e., inter-examiner measurement reliability).

In addition to the Examiner, a Dental Recorder must be present during the examination to enter the examination calls into the HCHS/SOL Dental Data Entry System (DDES). The DDES is an interactive program contained on a study laptop for entry of all clinical data as well as responses to questions assessing the need for prophylactic antibiotics. If the Recorder(s) cannot attend the central training, a train-the-trainer model will be used in which the Examiner will be trained and certified in use of the DDES and will in turn train one or more Recorders at the field center.

#### 4. SEQUENCE OF PROCEDURES

The following procedures and data collection forms are required at the Baseline Periodontal visit:

- Clinic room preparation for dental examination
  - o Check clinical exam data for vital signs taken that morning
  - o Check questionnaire data for responses to need for prophylactic antibiotics
- Welcome and seat the study participant
- Conduct Baseline Oral Exam
  - Tooth Count
  - Restorative Materials
  - o Caries: Coronal Surfaces
  - o Caries: Root Surfaces
  - o Periodontal Examination
    - Probing depths and cemento-enamel junction (CEJ) measures
    - Bleeding on Probing

- Recommendations for Care (feedback to participant)
- End of exam session procedures

#### 5. CLINIC ROOM PREPARATION FOR ORAL EXAMS

There are a number of specific tasks the Dental Examiner needs to complete at the beginning of each exam session. These are listed below.

- Wash hands;
- Turn dental light on; and
- Visually check the following pieces of equipment:
  - o The light;
  - o The air compressor and air tank valves;
  - o The sterilizer;
- Turn the air compressor on and close valve;
- Check airflow from air syringe; and
- Prepare the room for the examination complete all infection control procedures;
- Counter tops must be disinfected with an appropriate solution before arranging the instruments and supplies for daily use.
- Disposable barriers must be placed on the following items: chair cover, syringe, light head and controls, and mounted instrument tray.
- The Examiner must wear a facemask, safety glasses with side shields, and a new pair of powder-free exam gloves for each participant examination. Latex-free gloves should be used when indicated.

NOTE: If the Examiner adjusts the dental stool or the mask or touches any object, other than ones that have been covered or disinfected during an examination, he or she must rescrub and put on a new pair of gloves.

- Examiners and Recorders must wear neat and clean lab jackets or gowns. Exam gowns should not be worn outside of the exam room.
- Only properly sterilized instruments are to be used for dental examinations.
- Unsterilized instruments should be closed in the holding cassette and prepared for sterilization.

#### 6. VITAL SIGNS AND PERIODONTAL EXAM EXCLUSION

Participant vital signs will be assessed prior to the oral examination. Vital signs include pulse, respiration, and blood pressure.

If the response to the prophylactic antibiotic question is "don't know", the Examiner should ask additional questions to determine exclusion status and update questionnaire data.

## 7. BASELINE DENTAL EXAMINATION

The Baseline Dental Examination includes questions asked by the Dental Examiner to determine need for antibiotic prophylaxis, tooth status calls, coronal caries calls, restorative materials calls, root caries calls and a periodontal examination. All teeth present, except third molars are scored and the Recorder will enter the Examiner calls into the DDES. Participants who present with obvious dental pathology will be provided with documentation for referral purpose.

No radiographs are expected to be taken at this exam and are not required for study participation.

## 7.1. Tooth Count

Participants 18 years and older receive this examination which assesses the number of primary and permanent teeth, and the presence of surgical implants. Information on surgical implants is obtained from preliminary questions asked by the Examiner. The Dental Examiner examines the participant utilizing any guidance provided during the questioning.

#### 7.1.1. Examination Procedures

The Tooth Count Assessment involves examining the maxillary arch and the mandibular arch to identify the presence or absence of permanent and/or primary teeth in each tooth position of the mouth. There are 28 tooth positions in the mouth, excluding the third molars. The maximum number of permanent tooth spaces that can be indicated is 28. Tooth spaces must be examined in the following order: Maxillary right quadrant, maxillary left quadrant, mandibular left quadrant, and mandibular right quadrant. Within each quadrant, the Examiner should begin with the central incisor space and move to the posterior in order to the third molar space using the surface reflecting mirror and the #23 explorer.

The codes used for the tooth count calls are listed below. Only one code per tooth is to be entered.

| Code | Condition                                    |
|------|--|
| 1    | Primary tooth (deciduous)                    |
| 2    | Permanent tooth                              |
| 3    | Implant                                      |
| Е    | Missing due to caries or periodontal disease |
| М    | Missing due to trauma or other reason        |
| U    | Un-erupted or congenitally missing           |
| 5    | Permanent root tip is present                |

## 7.1.1.1. Surgical Implants

Surgical implants are posts surgically placed through the gingival tissue into the jawbone and are typically capped by a prosthetic tooth. Implants may replace a single tooth or may replace multiple teeth in longer segments of a dental arch. There may be more missing teeth restored with pontics than there are implants, similar to a traditional fixed bridge. The surgical implant question will be asked for all participants.

Surgical implants may be used to replace specific teeth or to support fixed or removable appliances. Surgical implants may be difficult to detect without suitable radiographs. Therefore, in addition to the clinical assessment, questions must be posed to all participants to determine whether implants are present. The Examiner should ask the question in the following way: "Do you have one or more teeth that are missing, or were removed, and have been replaced with a surgical implant?"

If the participant responds "Don't know," repeat the question and define implants as follows: "Surgical implants have a post surgically placed through your gum and into the bone and are often capped by an artificial tooth or bridge."

The answer to this question must be called to the Recorder. If the participant's response is "Yes," the following questions will be asked:

- Do you know how many surgical implants you have in your mouth?
- Can you point to the area of your mouth where the surgical implant(s) was/were placed?

The participant may be able to indicate the exact tooth position or the general location of the implant. If the participant indicates a "Yes" response, encourage the participant to indicate where in the mouth the surgical implants are. The Dental Examiner should then examine the whole mouth for implants.

If the participant does not know whether they received a surgical implant or not, go over the fact that this is a procedure where the implant is surgically (emphasis on surgically) implanted into the bone. If they still do not know, then answer "NO", and the Dental Examiner should do a thorough examination of the mouth visually to see if there is an implant. The implant box can be checked and unchecked at any point in the tooth count.

The location of the implant is called during the tooth count assessment along with the other codes. If a tooth space has been replaced with a surgical implant, a code of "3" is assigned for that space; otherwise, a code of "1," "2," "E,", "M", "U" or "5" is assigned to the tooth space, as appropriate.

If through the examination the Examiner determines no implants are present, then he/she should tell the recorder to change the "yes" box to a "no" box on the tooth count screen.

#### 7.1.2. Guidelines for Scoring

To assist with the guidelines listed below, the codes used in the tooth count are listed below, again.

| Code | Condition                                    |
|------|--|
| 1    | Primary tooth (deciduous)                    |
| 2    | Permanent tooth                              |
| 3    | Implant                                      |
| Е    | Missing due to caries or periodontal disease |
| М    | Missing due to trauma or other reason        |
| U    | Un-erupted or congenitally missing           |
| 5    | Permanent root tip is present                |

- a. A tooth is considered to be present if any part of its crown projects through the gum.
- b. If a permanent and a primary tooth are visible in the same tooth space, the permanent tooth is assigned to the tooth space.
- c. In instances of supernumerary teeth, the Examiner must decide which tooth is the "legitimate" occupant of the space.
- d. Orthodontic extractions First bicuspids (premolars) are often extracted as part of orthodontic treatment. These teeth are coded as Tooth not Present ("M"). For the sake of

- uniformity, all bicuspids extracted for orthodontics are scored as first bicuspids. The Examiner must make the determination that the teeth were in fact extracted for orthodontic reasons. This is usually not difficult to detect because of the symmetric pattern of orthodontic extractions. The Examiner should confirm this with the Participant prior to coding the teeth.
- e. When at least 90% tooth crown is destroyed by caries or there is a retained root tip present, score the tooth as Permanent root tip present ("5"). Root tips are classified as any permanent residual tooth structure that is predominately composed of dental root structure with less than 90 percent of the CEJ visible, with less than 90 percent of the coronal structure visible, and occupies a dental position within the dental arch. Because multi-rooted posterior teeth may present as multiple root tips, Examiners will assign multiple root tips to the appropriate dental position in the arch and code as a "5".

## **7.1.3.** Recording Procedures

The recorder first enters the code called by the Examiner for the question about surgical implants. The recorder then uses the next screen, the Tooth Count screen, to enter the tooth count calls made by the Examiner.

NOTE: It is extremely important that the correct calls be made by the Examiner and entered correctly by the Recorder on this screen, as the outcome of this assessment determines how other assessments are performed and coded. For example, root caries, is assessed only on permanent teeth as defined in the tooth count.

Whenever a call in the Tooth Count precludes a later assessment, such as primary teeth not eligible for Root Caries assessment, the program automatically shades data entry space of the affected tooth in the subsequent assessment. In subsequent assessments, the computer program will skip these tooth positions and the cursor will move to the first blank tooth space. To change this, the Tooth Count code for that tooth must be changed on the Tooth Count Screen.

## 7.2. Restorative Materials Component

#### 7.2.1. Objective

This component identifies specific restorative materials noted in the oral health examination. They will be counted as amalgam, resin, gold, other, and full coverage crowns.

#### 7.2.2. Examination Procedures

The examination will be visual and tactile (an explorer will be used if needed), with **one score per restored tooth.** 

#### 7.2.3. Scoring Codes

| Category | Description  |  |  |
|----------|--|--|--|
| Α        | Amalgam: restorations composed of any type of amalgam    |  |  |
| R        | Resin: all types of composites and resins                |  |  |
| G        | Gold: gold inlays, onlays, gold foils, or partial crowns |  |  |
| 0        | Other: anything other than an amalgam or composite or    |  |  |

|   | gold, such as porcelain onlays, inlays, or glass ionomer restorations when they can be distinguished from composites        |
|---|---|
| С | Crown: full coverage crowns made of any material (including gold, stainless steal, porcelain, and porcelain fused to metal) |
| N | <b>No</b> (Restoration not present)   |

If a restored **tooth** contains more than one type of material the selected material category will be based on the material with the greatest coverage of tooth surface.

## 7.3. Coronal Caries Assessment

Each participant receives the coronal caries assessment. All teeth except the third molars are assessed.

#### **7.3.1.** Examination Procedures

Each quadrant is dried with air and examined with a surface reflecting mirror and a No. 23 explorer. The Examiner begins the assessment in the maxillary right quadrant with the right central incisor and continues distally through the second molar in the same quadrant. The same sequence is followed for the upper left, lower left, and lower right quadrants. Tooth surfaces are examined in the following order: lingual, facial (buccal), mesial, and distal for anterior teeth, and lingual, occlusal, facial, mesial, and distal for posterior teeth. It is not advisable to call out the individual tooth surface codes until the surfaces of the whole tooth are examined, as this can be confusing to the recorder. Thus, the Examiner will mentally accumulate surface calls for a given tooth and then dictate the calls to the recorder.

The DDES has color-coded each data entry box per tooth. A gray box indicates an unscoreable tooth (i.e. 3<sup>rd</sup> molar, missing tooth), a blue box indicates a permanent tooth, and a red box indicates a primary tooth.

The codes characterizing a whole tooth condition are referred to as "tooth calls." The allowable codes are as follows:

| Code | Condition  |
|------|--|
| D    | Sound primary (deciduous) tooth  |
| K    | Primary tooth with surface condition   |
| S    | Sound permanent tooth (no decay or filling on any surface)                     |
| Z    | Permanent tooth with surface condition   |
| J    | Permanent root tip is present but <u>no</u> restorative replacement is present |
| Т    | Permanent root tip is present but a restorative replacement is present         |
| U    | Unerupted tooth  |
| Р    | Missing, but replaced by a removable restoration                               |
| R    | Missing, but replaced by a fixed restoration                                   |

| V | Missing and not replaced  |
|---|---|
| W | Missing, but no space (<2mm); if there is a missing tooth with no space, but was the result of orthodontic extraction, then "O" code takes precedence |
| 0 | Missing for orthodontic reasons   |
| = | Tooth present, but condition cannot be assessed   |

The next examination pass indicates the condition of each tooth surface (5 per posterior and 4 per anterior). The codes characterizing the surface condition are referred to as "surface codes." The allowable codes are as follows:

| Code | Condition     |
|------|---------------|
| 0    | Sound surface |
| 1    | Caries        |
| 2    | Restoration   |

## 7.3.2. Assessment Diagnostic Criteria: Decayed, Missing, and Filled

## **7.3.2.1.** Decayed Tooth Surfaces (D Component of the DMFS Index)

Frank lesions are detected as gross cavitation and thus present few problems in diagnosis. Incipient lesions captured in this survey, on the other hand, are more difficult to diagnose consistently. Incipient lesions may be subdivided into three categories according to location, each with the following special diagnostic considerations:

- 1. Pits and fissures on occlusal, facial, and lingual surfaces
  - These areas are classified as carious when the explorer catches after insertion with moderate, firm pressure, accompanied by either softness at the base of the area and/or opacity adjacent to the area providing evidence of undermining or demineralization. In other words, a deep pit or fissure in which the explorer catches is not sufficient evidence of decay without one or both of the following:
    - Softness at the base of the area;
    - Opacity adjacent to the area providing evidence of undermining or demineralization.
- 2. Smooth areas on facial (labial or buccal) or lingual surfaces

These areas are carious if they are (1) either decalcified or if there is a white spot as evidence of subsurface demineralization and (2) if the area is found to be soft by:

- Penetration with the explorer, or
- Scraping the area with the explorer.

Visual evidence of demineralization is not enough to diagnose caries.

#### 3. Proximal surfaces

When areas are accessible to direct visual and tactile examination, i.e., when there is no adjacent tooth, the same criteria as that used for smooth areas on facial or lingual surfaces are used. When areas are not available to direct examination, other criteria must be applied.

- On anterior teeth, trans-illumination can serve as a useful aid in discovering proximal lesions. Trans-illumination is achieved by placing a mirror lingually and positioning the examining light so that it passes through the teeth and reflects into the mirror. If a characteristic shadow or loss of translucency is seen on the proximal surface, then this is indicative of caries on the surface. Ideally, the actual diagnosis should be confirmed by detecting a break in the enamel surface with the explorer; however, clear visualization of a lesion by transillumination can justify a positive diagnosis.
- On posterior teeth, however, visual evidence alone, such as undermining under a marginal ridge, is not sufficient proof for diagnosing a proximal lesion. A positive diagnosis is made only if a break in the enamel surface can be detected with the explorer.

## **7.3.2.2.** Missing Teeth (the M Component of the DMFS Index)

This criterion traditionally represented permanent teeth extracted only as a result of caries. However, because of the difficulty of correctly distinguishing between teeth extracted due to caries and those extracted for periodontal reasons, no attempt is made at the time of the examination to differentiate between these two causes of tooth loss. It is essential, however, to distinguish between teeth extracted because of caries or periodontal disease and those extracted or missing for other reasons.

- The code "E" is used to indicate teeth extracted because of caries or periodontal disease
- The code "M" is used for teeth missing due to trauma, orthodontic treatment, or other nondisease related causes.
- The code "U" is used to identify unerupted or congenitally missing teeth

In order to determine whether an "E," "M," or "U" is called, the Examiner will ask the participant about the reason for tooth loss. Separate codes are used when a missing tooth has been replaced by a fixed or removable prosthesis. This assessment using these codes will be entered on the Coronal Caries/Reason Missing Screen.

- "P" is used to designate a tooth that is missing but has been replaced by a removable restoration.
- "R" is used to designate a tooth that is missing but has been replaced by a fixed restoration.
- "V" is used to designate a tooth that is missing but is not replaced
- "W" is used to designate a tooth that is missing but there is no space (less than 2 mm. If there is a missing tooth with no space and it was a result of orthodontic extraction, then the "O" code takes precedence.)
- "O" is used to designate a tooth that is missing for orthodontic reasons
- "=" is used to designate a tooth that present but the condition cannot be assessed

A fixed or removable prosthetic replacement is considered to exist when it is visible in the mouth. If an appliance is not visible, the Examiner should ask the participant if one exists. If the

participant reports the existence of a removable appliance, the replacement is considered to exist if the participant reports he/she wears the appliance, no matter how infrequently.

When a replacement exists, the Examiner does not consider its condition or adequacy when making the call. When a replacement does not exist, the Examiner does not attempt a clinical judgment of the need or adequacy of space for a replacement, even if tooth movement has closed the space.

When more than one tooth has been replaced by a single pontic, each tooth space is scored as replaced.

When an implant is identified in Tooth Count, a code of "3," the appropriate restorative codes for Coronal Caries would be "R"

## 7.3.2.3. Filled Tooth Surfaces (the F Component of the DMFS Index)

The F component represents a tooth surface that has been filled with either a permanent or a temporary restoration as a result of caries. It is necessary to distinguish between surfaces restored because of caries and those restored for other reasons, such as trauma, hypoplasia, malformation, or bridge abutment. The Examiner may question the participant as necessary to make the correct call.

## **7.3.3.** Scoring Permanent Teeth

On the first pass through the mouth, the examiner has identified the status of each tooth using specific codes as to the presence, absence, and replacement. On the second pass through the mouth, the examiner will determine the presence of restorative materials. On the third pass through the mouth, the examiner will make a tooth call based on the caries status of the tooth, i.e. sound permanent teeth ("S") are distinguished from permanent teeth with restorations or caries ("Z). The "Z" code precedes any other legitimate diagnostic call for decayed or filled surfaces.

On the fourth pass through the mouth, the DDES will move from surface to surface per tooth with the examiner making a call of 0 (sound), 1 (caries), or 2 (restoration). The sequence of surfaces for molars will be: lingual, occlusal, buccal, mesial, distal. For anterior teeth, the sequence is: lingual, labial, mesial, distal. For example, if a permanent molar has occlusal caries and is otherwise sound with no restorations, the codes would be called out in the following sequence: 0 (lingual), 1 (occlusal), 0 (buccal), 0 (mesial), 0 (distal). If the permanent tooth is sound, the "S" code is used alone. For permanent teeth coded as a "5" in the tooth count screen, the "T" or "J" codes must be used. The DDES will not accept any other coronal caries codes.

Any permanent root tip that has had a replacement made for the appropriate coronal structure or serves as a supporting structure for an overdenture will be coded as a "T." This includes visible residual roots present under any type of removable complete or partial denture. If a visible residual root is present and no replacement has been made, the correct code will be a "J."

The specific codes for permanent teeth are listed below:

| Code | Condition   |
|------|---|
| S    | Sound permanent tooth (no decay or filling on any |

|   | surface)   |
|---|--|
| Z | Permanent tooth with surface condition   |
| J | Permanent root tip is present but <u>no</u> restorative replacement is present |
| Т | Permanent root tip is present but a restorative replacement is present         |

If the subject is edentulous except for the two anchor teeth, then consider them as canines.

## **7.3.3.1.** Scoring Primary Teeth

Decayed or filled surfaces of primary teeth are scored in the same manner as permanent teeth, using the same diagnostic criteria. While youngest age for inclusion in this study is eighteen years, there still may be some deciduous teeth, so it is necessary to call sound primary teeth with a "deciduous" score ("D") to distinguish them from sound permanent teeth ("S"). The "K" code is used for primary teeth with restorations or caries to distinguish them from permanent teeth with restorations or caries ("Z"). The "K" code precedes any other legitimate diagnostic call for decayed or filled surfaces on primary teeth. For example, if a primary molar has occlusal caries and is otherwise sound, the "K" code is used on the coronal caries screen and then for the coronal surface call screen the surface calls will be used, i.e. 0 (lingual), 1 (occlusal), 0 (buccal), 0 (mesial), 0 (distal). If the primary tooth is sound, the "D" code is used in the coronal screen and the tooth will be skipped by the DDES program in the coronal surface screen.

The specific codes for primary teeth are listed below:

| Code | Condition                            |  |
|------|--------------------------------------|--|
| D    | Sound primary (deciduous) tooth      |  |
| K    | Primary tooth with surface condition |  |

Note again if both a permanent and a primary tooth are visible in the same tooth space, only the status of the permanent tooth is described and no score is assigned for the primary tooth.

#### 7.3.3.2. General Guidelines for Scoring

The following conventions have been adopted in the interest of achieving diagnostic consistency:

- 1. Only one entry can be made for each tooth surface. In the event that a surface has both decay and a filling, only the decay is called. If the Examiner gives two calls for the same surface, the data entry system will beep and a message will be displayed in the lower right portion of the screen. Data entry is prohibited until an allowable response is entered. The recorder should bring this to the Examiner's attention immediately.
- 2. If a tooth has rotated, surface calls should be assigned to the anatomical surface not to the current position of the surface.
- 3. Incisal edges of anterior teeth are not considered to be separate surfaces. If a lesion or restoration is confined solely to the incisal edge, its score should be assigned to the nearest adjacent surface. If the lesion is equidistant from the surfaces, code lingual.
- 4. Anterior teeth have four surfaces that are coded lingual, facial, mesial, and distal.
- 5. Posterior teeth have five surfaces that are coded lingual, occlusal, facial, mesial, and distal

- 6. When a caries lesion extends beyond the line angle onto another surface, that surface is also scored as carious. For restorations, however, the following rules apply:
  - On anterior teeth, a proximal filling is not considered to involve the adjacent facial or lingual surface unless it extends at least one-third of the distance to the opposite proximal surface. The reason for this criterion is that the tooth structure on facial or lingual surfaces of anterior teeth must often be removed to provide access for the proximal restoration.
  - On posterior teeth, to guard against a similar possibility of overcalling, a proximal restoration should extend more than a millimeter past the line angle before it is considered to involve the adjacent facial or lingual surface.
- 7. If abfraction is suspected and present, ask the subject why the restoration was placed.
- 8. If a tooth has a full crown restoration placed because of caries, the tooth will be coded as "2," on all surfaces (unless caries is detected), which represents the maximum number of surfaces for the tooth type, i.e., four surfaces on anterior teeth and five surfaces on posterior teeth. The following conventions apply:
  - All full crowns on posterior teeth, including abutment teeth for fixed or removable prostheses, will be considered to have been placed due to caries.
  - On anterior teeth, however, the Examiner should make a determination of the reason for crown placement. If it can be determined that the crown was placed solely for a reason other than caries, such as fracture, malformation, or bridge abutment, the tooth is coded "=".

For three-quarter crowns, the following rules apply:

- In general, if a tooth has been restored with less than full coverage, each surface is examined and scored in the usual manner. However, when the crown coverage extends onto the facial (labial or buccal) or lingual surface for cusp protection, the surface is not scored as restored unless the coverage extends more than two millimeters cervical from the cusp tip or incisal edge.
- For three-quarter crowns used as abutment teeth, all surfaces are scored in the usual manner if the abutment is a posterior tooth. On anterior teeth, if it can be determined that the crown was placed solely for purposes of abutment and not for caries, the restoration is not scored, but surfaces without crown coverage are examined and scored in the usual manner.
- 9. Teeth that are banded or bracketed for orthodontic treatment are examined in the usual manner and all visible surfaces are scored.
- 10. Certain teeth, notably first bicuspids, may have been extracted as part of orthodontic treatment. These teeth are coded *missing due to other causes* ("M") and will be excluded from the DMFS analysis. The Examiner must make the determination that the teeth were in fact extracted for orthodontic reasons. This is usually not difficult to determine because of the typically symmetric pattern of these extractions. For the sake of uniformity, all orthodontically-extracted bicuspids are scored as first bicuspids. Teeth other than bicuspids may also be extracted for orthodontic reasons. In many cases the Participant will have good recall of the reason for the extractions and can help in making the correct determination.
- 11. Non-vital teeth are scored in the same manner as vital teeth. However, if a restoration on a non-vital tooth was placed solely to seal a root canal and not for caries, that restoration

- is not scored. If no other lesions or restorations are present, the tooth will be called *sound* ("S").
- 12. Hypoplastic teeth are scored in the usual manner. However, if it can be determined that a restoration was placed solely for esthetic reasons and not for caries, that restoration is not scored. If a hypoplastic tooth is restored with a full crown, it is to be coded "=".
- 13. Malformed teeth are scored in the usual manner except when they have been restored with a full crown for esthetic reasons, in which case they are coded "=".
- 14. When the primary tooth crown is destroyed by caries and only the roots remain, score all surfaces carious (5 surfaces on the posterior teeth lingual, occlusal, facial, mesial, distal; and 4 surfaces on the anterior teeth lingual, facial, mesial, distal).
- 15. When the same tooth surface is both carious (scored 1) and filled (scored 2), only the caries is scored.
- 16. Fractured or missing restorations are scored as if the restoration was intact unless caries is found to be present. In that case, the involved surface is scored as carious rather than restored.
- 17. In the case of supernumerary teeth, only one tooth is scored for the tooth space. The Examiner must decide which tooth is the "legitimate" occupant of the space.
- 18. If both a deciduous and a permanent tooth occupy the same tooth space, only the permanent tooth is scored.
- 19. Third molars are not scored. When examining second molars it is important to note that a drifted third molar may occupy the space of a missing second molar. In such cases, the diagnosis and score must relate to the status of the missing second molar, not the third molar. If the second molar, for example, was extracted due to caries and a sound third molar now occupies the space, the second molar is scored as *extracted* ("E") and the third molar is not scored.
- 20. A tooth is considered to be in eruption when any part of its crown projects through the gum. This criterion is easier to standardize than one based on a more advanced stage of eruption.
- 21. Stain and pigmentation alone should not be regarded as evidence of caries as either can occur on sound teeth.
- 22. If the surface is called a "5" for a root tip, then if caries is present on the root tip, the examiner will have to consider it as root caries and not coronal caries.
- 23. For a temporary filling, the material would be coded as *other* ("O") (i.e. IRM, etc.).
  - If it is an anterior tooth, determine that the root canal is due to deep decay and not trauma. For caries status, a posterior tooth would be coded as having a *surface* condition ("Z").
- 24. If a fabricated crown has fallen off, then the material would be coded based on the type of material that the buildup was made of (i.e. amalgam, resin).
  - For a posterior tooth, the caries status would be coded as having a *surface condition* ("Z"). The number of surfaces would be 5 surfaces coded as *restorations* ("2") unless there are caries; then those surfaces are coded as *caries* ("1").
  - For an anterior tooth, the examiner would ask the person whether or not the placement of a crown was due to an accident or injury and that they never had any decay in the tooth.
    - 7 If it was due to decay, there would be four surfaces coded as *restorations* ("2").

- 8 If it was due to trauma, then code the tooth as *cannot be assessed* ("="). Although, if decay is present, code as a *surface condition* ("Z") and code any decayed surfaces for caries and note it was prepped for a crown.
- 25. A temporary bridge in the posterior with poor margins is coded as a *surface condition* ("Z") on both abutment teeth.
  - For the pontic, code as *missing*, but replaced with a fixed restoration ("R") for that tooth.
  - All surfaces of abutment teeth are coded as *restorations* ("2") unless softness is seen or felt and the examiner would note that surface (the assumption is that there is no decay way underneath, just like any other permanent crown)

If the tooth is permanent with no decay or filling on any surface, the Examiner calls "S." If the tooth is permanent and is not sound, the Examiner calls "Z" and the appropriate surface condition codes as described below. "D" is entered for all sound primary calls while "K" and the appropriate surface condition codes are entered if the primary tooth has surface conditions (caries, restoration). If the tooth is missing and characterized by one of the other "tooth" calls, the Examiner calls out the appropriate letter.

The recorder records the appropriate tooth condition code in the first space for the tooth. After this first space, there is a separate block of data entry spaces to accommodate the surface calls for that tooth as necessary.

If the tooth is permanent with decay or restorations on one or more surfaces (Z), the Examiner calls the number(s) which correspond(s) to the surface(s) having decay or a restoration. Some examples are listed below:

- If the examiner calls a "Z" for the second molar, then for each of the five surfaces in order (lingual, occlusal, buccal, mesial, distal) the examiner will call a "0" (sound), "1" (caries), or "2" (restoration).
- If the examiner calls a "Z" for the central incisor, then for each of the four surfaces in order (lingual, labial, mesial, distal) the examiner will call a "0" (sound), "1" (caries), or "2" (restoration).
- If there is a crown on that tooth, combinations of caries and restorations on different surfaces are allowed. For a molar example, if the Examiner calls a "0", "1", "0", "2", "2"; it means that there is caries on the occlusal surface and a restoration on the mesial and distal surfaces. The lingual and buccal surfaces are sound. This procedure continues to the second molar for each of the four quadrants of the mouth.

## 7.4. Root Caries Assessment

All dentate participants receive this assessment to determine the prevalence of root caries and root restorations.

## **7.4.1.** Examination Procedures

Only teeth that have recession should be assessed for the presence of root caries and root-restorations. Recession exists if the Examiner can see the root surface below the CEJ. If recession is present but the root surfaces are sound, then the score is "2." If recession is not present, the score is also a "2". All exposed portions of a tooth's root surface should be examined carefully in the following sequence: the Examiner begins with the maxillary right quadrant with the right central incisor and continues distally through the second molar in the same quadrant. The same sequence is followed for the upper left, lower left, and lower right quadrants.

Each quadrant with recession is dried with air and examined with a surface reflecting mirror and a No. 23 explorer. The most difficult areas to examine are approximal surfaces in posterior teeth, particularly those that contain approximal restorations. Subgingival inspection is not recommended because few lesions are confined subgingivally and it may produce bleeding. Data are captured as overall presence or absence of root caries and overall presence or absence of root restorations.

## 7.4.2. Scoring Codes

For this assessment, the presence of any root caries and any restorations will be recorded as "whole mouth" calls. Therefore, the exposed surfaces of individual teeth will be assessed, but not recorded as individual surfaces. The allowable "whole mouth" codes for ROOT CARIES are as follows:

| Code | Condition of root caries |
|------|--------------------------|
| 1    | Root caries detected     |
| 2    | No root caries detected  |
| _    | Cannot be assessed       |

The allowable "whole mouth" codes for ROOT RESTORATIONS are as follows:

| Code | Condition of root restorations |
|------|--------------------------------|
| 1    | Root restoration detected      |
| 2    | No root restoration detected   |
| =    | Cannot be assessed             |

Once a carious lesion on the root is identified, then no other teeth need to be examined for a root caries score.

## 7.4.3. Diagnostic Criteria

Caries occur on root surfaces of teeth only where there has been loss of normal gingival attachment, apical recession from the cemento-enamel junction (CEJ). Generally, caries on root surfaces occurs coronal to the present gingival margin but apical to the CEJ; very few lesions exist solely in the gingival pocket. Although all exposed root surfaces are susceptible, it has been reported that root caries predominantly occurs in approximal and facial aspects.

Root caries starts at or just below the cemento-enamel junction. Most commonly, early root caries lesions are small and round. However, they may spread laterally along the cervical junction, sometimes coalescing with neighboring lesions to produce a collar of caries around the root. Caries that begins in a root surface does not tend to affect the adjacent coronal enamel surface directly. Rather, they may undermine the cervical enamel and invade coronal dentin,

leaving a cervical enamel spur or ledge. If the carious process continues, pieces of this ledge may fracture, making it appear as if the caries had originated in the enamel as well as the cementum. The opposite sequence can occur as well, with cervical coronal caries spreading apically to involve the CEJ and then the root surface. Some scoring guidelines are listed below.

- When a single caries lesion that extends at least 1 mm past the CEJ in both incisal and apical directions affects both the coronal and root surfaces, both surfaces should be considered decayed, thus this lesion would be assessed for root and coronal caries.
- A lesion affecting both crown and root surfaces that extends less than 1 mm in either direction, the surface on the side of the CEJ that involves more than 50 percent of the area of the lesion should be scored.
- When it is impossible to apply the ">50 percent rule," i.e., both coronal and root surfaces appear equally affected, both surfaces should be considered "decayed." For restorations, the same rules apply.

Defective margins of fillings with suspicious carious areas should be checked with an explorer for recurrent decay and the criteria for assessing "decayed and filled" root surfaces should be the same as for coronal surfaces, that is, decay takes precedence over a filling. Full crown coverage is considered to have been placed for coronal caries even if the margin of the crown extends on to the root surface. Thus, a root surface with a crown margin free of recurrent decay should be considered sound.

Areas of abrasion or erosion in root surfaces rarely become carious because they are generally kept clean and are free of plaque. Root caries frequently occur beneath plaque, but rarely beneath calculus. Accumulations of plaque, which obstruct the examination procedure, should be removed. Surfaces covered entirely by calculus are considered sound.

Active carious lesions in root surfaces are yellow/orange, tan, or light brown in color. Lesions in remission may or may not be cavitated. They are hardened and tend to be darker, sometimes almost black. When root caries are covered by small amounts of plaque, the discoloration of the lesions usually shows through.

In some incipient lesions the carious area of the root surface may merely be discolored without cavitation, but the area will be soft to exploration. Cavitation with jagged margins and a roughened, but soft floor or base usually occurs in advanced lesions. Normal cementum is softer than enamel, and frequently will yield to pressure from the tip of an explorer. Areas of root caries, however, are softer than surrounding cementum; therefore, it is possible to differentiate sound cementum from carious cementum based on tactile sense. In the presence of root caries, an explorer penetrates the tissue but usually can be removed easily. However, if the explorer penetrates but resists withdrawal or "sticks," the surface is usually sound cementum. With experience and training, it is possible to develop a tactile sense to differentiate sound from carious cementum. Note that for areas without gross cavitation, visual criteria related to location, shape, and discoloration of the suspected area do not, in themselves, define root caries. The tactile criteria of softness to an explorer tip must be met for a definitive diagnosis of root caries to be made.

#### 7.4.4. Guide for Referral and Follow-up

Presence of any root caries flags a computer recommendation telling the participant to see a dentist at his/her earliest convenience (Level 2 recommendation). Levels of recommendation are discussed in detail later in this chapter.

## 7.4.5. Recording Procedures

A maximum of 28 permanent teeth will be examined for each participant. Third molars, or wisdom teeth, are not examined for root caries.

The Root Caries screen consists of two "whole mouth" variables. Space has been provided to indicate whether any root caries or root restorations exist in the Participant's mouth.

If the subject has a need for prophylactic antibiotic coverage, then they shall be excluded from the root caries exam component.

#### 7.5. Periodontal Assessments

The periodontal section includes two parts: measurements to determine the loss of attachment and the identification of bleeding from probing. The objectives of the periodontal disease component of the survey are to:

- Establish age-specific data for the prevalence of periodontal diseases in this sample
- Provide an estimate for prevalence of periodontal diseases using full-mouth measurements
- Provide a basis for comparisons with past and future surveys
- Provide baseline data for possible follow-up
- Provide a basis for studying the association between periodontal diseases prevalence

## 7.5.1. Participant Eligibility for the Periodontal Assessment

The periodontal assessment is performed only on participants without need for prophylactic antibiotics. Periodontal attachment levels and bleeding from probing are assessed on all teeth present, except for third molars. Only fully erupted permanent teeth are scored. Six sites from each tooth are assessed: the distal-facial, the mid-facial, the mesial-facial, the mesial-lingual, the mid-lingual, and the distal-lingual.

## 7.5.2. Examination Procedure

Clinically and quantitatively the loss of attachment is the distance in millimeters (mm) from the cemento-enamel junction (CEJ) to the bottom of the sulcus. The computer program calculates loss of attachment. The examiner takes two measurements per site for use in this calculation. In addition, Bleeding on Probing (BOP), the clinical observation of the presence of blood, after a site has been probed to produce a sulcus (pocket) depth measurement is also scored.

Each surface is dried with air and then examined with a surface reflecting mirror and a periodontal probe. For each site, the distance from the free gingival margin (FGM) to the bottom of the pocket is measured first, then the distance from the FGM to the CEJ is measured. Where the gingival margin is subject to recession and the CEJ is exposed, the distance from the CEJ to the gingival margin is a called a negative value.

The periodontal probe (UNC-12) is graduated in 1 millimeter increments and coded as thin black bands and two thick black bands. The first thick black band represents a probe reading of 4 mm

at the bottom of the band and 5 mm at the top of the band. The second black band is measured as 9 mm at the bottom of the band and 10 mm at the top of the band. The periodontal probe is to be held with a light grasp and pointed toward the apex of the tooth. Each measurement is rounded to the lowest whole millimeter. Six probe measurements will be made on each tooth. The probe measurements from the facial will be taken at the distofacial, facial, and mesiofacial surfaces. The probe measurements from the lingual will be taken at the distolingual, lingual, and mesiolingual aspects.

For the interproximal sites, 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 true facial and lingual assessments are always made at the location of mid-facial and mid-lingual furcation areas, keeping the probe parallel to the long axis of the tooth.

The allowable range for the FGM to CEJ measurement is:

| Code    | Measurement                |
|---------|----------------------------|
| -9 to 9 | Measurement in millimeters |
| +A      | +10 millimeters            |
| +B      | +11 millimeters            |
| +C      | +12 millimeters            |
| =       | Cannot be assessed         |

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

| Code   | Measurement                |
|--------|----------------------------|
| 0 to 9 | Measurement in millimeters |
| Α      | 10 millimeters             |
| В      | 11 millimeters             |
| С      | 12 millimeters             |
| =      | Cannot be assessed         |

The presence of bleeding is assessed after the probing measurements are made. The probed sites for each tooth are examined for bleeding points, and the appropriate score is called for each site at each tooth as follows:

| Code | Level of bleeding              |  |
|------|--------------------------------|--|
| 1    | Bleeding from probing detected |  |
| 2    | No evidence of bleeding        |  |
| =    | Cannot be accessed             |  |

The periodontal assessment is conducted in the following order:

| Examination Sequence                 |           |          |            |
|--------------------------------------|-----------|----------|------------|
| CEJ and Bleeding on Probing Measures |           |          |            |
| Quadrant                             | Direction | Sites    | Then:      |
| Max Right                            | P to A    | Df to Mf | Record BOP |
| Max Left                             | A to P    | Mf to Df | Record BOP |
| Max Left                             | P to A    | DL to ML | Record BOP |
| Max Right                            | A to P    | ML to DL | Record BOP |
| Mand Left                            | P to A    | Df to Mf | Record BOP |
| Mand Right                           | A to P    | Mf to Df | Record BOP |
| Mand Right                           | P to A    | DL to ML | Record BOP |
| Mand Left                            | A to P    | ML to DL | Record BOP |

The sequence to be used to collect periodontal information will begin on the most posterior eligible tooth in the maxillary right quadrant. The examiner will take the disto-facial probe reading from the free gingival margin to the base of the pocket. The CEJ measurement is then taken in the same site. The examiner will then proceed to the mid-facial site on the tooth and take the pocket depth reading followed by the CEJ measurement. Then, the examiner will move to the mesio-facial site and repeat the same measurements. The examiner will continue this process moving anterior tooth by tooth. Once the quadrant is completed, the examiner will return to the most posterior eligible tooth and evaluate each for bleeding. The site will be coded as a 0 for no bleeding and a 1 for bleeding. The examiner then proceeds to the mesio-facial site on the most anterior tooth in quadrant II. The same examination sequence is followed from anterior to posterior. After bleeding on probing is recorded, the examiner then begins on the most posterior tooth in quadrant II on the disto-lingual site. The examination will then continue to quadrant I on the lingual surfaces. The next quadrant examined will be the facials of quadrant III and IV. Lastly, the lingual surfaces of quadrant IV and III are examined.

If a site cannot be assessed, the examiner calls a "=."

#### 7.5.3. Special Considerations

- 1. Calculus at mesiofacial or midfacial 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 "=" 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 "=" by the computer 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 "=" should be used for all designated probing sites of the excluded tooth. If the entire quadrant cannot be scored, the single code of "=" (can not be assessed) should be called and the recorder will enter "=" for each tooth present in that quadrant.
- 8. Implants are excluded from all periodontal assessments.
- 9. Although bleeding from probing is a site-specific call, if blood has pooled from a previously probed site and covered any other site of the same tooth, that site is scored a "1" as well.
- 10. Do not probe primary teeth.
- 11. If the subject leaves and the exam was not completed, then the examiner should use the drop down box for the note log and make a notation. Then each screen that remains empty should be marked as permanently missing. Do this for every screen.

## 7.5.4. Guide to Referral and Follow-up

An examination recommendation for care level must be assigned to each and every Participant by the examiner.

## 7.6. Recommendation for Care Recording Procedure

Recommendation for care is done in two steps. The first step is for the examiner to fill out the two conditions that appear on the END data management system form and to complete the Summary of Oral Health Results Form (preprinted paper form) to hand to the study participant at the completion of the exam. The second step occurs four to six weeks after the exam when complete medical and dental findings are mailed to the participant. In that mailing, the codes that are put into the END form will be automatically translated into a modified Summary of Oral Health Results Form.

#### 7.6.1. Recommendation for Care (END) Screen

The END screen has two Conditions listed with a box after each condition that allows the examiner to record a code based on the exam findings. To access the summary Report of findings, the examiner will click on the "Display Tab" at the top of the page. A drop-down box called "End of Report" will appear that requires the examiner to click on the drop-down box to display a summary of the findings for coronal caries, root caries and periodontal status. The system automatically pulls data from the assessments performed to aid the examiner's professional judgment, and generate a report for the Participant.

The computer creates the summary statements using the following criteria:

- (1) Any coronal caries call triggers a summary statement
- (2) A root decay call triggers a summary statement, and
- (3) A periodontal call for any of the following conditions will generate a summary statement:
  - a. More than 2 sites with a sulcus depth > 4mm, or
  - b. More than 2 sites with a depth from FGM to CEJ  $\leq$  -4mm; or
  - c. More than 1 site has a level of attachment loss  $\geq 4$ mm.

Such conditions include but are not limited to: severe tooth pain, hemorrhage of the oral tissues, acute infectious processes of the oral cavity, traumatic injury to the teeth and surrounding tissues, unusual swelling of the face, gums, or other oral tissue, or oral conditions that obstruct the airway.

The codes to be used to fill in the Conditions boxes are as follows:

| Code | Condition  |
|------|--|
| 1    | No conditions found  |
| 2    | Possible cavities  |
| 3    | Potential gum problems, such as pockets around one or more teeth or loss of bone support for one or more teeth |
| 4    | Suspicious soft tissue lesion in the mouth   |
| 5    | Potentially acute condition  |

## **7.6.2.** Guidelines for Assigning Condition Codes

- If there are no oral conditions noted, the examiner should code Condition 1 as a "1".
- If there is a "caries" finding (coronal or root), then the examiner should code Condition 1 as a "2".
- If there is a periodontal finding, the examiner should code Condition 1 as a "3".
- If there is both a caries and a periodontal finding, then findings are noted in both Conditions boxes.
- A "4" or a "5" code represent conditions that would not normally be part of the examination procedure. However the examiner may see a condition that would warrant such a code. Such conditions include but are not limited to: a suspicious soft tissue lesion, severe tooth pain, hemorrhage of the oral tissues, acute infectious processes of the oral cavity, traumatic injury to the teeth and surrounding tissues, unusual swelling of the face, gums, or other oral tissue, or oral conditions that obstruct the airway.

If a condition warrants a "4" or "5" code, record that code in the Condition 1 box. If there other conditions also present, choose the one considered to be the most severe problem and code it in the second Condition Box.

The examiner should then take the preprinted referral form (Exhibit 7.6.1) and check the appropriate box and may enter comments. The examiner should go over the results of the field examination, and may comment on the tooth number(s) associated with the condition of concern. Since the HCHS/SOL exam is not diagnostic, the examiner does not want to discourage the Participant's dentist from making an independent evaluation.

If the situation warrants it, the examiner may ask HCHS/LOS physician to assume responsibility for the Participant. This would be especially appropriate if an oral condition is discovered with significant medical ramifications (e.g., the examiner notices a suspicious oral lesion). As mentioned above, the realities of dental practice must be kept in mind in making the final choice.

## SUMMARY OF ORAL HEALTH RESULTS FOR SOL PARTICIPANTS

| Participant's name:  | Birth date://  |
|--|--|
| Date of visit to the SOL center://   |  |
| Thank you for participating in the Oral Health examiner did not conduct a complete examinat office and cannot provide you with a diagnosis. examiner may see some obvious conditions that the collection of dental information for this study, i | tion like one conducted in a dentist's<br>However, in some circumstances, the<br>your dentist should check. Based or |
| O 1. You should continue with your rou   | itine dental care as suggested by you  |
| You should make an appointment to visit your der  O 2. possible cavities   | ntist due to:  |
| <ul> <li>3. potential gum problems, such as<br/>teeth or loss of bone support for one or</li> </ul>  | •  |
| You should see your dentist immediately to:  O 4. Have the dentist look at a suspiciou   | s soft tissue lesion in your mouth.  |
| O 5. Evaluate a potentially acute conditio   | n.   |
| Comments:  |  |
|  |  |
|  |  |
|  |  |
| Signature of Examiner  |  |

## 8. POST-EXAMINATION PROCEDURES

- 1. Complete the Dental Examination Screens.
- 2. Return the Participant to the coordinator for assignment to another component.
- 3. Set the room up for the next Participant.

## 8.1. Infection Control after Each Examination

The sequence of procedures for maintaining infection control between Participant examinations is as follows:

- Used instruments will be deposited in the used instrument containers partially filled with the appropriately diluted solution of Restore.
- Soiled adhesive covers, syringe covers, chair covers, and instrument sterilization
  packets must be removed and thrown in the hazardous waste container prior to
  degloving.
- Disposable air tips should be disposed of in the biohazards bag.
- Gloves should be turned inside out as they are removed and thrown into the biohazard bag.
- Reglove and replace adhesive covers, syringe covers, chair covers, and instrument sterilization packets for the next Participant.

#### **8.1.1.** Instruments

All mirrors, explorers, and probes must be sterilized prior to first use and after each use. Having a sufficient number of sterilized instruments available for each examination session is the responsibility of the Dental Examiner. The Examiner must wear Nitrile utility gloves whenever handling used instruments.

To prepare instruments for sterilization:

- If an ultrasonic cleaner is available for cleaning unsterilized instruments, then place the instruments in the cleaner for the manufacturer's recommended length of time. Remove the instruments and rinse them thoroughly. Place them in the instrument cassette and close it securely. Be careful to prevent cutting your hands while scrubbing contaminated instruments.
- If manually cleaning the instruments, then scrub the instruments clean using soapy water with an instrument brush. Rinse the instruments thoroughly. Place them in the appropriate instrument cassette and prepare them for the sterilization container.

#### 9. Dental Examiner Certification

**9.1.** Credential Requirements, Training, Certification & Recertification of Examiners Individuals are required to be credentialed in the following areas in order to be eligible to be a Dental Examiner in this study. Each must have:

- graduated from an ADA accredited dental or dental hygiene program,
- a current regional or state license to practice dentistry or dental hygiene
- a current CPR certification
- completed the IRB ethics training
- a yearly negative TB test

The training component for the Dental Examiners is composed of two sections: certification with the Reference Examiner plus a verification of exam scores completed on practice subjects. A site visit to will be conducted by the Reference Examiner within two months after exams have started to observe each Examiner to ensure the study protocol is being followed. The Dental Examiners will be responsible for conducting the dental examination and any follow-up dental/periodontal evaluations. For all measurements and indices to be utilized in the study, the Dental Examiners are certified to ensure adequate agreement with the Reference Examiner and inter-examiner agreement among each other (see QC MOPl for details). Only Examiners who have been certified and reached the stipulated level of examiner agreement can undertake HCHS/SOL dental examinations.

#### 9.1.1. Certification

Each examiner will attend a three day central training that includes a review of the study protocol and dental indices as well as examining several subjects for the purpose of ensuring agreement with the Reference Examiner and other examiners. The examiners will also be trained on the use of the DDES. Specific details for the exam procedures are described in the QC MOP. The specific central training schedule is included in the Appendix.

## Day 1

The examiners will have reviewed the exam protocol and indices prior to attending the training. The training will begin with a general overview of the study. The Reference Examiner will then present each step of the exam and indices using a Powerpoint presentation with explanatory slides and specific examples of each oral condition to be scored. Models and probes will be used to demonstrate the correct placement and reading of the probe for pocket depth and CEJ measurements. Examiners will demonstrate the correct placement on the model. The training material will be presented in an informal setting and clarification questions can be asked at any time

The Examiners will then have an opportunity to practice the exam indices, sequence, and protocol on a practice subject. Following this session, the Examiners will have an opportunity to discuss any questions that occurred during the practice session. During the lunch session, a presentation of the DDES will be reviewed.

In the afternoon, each Examiner and the Reference Examiner will examine six subjects that have a variety of restorations and carious lesions. These exams will be for tooth status, restorative materials, and caries only. Disagreements between the examiner and standard examiner will be reviewed immediately with the correct call discussed. At the end of the day, an opportunity will be provided to examiners to discuss any questions they may have. During the afternoon session, each examiner will have an opportunity to perform as a recorder and ask questions as needed.

#### Day 2

Ten subjects with periodontal disease (light to moderate) will be scheduled (5 in the morning and 5 in the afternoon). Each examiner will conduct the periodontal exam only (probing, CEJ, and BOP). The Examiners will be paired to the Reference Examiner on six subjects. In addition, each Examiner will be paired with each of three other Examiners. Again, the agreement scores will be immediately assessed and the Reference Examiner will review any discrepancies while

the subject is present. The probing score agreement will be within 1 mm. Examiners must achieve a minimum level of 90 percent agreement.

## Day 3

An additional 10 subjects with light to moderate periodontal disease will be scheduled. Each examiner will have an opportunity to examine each subject performing the entire exam. These exams will be matched with the Reference Examiner. Discrepancies will be identified immediately and discussion will occur while the subject is present. An agreement level between the Reference Examiner and the Examiner must minimally be 90%. An opportunity for discussion will occur at the lunch session and end of the day.

#### Return to Field Center

Once the examiner returns to the field site, each examiner will examine five practice subjects and submit the recorded data to the coordinating center within four weeks. The data will be reviewed and the examiner certified if the data are acceptable. A pilot study of 10 subjects will then be conducted by the site. This will be completed prior to the projected start date of November 1. After certification and completion of the pilot study, the examiner will begin the exams on study subjects. Within two months, the Reference Examiner will visit the site and observe the examiner conducting an exam on a study participant. The Reference Examiner will submit a monitoring report to the Coordinating Center based on the site visit.

## 9.1.2. Re-certification and re-training

Each Examiner will be retrained and recalibrated annually to maintain a high standard of reliability. The Examiner will conduct replicate exams with the Reference Examiner to determine examiner drift that may have occurred over the year. As indicated by the drift results, retraining is then focused to correct any misinterpretation of the indices. The Reference Examiner and Examiner will conduct replicate exams on six subjects achieving an agreement level of 90%.

9.2. Training and Certification Requirements for Dental Data Entry System (DDES) The DDES was developed by the CC and is based on one created at the UNC Dental School. Most of the examiners in HCHS/SOL will be unfamiliar with this program. Though many will be experienced with other periodontal examination data entry systems, the data field ordering, naming conventions, and nomenclature are not always standard. Data entry of a periodontal exam requires synchronization and communication between the examiner and the recorder in order to provide quality assurance of data, and to reduce examination time considerably. Practice sessions during the training will provide familiarization with the system, and allow piloting of the HCHS/SOL forms and procedures prior to the study start. These practice sessions are required as certification for Examiners and Recorders in HCHS/SOL.