CHAPTER 8

MEDICAL HISTORY AND PHYSICAL EXAMINATION

8.1 Medical History

8.1.1 Introduction

A medical history is taken annually in DISC for the following purposes:

1. To ascertain whether the participant is eligible for DISC.
2. To obtain basic medical information concerning the participant and his/her family, including information on risk for cardiovascular events.
3. To obtain pertinent, integral medical information during the course of the study.

8.1.2 Baseline Medical History

The DISC baseline medical history is taken in parts. At Screening Visit 1 (SV1) information pertinent to eligibility criteria are collected using the Screening Visit 01 Form (Form 01) and the Screening Visit 01 Summary (Form 02). At Screening Visit 2 (SV2) additional information on the medical history is collected using the Parent/Guardian Information Form (Form 07) and the Child History Form (Form 08).

8.1.2.1 Screening Visit 01 Form (Form 01)

Screening Visit 01 Form is a self-administered form to be completed by parents/guardians of potential DISC participants prior to SV1. Parts II and III of the form ascertain information on the child's medical history related to DISC exclusion criteria. Questions attempt to identify children who:

1. Have diseases that affect growth or cause secondary hyperlipidemia.
2. Take medications that affect blood lipids or iron nutrition.
3. Have physical or mental handicaps that could affect their ability to participate fully in DISC.

Item 9 of Form 01 asks about diseases which are DISC exclusion criteria. Since families sometimes do not know the full medical name for their children's ailments, multiple names for certain conditions are given. It is important to be certain that any "Yes" answers to item 9 in fact represent the presence of a disease which is a DISC exclusion criterion (see Chapter 3 for specific exclusion criteria).

Item 10 asks about sudden changes in weight and may reflect the presence of bulimia and anorexia if positive.

Item 11 asks about hospitalizations and operations. It provides another opportunity for parents/guardians to recall and provide information on diseases that are DISC exclusion criteria. Additionally, information on other medical conditions will be ascertained.

Items 12 and 13 ask about school absence. Specifically, item 12 asks about usual frequency of absence. Any child who is <u>usually</u> absent from school $\geq$ 2 times per week is not eligible for DISC because it is indicative of a chronic problem that could interfere with the child's ability to participate fully in intervention in DISC. Item 13 is concerned with recent absences. The response to this question may reveal information about exclusion criteria not offered elsewhere. Additionally, the response to this question may indicate another problem not specified in DISC eligibility criteria that the screener feels should make the child ineligible.

Item 14 elicits information on the presence of handicaps which, if present, would result in the child not being eligible for DISC because it would make it difficult for him/her to participate in the intervention. For example, if the child is blind he/she will not be able to understand written intervention materials and, therefore, the child would not be eligible for DISC.

Item 15 lists medications which are either DISC exclusion criteria or are used to treat illnesses which are exclusion criteria. Commonly used drug names (trade and generic) are listed. These lists are not exhaustive, particularly with regard to steroids and lipid-lowering medications. Any use of steroids other than intermittent topical therapy for skin rashes is an exclusion. Similarly, any use of lipid-lowering medications is an exclusion. Please review all medications brought to SV1 and all medications listed by the parents to make certain an exclusion criteria for medications is not met. If you are not certain about what is in a specific medication, refer to the Physicians Desk Reference.

Item 16 asks about medications used intermittently. This question is specifically designed to uncover use of medicines such as steroids and retinoids which may have been used in the past but are not used now.

Items 19 and 20 are aimed at ascertaining information on mental or behavioral problems that may affect a child's ability to participate in intervention. Item 19 asks if the child has repeated two or more grades; these children will not be eligible for DISC. Item 20 asks about participation in special education classes. The type of special education needs to be obtained because children in accelerated programs for the gifted and talented will be eligible whereas children in classes

for the mentally handicapped, learning disabled or with behavior problems will be excluded.

8.1.2.2 Screening Visit 01 Summary (Form 02)

The Screening Visit 01 Summary is completed by an interviewer certified in taking a medical history. Items on the form pertinent to the medical history are Items 3, 4, 10, 11, 12. Answers to these items should be provided after reviewing Form 01 with the child's parent/guardian. Item 3 refers to Form 01 item 9, and asks you to identify any medical conditions the child might have which would make him/her ineligible for DISC. Refer to Chapter 3 for specific exclusion criteria. Item 4 is concerned with exclusion medications, and again, any ineligible medications should be checked. It is important that all parts of Item 3 and 4 be answered with check marks. Items 10-12 relate to school and correspond to items 12, 14, 19 and 20 on Form 01.

8.1.2.3 Parent/Guardian Information Form (Form 07)

The Parent/Guardian Information Form should be completed by a parent/guardian who is living with the child and returned to the clinic at SV02. Data collected on the form are primarily demographic; however, some medical history data are also included. Items 3, 4 and 5 ask for the presence of heart disease and risk factors for heart disease in the child's biologic or natural family. Items 9 and 12 ask for information on vital status and age of biologic parents. These questions relate only to genetically related parents and family members.

8.1.2.4 Child History Form (Form 08)

The Child History Form should be privately administered to the child at SV2. Items 3, 4 and 5 should be asked exactly as they are written on the forms. The purpose of these questions is to determine if

other risk factors for heart disease -- specifically cigarette smoking and oral contraceptive use -- are present, and if the child might have significant behavior problems which would impair his/her ability to participate in DISC.

The Form 01 checklist of the child's medications provided by the parent should be in hand when interviewing the child about medication usage. The child should be questioned about significant discrepancies between the list and the parent's list. The interviewer should not discuss any discrepancies with the parents/guardians since it is crucial that the child be assured that the information he/she has provided is confidential and will not shared with the parents/guardians. In extreme circumstances where the child reports a drug or alcohol usage that could be extremely harmful to his/her health, it may be necessary to inform the parents/guardians.

8.1.3 Annual and Final Visit Medical History

At annual and final follow-up visits, participant medical history is taken from a parent using the Child Medical Information Follow-up Form (Forms 15 and 68), and from the participant using the Child History Form (Forms 08 and 67) as well as questions on annual visit summary forms (Forms 28, 39, 56, 65, 66). Medical history information is collected from the participant in a private setting with no parents present.

In addition to routine questions on medical events and medications, beginning at 12 months female participants and their mothers are asked if the participants have started their menstrual periods and the date of their first period. Starting at 36 months, female participants and their mothers are asked for information on participant pregnancy and contraceptive use. Clinic personnel introduce these subjects to

participants and their parents in ways designed to be inoffensive. Beginning at the Year 7 annual examination, questions on pregnancy will be expanded to include information on expected due date or date the pregnancy ended. Questions on contraceptives will be expanded to include methods such as Norplant or contraceptive injections.

Final visit medical history is collected from participants using the Form 67, Participant Medical History, and from a parent using the Participant Medical History Follow-up Form 68. Parents are asked to report the participant's weight at birth after checking their personal records before the visit. They are also asked to bring the participants' birth certificate to the final visit in order to verify their recollection. If a parent does not accompany the participant to the final visit, the Form 68 will be mailed or completed by phone interview.

8.2 Physical Examination

8.2.1 Introduction

A physical examination is being performed in DISC for the following purposes:

1. Assure the general health of the participant.
2. Exclude the presence of acute infection which could confound data analysis.
3. Exclude the presence of physical findings associated with exclusion criteria at baseline.
4. Subsequent annual physical examinations on DISC study children are intended to assess their general physical health, and provide a setting for the assessment of growth and maturation during the course of this study.

Information from the physical examination will be recorded on the Physical Examination Form (Form 06) at baseline and 12 months. Information from annual physical examinations will be recorded on the Stature-Maturity Form (Forms 26 and 29). After participants have reached Tanner stage 5, maturation staging will no longer be performed and the participant physical exam is optional.

Physical examination data are of two types: dichotomous responses regarding the presence or absence of a specific findings and open ended comments. The dichotomous responses are for the study data analysis. The comments are for recording specific abnormal findings for the Clinical Center's records. For example, if an otitis media is diagnosed, it would be useful to record this as a comment for follow-up purposes. Thus, the physical examination must include all data to be collected as part of the study but is not limited to that data.

The examination should be performed by either a Pediatric Nurse Practitioner, a Child Health Associate or a Pediatrician. Whenever possible, the examiner should remain the same for each participant throughout the study and, if feasible, he/she should be the same gender as the study participant.

During this study participants will present with acute illnesses, such as otitis media, pharyngitis and asthmatic bronchitis. Children with acute illnesses (particularly at SV2) should have data collection visits rescheduled. Participants with chronic problems such as scoliosis, an inguinal hernia, or a significant heart murmur, may require evaluation, treatment and/or follow-up and should be referred to their usual health care providers.

8.2.2 General Instructions

Generally, participants in the DISC age group are easy to examine and cooperative. Physical examinations should be brief but complete, lasting approximately 10-15 minutes. The examination should be performed by either a Pediatric Nurse Practitioner, a Child Health Associate or a Pediatrician. Whenever possible, the examiner should remain the same for each participant throughout the study and, if feasible, he/she should be the same gender as the study participant.

During the examination it is important to establish rapport with the participant because he/she will either be examined or have blood drawn as part of the study several times. A few good rules to follow in approaching a participant in this age group are:

1. Engage the participant directly in conversation to develop a true examiner-patient relationship.
2. Begin the examination with the abdomen, then the chest, then the head and neck, then the extremities. Leave the Tanner staging for last.

8.2.3 Specific Instructions

With the participant undressed except for underpants and gown, the physical examination should proceed as follows:

1. General appearance: Observe whether the participant is well or ill appearing, alert or lethargic, generally fit or unfit appearing.
2. Skin: Specifically inspect and feel the skin for xanthomas along the tendon sheaths (especially the achilles), the creases of the palm, the extensor tendons of the hand, and extensor surfaces of the elbows. Look for eczema, follicular hyperkeratosis or other skin abnormalities.

3. Ears: Look for any evidence of active disease in the external auditory canal or middle ear.

4. Nose: Examine the nose for rhinorrhea or epistaxis.

5. Mouth: Observe the lips for any evidence of angular scars or cheilosis. Notice if the tongue shows glossitis, magenta color or atrophy of the papillae. Examine the pharynx for evidence of pharyngitis. Check for tonsillitis, ulcerations in the buccal mucosa and gingivitis.

6. Eyes: Observe for the presence of xanthelasma and arcus cornea (a grayish white arc partially or totally circling the cornea). Examine for abnormalities of the lids, conjunctivae, pupils and look for corneal xerosis. Briefly examine the fundi in a darkened room and note the presence of lipemia retinalis.

7. Neck: Observe for enlargement of the thyroid by asking the child to hyperextend the head and swallow. Palpate for enlarged cervical, submental or submandibular lymph nodes and a palpably enlarged thyroid.

8. Lungs: Perform a brief auscultation over the lung fields noting an increased expiratory phase or the presence of rhonchi, wheezing or rales. A diagnosis of asthmatic bronchitis or pneumonia should be noted.

9. Heart: Observe and palpate the apical impulse with the child sitting and leaning forward. Palpate the precordium for a cardiac thrill. Briefly check the carotid, brachial and radial pulses. Listen for abnormal heart sounds over the mitral, pulmonic and aortic areas. Note any murmurs and describe them according to the intensity, quality, position in

the cardiac cycle and location of maximum intensity. Indicate a suspected anatomic and ideologic diagnosis.

10. Abdomen: Palpate the abdomen for organomegaly or masses. Check axillary and inguinal areas for adenopathy. Examine for the presence of umbilical or inguinal hernias and check femoral pulses.

11. Genitalia:

    Males: Refer to Chapter 9 on Tanner staging for pubic hair and genital development.

    Females: Refer to Chapter 9 on Tanner staging for pubic hair and breast development.

12. Back: With the patient standing sideways, note presence of accentuated lordosis or kyphosis. Observe back for prominent scapula, shoulder asymmetry and unequal hips. With patient's feet together and hands together, and without bending the knees, observe the back for rotation of the spine while the patient is bending forward with arms hanging as if in a diving position. Have patient forward bend away from the examiner and toward the examiner. Record rotation of the spine as mild, moderate or severe. If rotation if present, check the leg length for difference using a tape measure and measuring from the anterior iliac spine to the medial malleolus.