



National Health and Nutrition Examination Survey (NHANES)

National Youth Fitness Survey (NYFS)
Nurse Review Program Manual



January 2012

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1. NURSE REVIEW APPLICATION

1.1 Nurse Review Application Overview

The overarching concern for the study participants in the youth fitness survey is to assure that all physical activities are safe for the children who are recruited into the study. The Nurse Review (NR) application was developed to support safety and reporting procedures with the following functionalities:

1. Provide the nurse practitioners with a comprehensive application in which to administer safety exclusion and component screening questionnaires with the parent or guardian. The exclusion questions are designed to identify conditions that will result in an exclusion from any of the following exams: treadmill, gross motor skills, plank, pull-up, grip strength, physical activity monitor, and lower body muscle strength (see Chapter 2).
2. Review the medications and health history information obtained during the home interview.
3. Give the nurse practitioners an opportunity to review and verify that all the exams are safe and appropriate for the National Youth Fitness (NYFS) staff to administer.
4. Allow the nurse to print a provider referral letter with comments if any clinical findings were discovered during any of the exams (see Chapter 3).
5. Provide a platform in which to document incidents and emergencies (see Chapter 4).

1.2 Introduction to the Nurse Review Program

This section provides an introduction to the Nurse Review Program and general guidelines for navigating through the interview. The menu items are located at the top of the Nurse Review window and can also be accessed from the toolbar buttons as defined in Exhibit 1-1 and Table 1-1. Dimmed toolbar buttons are not available for the window or pane that is currently active.

Exhibit 1-1. Nurse Review menu and toolbar options

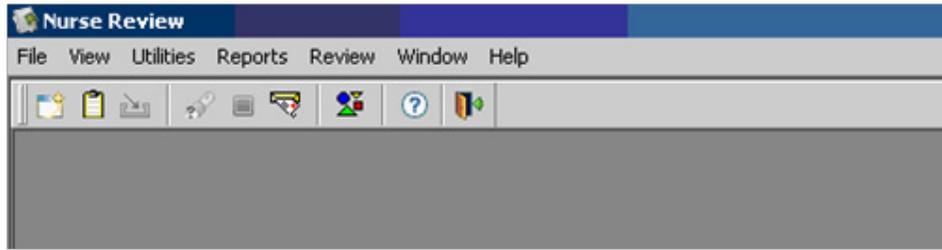


Table 1-1. Toolbar icons

| Icon | Corresponding menu commands: |
|---|--|
|  | File\ Open |
|  | File\Review |
|  | File\Close |
|  | Utilities\Exam Pause |
|  | Utilities\Send Message |
|  | Customizes toolbar buttons (rarely if ever needed) |
|  | Displays program help |
|  | File\Exit |

1.3 File Menu

The File menu (Exhibit 1-2 and Table 1-2) is the same as those found in other NYFS applications.

Exhibit 1-2. File drop-down menu

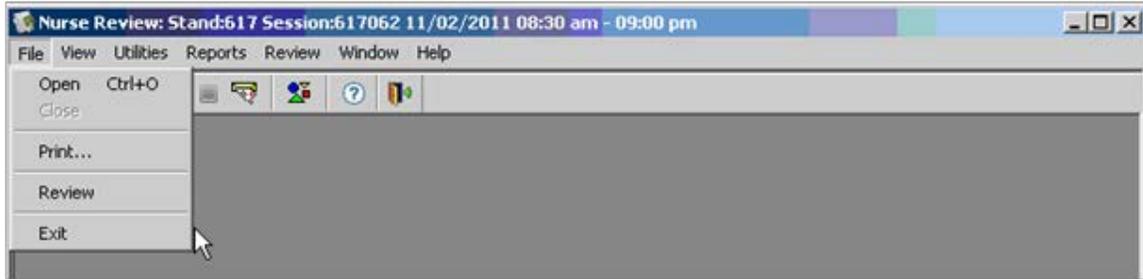


Table 1-2. File menu options

| | |
|---------------|--|
| Open | Opens a new Nurse Review safety exclusion interview; brings up the sample person logon window |
| Close | Closes the current exam the user is logged into |
| Print | Prints the current page |
| Review | Allows the user to review only completed Nurse Review safety exclusion interviews for that session in a read-only format |
| Exit | Closes the Nurse Review application |

1.4 Utilities Menu

Exhibit 1-3. Utilities drop-down menu

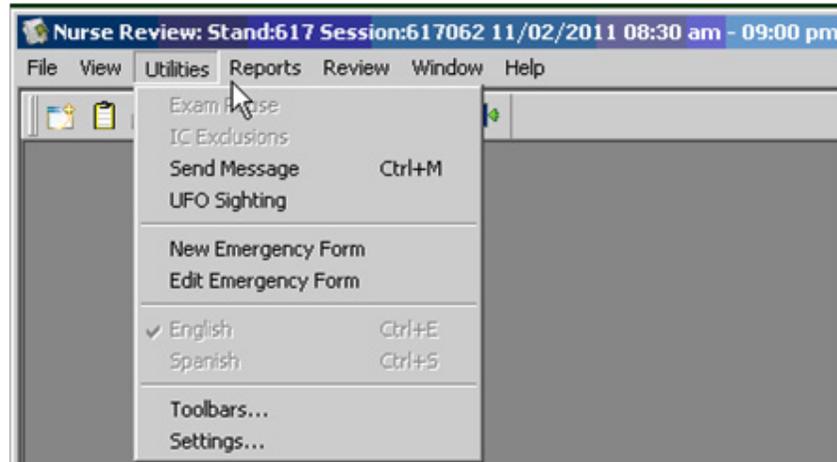


Table 1-3. Utilities menu options

| | |
|---|--|
| Exam Pause | This pauses the exam temporarily to stop the exam timer; when the user selects this, a message to the coordinator is sent (exam paused). This should also be used in case of an emergency in the MC if the nurse is in the process of conducting a Nurse Review interview. |
| IC Exclusions | Inactive functionality |
| Send Message | This function allows the nurse to send a message to the coordinator. |
| UFO Sighting | This feature allows the user to document any unusual occurrence that is observed during the operation of a stand. All MEC staff use the UFO utility to document issues relating to equipment, software, protocols, SPs, trailer facility, supplies, and inventory. |
| New Emergency Form and Edit Emergency Form | Select this utility when documenting a new Incident/Emergency Form. Refer to Chapter 4. Additional or followup information may be added to an existing Incident/Emergency Form using this utility. |
| English/ Spanish | The default setting for language is English, but this utility allows the user to switch between English and Spanish. The nurse, when using an interpreter for a Spanish-speaking SP, will switch the application to Spanish for the interpreter's benefit. |

1.5 Reports Menu

To preview a list of SPs in the current session, select “Reports” from the toolbar and select the appropriate session (Exhibits 1-4 and 1-5). The “Session Preview Report” displays a list of SPs in the current session. The ID, SP Type, SP Name, Age, Gender, Special Considerations, and Consent Comments are displayed. This report provides information about special needs or consideration for each SP, such as wheelchair used for mobility, disabilities, and consent issues.

Exhibit 1-4. Reports drop-down menu

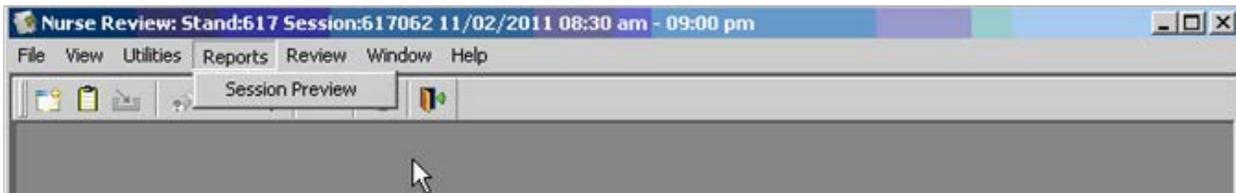


Exhibit 1-5. Session preview report

A screenshot of the "Session Preview Report" window in the Nurse Review application. The window title is "Nurse Review Stand:291 Session:291059". The report title is "Session Preview Report" with a subtitle "Stand: 291" and a timestamp "12/27/11 11:15". The report content is a table with the following data:

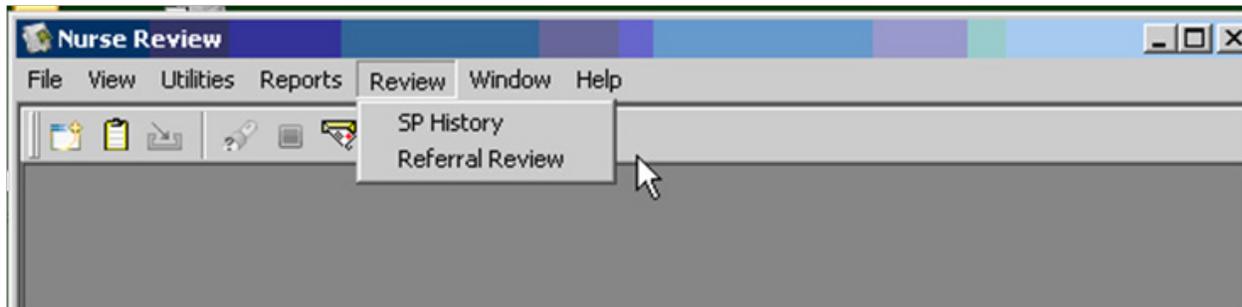
| Session: | SP | SP Type | SP Name | Age | Gender | Special Considerations |
|-------------------|--------|---------|-------------------------|----------|--------|------------------------|
| 291-02-2009-01-08 | 671246 | Partial | SP8 T1 | 15 years | Female | |
| 291-02-2009-02-05 | 915437 | Primary | ALICE WONDER | 5 years | Female | |
| 291-02-2009-02-06 | 239428 | Primary | SAMUEL CLEMENS | 6 years | Female | |
| 291-02-2009-02-07 | 647396 | Primary | WILLIAM RANDOLPH HEARST | 7 years | Male | |
| 291-02-2009-05-02 | 635903 | Primary | SP2 T5 | 12 years | Male | wC |
| 291-02-2010-03-01 | 440932 | Primary | JUSTIN BIEBER | 15 years | Male | |
| 291-02-2010-03-02 | 563754 | Primary | SPONGEBOB SQUAREPANTS | 11 years | Male | |

The report is on "Page 1 of 1". The status bar at the bottom shows "Ready", "MEC Layer: 11/17/2011", "Application: 10.0.5", "Connected to Coordinator", "SP not assigned to room", and "11:14 AM".

1.6 Review Menu

The Review menu (Exhibit 1-6) contains two functions: (1) SP history and (2) Referral Review.

Exhibit 1-6. Review drop-down menu



1.6.1 SP History

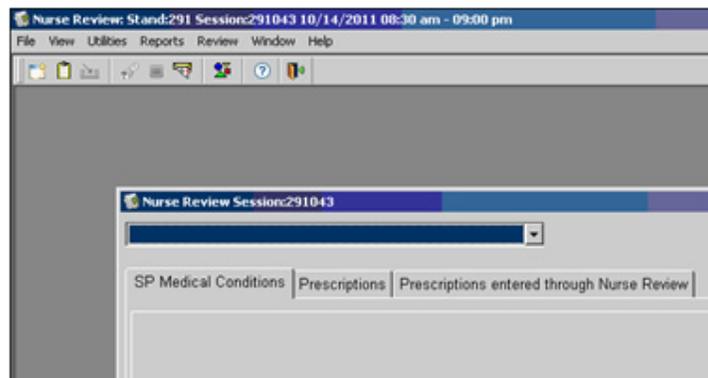
To access “SP History,” select “Review” from the toolbar and then choose “SP History.” (See Exhibits 1-7 and 1-8.) Medical conditions and medications reported during the home interview for all SPs in the session can be reviewed under “SP History.” The nurse may review the data in the SP History at any time during the session, and especially at the start of the day before the SPs arrive.

The responses to the following questions from the home interview populate the SP History screen:

- Has a doctor or other health professional **ever** told {SP} that {SP has} asthma?
- {Does SP} still have asthma?
- During the **past 12 months**, {has SP} had an episode of asthma or an asthma attack?
- During the **past 3 months**, {has SP} taken medication prescribed by a doctor or other health professionals for asthma?
- Have {SP's} periods or menstrual cycles started yet?
- How old was {SP} when she had {her} first menstrual period?

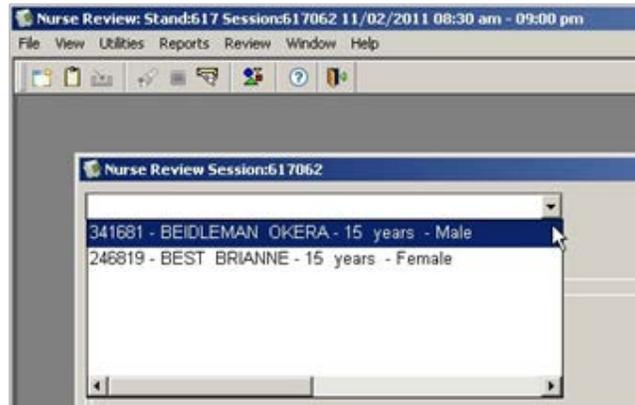
- {Has SP} **ever** been told by a doctor or other health professional that {s/he/SP} has diabetes or sugar diabetes?
- How old {was SP} when a doctor or other health professional **first** told {him/her} that {s/he} had diabetes or sugar diabetes?
- {Has SP} **ever** been told by a doctor or other health professional that {SP has} any of the following: pre-diabetes, impaired fasting glucose, impaired glucose tolerance, borderline diabetes or that {your/her/his} blood sugar is higher than normal but not high enough to be called diabetes or sugar diabetes?
- {Is SP } **now** taking insulin?
- {Is SP/} **now** taking diabetic pills to lower {{his/her}/your} blood sugar? These are sometimes called oral agents or oral hypoglycemic agents.
- In the **past 12 months**, has {SP's} chest sounded wheezy during or after exercise or physical activity?
- During the **past 12 months**, how much did {SP} limit {his/her} usual activities due to wheezing or whistling?

Exhibit 1-7. SP History screen



A drop-down menu allows access to all SPs from the current session only. Two tabs appear on the screen—SP Medical Conditions and Prescriptions. Medical conditions include reported illnesses. The Medications tab displays only those medications that were reported during the home interview.

Exhibit 1-8. SP History drop-down menu to select SP from current session



Each SP's ID number, name, age, and gender is displayed. Highlight the name of the SP to view the medical conditions and medications.

Exhibits 1-9 and 1-10 show no data available under SP Medical Conditions and Prescriptions tabs. Please note that these two screen shots reference the Physician application and not the Nurse Review application, but the functionalities are the same.

Exhibit 1-9.
No data available under SP Medical Conditions tab

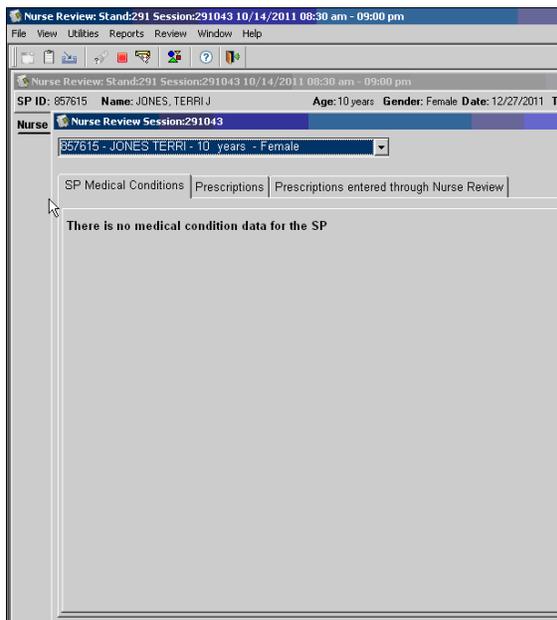
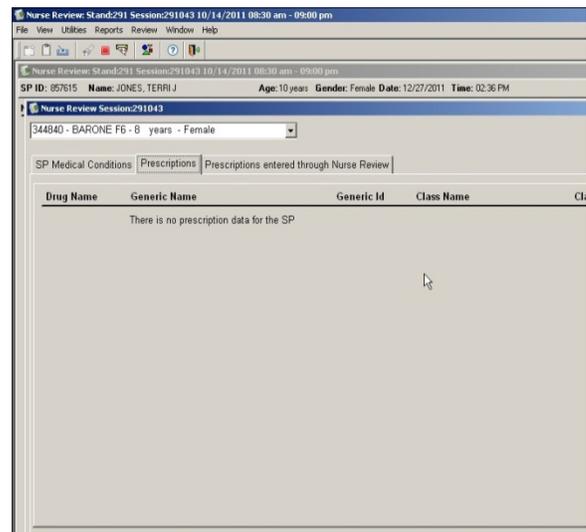


Exhibit 1-10.
No data available under Prescriptions tab



Switch between the tabs to review medications and medical conditions. If no medications or medical conditions have been reported, the screens will indicate this to alert the user that the application is functional, and that the screen is blank because nothing was reported during the interview.

Exhibit 1-11 below illustrates the appearance of a medical condition and menarche response, and Exhibit 1-12 illustrates the appearance of reported medications.

Exhibit 1-11. SP History medical data appearance

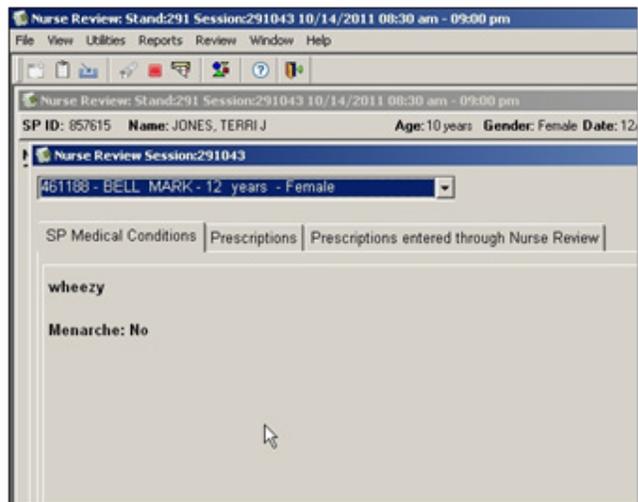
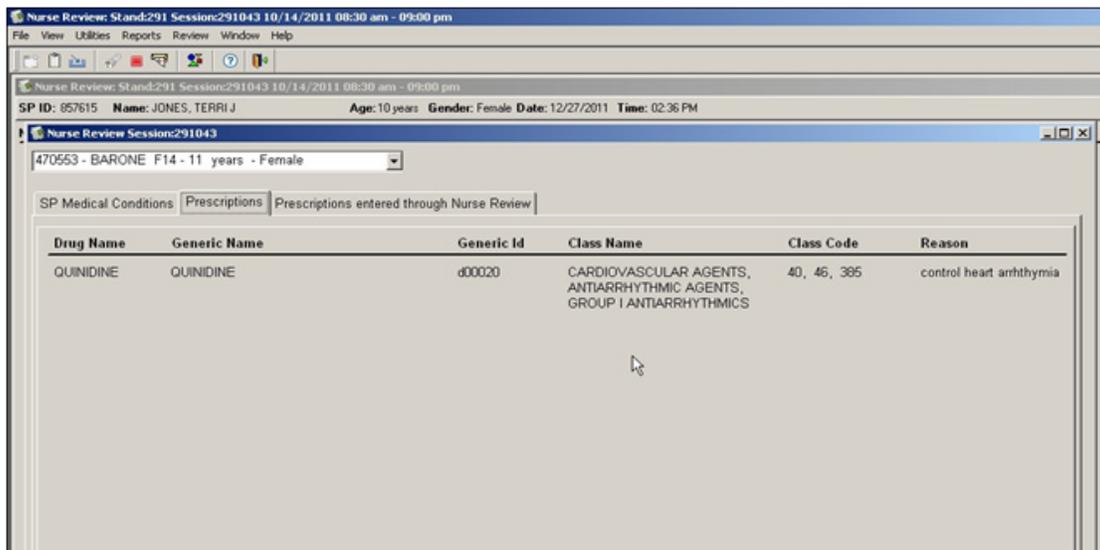


Exhibit 1-12. SP History reported medications during home interview



It is important to bear in mind that the field interviewers who gather this information record only the medication information provided by the SP, and the indication for the medication as the SP understands it. Therefore, if the nurse observes a medication and has any further questions about the medication, the nurse may ask the SP during the Nurse Review interview. If the parent/guardian reports a new medication during the Nurse Review interview, it will appear under the tab, “Prescriptions entered through Nurse Review.” See Exhibit 1-13 below:

Exhibit 1-13. SP History reported medications during Nurse Review

The screenshot shows the 'Nurse Review' application window. At the top, it displays the session information: 'Nurse Review: Stand:291 Session:291043 10/14/2011 08:30 am - 09:00 pm'. Below this, the patient information is shown: 'SP ID: 057615 Name: JONES, TERRI J Age: 10 years Gender: Female Date: 12/27/2011 Time: 02:36 PM'. The main area has three tabs: 'SP Medical Conditions', 'Prescriptions', and 'Prescriptions entered through Nurse Review'. The 'Prescriptions entered through Nurse Review' tab is active, displaying a table with the following data:

| Drug Name | Generic Name | Generic Id | Class Name | Class Code | Reason |
|-----------|--------------|------------|---|-------------|-----------|
| QUINIDINE | QUINIDINE | d00020 | CARDIOVASCULAR AGENTS, ANTIARRHYTHMIC AGENTS, GROUP I ANTIARRHYTHMICS | 40, 46, 385 | test meds |

1.6.2 Referral Review

The referral process is fully automated and supported by the Nurse Review application and the coordinator application. The referral protocol is presented in detail in Chapter 3.

2. NURSE REVIEW SAFETY EXCLUSION REVIEW

2.1 Introduction to Nurse Review Safety Screening Interview

All SPs and their parents or guardians must undergo the Nurse Review (NR) interview before proceeding to any physical activity exams. The Nurse Review application is available on any workstation; however, bear in mind that these questions are confidential in nature and that the respondent's confidentiality must be protected. The NR safety exclusion interview consists of five sections:

1. **Nurse Review Questionnaire** – The Safety Exclusion Questionnaire consists of a series of questions designed to capture all exclusion and screening criteria for the following physical activity exams: gross motor skills, treadmill, modified pull-up, plank, muscle strength (grip strength), and lower body muscle strength. This questionnaire is administered in a Blaise program format that appears differently from the other portions of the NR program.
2. **Muscle Strength Screener Questionnaire** – The parent/guardian of the study participant is asked a series of questions to determine if he or she should be excluded from parts of the exam and to collect information on items that may influence the results. These responses are transferred and displayed in a read-only format into the muscle strength exam application.
3. **Nurse Component Status Review** – This screen displays the status, i.e., if excluded/not excluded, from the physical activity components based on the responses to the above two questionnaires. It also transfers in the response to the question, “*Has a doctor said {SP Name} CURRENTLY should not participate in sports or other physical activities because of a health condition?*” If the parent/guardian names a health condition other than a heart condition, this response is imported into this screen. The nurse will review this condition for exclusion from the treadmill based on specific clinical guidance. The nurse will also have an opportunity to assess all the exams that have not been excluded from the questionnaires, and based on professional judgment, exclude other components at this screen.
4. **Critical Data Item Verification** – The nurse will review the street address, mailing address, and phone number with the parent/guardian.
5. **Exam Status Screen** – This final screen tabulates the data collected from the Nurse Review application, and communicates the status of each exam to the coordinator and relevant exam applications. When the application is completed and the “Finish” button is pressed, a Study Participant Information Sheet (Exhibit 2-1) is automatically printed. This hard-copy information sheet lists all exams for which the SP is eligible, and the exam status. This form follows the SP through the mobile center (MC) to each exam.

Exhibit 2-1. Study Participant Information Sheet

| NHANES National Youth Fitness Survey | | | |
|--|---------------------------|---|----------|
| Study Participant Information Sheet | | | |
| Date: | 2/21/2012 |  | |
| SP ID: | 751547 | | |
| Name: | Terence Patty | | |
| Age: | 11 | | |
| Component | Comments and Observations | | Examiner |
| <input type="checkbox"/> Nurse Review | complete | | |
| <i>Albuterol Inhaler taken during NR Interview at 10:20AM.</i> | | | |
| <input type="checkbox"/> Body Measures | complete | | |
| <input type="checkbox"/> Grip Strength | | | |
| <input type="checkbox"/> Lower Body Muscle Strength | | | |
| <input type="checkbox"/> Plank | | | |
| <input type="checkbox"/> Pull-Up | | | |
| <input type="checkbox"/> Treadmill | | | |
| <input type="checkbox"/> Dietary | complete | | |
| <input type="checkbox"/> Physical Activity Monitor | | | |

2.2 Nurse Review Questionnaire

The first section of the safety exclusion questionnaire is programmed in a questionnaire format (Table 2-1). A series of questions have been designed to detect any condition that would disqualify an SP from an exam based on a safety exclusion concern. Below are the questions and the conditions that lead to exclusions.

Table 2-1. Nurse Review Screening and Safety Exclusion Questionnaire

| Screening and Safety Exclusion Questionnaire | | | |
|--|-----------|---|---|
| Question | Age Range | Response | Exclusion Criteria |
| <p>Is (<u>SP NAME</u>) pregnant?</p> <p>Girls ages 8-11 years who are menstruating and all girls 12-15 years.</p> <p>Parents/guardians of girls 8-11 years will be asked in the household interview if the participant had started menstruating, and if Yes, when she began.</p> | 8–15 | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/> Ref. | <p>If Yes, Refused, or Don't Know, exclude from:</p> <ul style="list-style-type: none"> ➤ Treadmill, ➤ Lower body muscle strength, ➤ Modified pull-up, and ➤ Plank. |
| <p>Ask the SP separately from the parents. If the girl is between the ages of 8–11, and the girl has undergone menarche, this will be noted in the SP history section. Make sure to review the SP history section for each session.</p> | | | |
| <p>2. Is the participant in a wheelchair (Observation only)?</p> | 3–15 | <input type="checkbox"/> Yes <input type="checkbox"/> No | <p>If Yes, exclude from:</p> <ul style="list-style-type: none"> ➤ Treadmill, ➤ Lower body muscle strength, ➤ Modified pull-up, and ➤ Gross motor skills components. |
| <p>SP must be able to transfer from the wheelchair to another seat with minimal assistance; do not ask SP to transfer if she or he is non-weight bearing.</p> | | | |

Table 2-1. Nurse Review Screening and Safety Exclusion Questionnaire (continued)

| Screening and Safety Exclusion Questionnaire | | | |
|--|-----------|--|---|
| Question | Age Range | Response | Exclusion Criteria |
| 3. Has a doctor said _____ (<i>SP NAME</i>) currently should not participate in sports or other physical activities because of a health condition? | 3–15 | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If Refused or Don't Know, exclude from: ➤ Treadmill |
| 3a. Specify Condition | 3–15 | | If the participant has a heart condition, he or she will be excluded from the treadmill component. The nurse practitioner will determine if the participant will be excluded from any other components based upon the condition. |
| <p style="text-align: center;">Clinical guidance on how to assess the health condition is found in the section that covers the Nurse Component Status Review screen in Section 2.4 of this chapter.</p> | | | |
| 4. Have any of (<i>SP NAME</i>)'s close biological relatives, that is, blood relatives including grandparents, father, mother, sisters or brothers, died of heart problems or sudden death before the age of 35? | 6–15 | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If Yes, Refused, or Don't Know, exclude from: ➤ Treadmill |
| 5. Does (<i>SP NAME</i>) have any amputations other than toes? | 3–15 | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If Yes, Refused, or Don't Know, exclude from: ➤ Modified pull-up, ➤ Plank, and ➤ Gross motor skills. |

Table 2-1. Nurse Review Screening and Safety Exclusion Questionnaire (continued)

| Screening and Safety Exclusion Questionnaire | | | |
|--|-----------|---|--|
| Question | Age Range | Response | Exclusion Criteria |
| 5a. Where is the amputation? | | Amputations on Right Side: <input type="checkbox"/> Leg & Foot <input type="checkbox"/> Foot <input type="checkbox"/> Arm <input type="checkbox"/> Hand or Thumb <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused Amputations on Left Side: <input type="checkbox"/> Leg & Foot <input type="checkbox"/> Foot <input type="checkbox"/> Arm <input type="checkbox"/> Hand or Thumb <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | <ul style="list-style-type: none"> ➤ If Yes and the amputation is of a leg or foot, exclude from the treadmill component. ➤ If Yes and both legs and both feet have been amputated, exclude from the lower body muscle strength component. ➤ If Yes and both arms, hands, or thumbs have been amputated, exclude from the grip strength component. ➤ If Yes and both arms have been amputated, exclude from the physical activity monitor component. |
| 6. Does (<u> </u> _{SP NAME}) have a pacemaker or automatic defibrillator? | 6–15 | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If Yes, Refused, or Don't Know, exclude from: <ul style="list-style-type: none"> ➤ Treadmill component. |
| 7. Has (<u> </u> _{SP NAME}) lost {his/her} balance because of dizziness two or more times during exercise? | 6–15 | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If Yes, Refused, or Don't Know, exclude from: <ul style="list-style-type: none"> ➤ Treadmill component. |
| 8. Has (<u> </u> _{SP NAME}) lost consciousness two or more times during exercise? | 6–15 | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If Yes, Refused, or Don't Know, exclude from: <ul style="list-style-type: none"> ➤ Treadmill component. |
| 9. Has a doctor or other health professional ever told you that (<u> </u> _{SP NAME}) has asthma? | 3–15 | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If Yes, go to question 9a. If No, Refused, or Don't Know, go to question 10. |

Table 2-1. Nurse Review Screening and Safety Exclusion Questionnaire (continued)

| Screening and Safety Exclusion Questionnaire | | | |
|---|-----------|--|--|
| Question | Age Range | Response | Exclusion Criteria |
| 9a. Does (<u>SP NAME</u>) currently take medication prescribed by a doctor or other health professional for asthma before participating in exercise or sports? | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If Yes, go to question 9b. If No, Refused, or Don't Know, go to question 10. |
| 9b. Do you want (<u>SP NAME</u>) to take the medication (inhalant) before participating in tests that include running? | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If Yes, see below: ➤ If the participant currently takes medication for asthma before participating in exercise or sports and he or she has brought the inhalant to the examination center, the participant will be asked if he or she wants to take the inhalant before participating in tests that include running. ➤ If the participant currently takes medication for asthma before participating in exercise or sports, but has not brought the inhalant to the examination center, the participant will be excluded from the treadmill and gross motor skills components. ➤ The nurse will encourage the SP to take the medication right away, i.e., during the nurse review interview, or immediately afterward. The SP must have taken the medication at least 30 minutes before participating in the treadmill exam. The major point is not to wait until just before the treadmill exam for the SP to take the medication. ➤ Further guidance is provided in Section 2.4 of this chapter. |
| 10. In the past 12 months has (<u>SP NAME</u>)'s chest sounded wheezy during or after exercise or physical activity? | 3-15 | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If Yes, go to question 10a. If No, Refused, or Don't Know, go to question 11. |
| 10a. Does (<u>SP NAME</u>) currently limit exercise or physical activity due to wheezing or whistling? | | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If Yes, exclude from: ➤ Treadmill ➤ Gross motor skills. |

Table 2-1. Nurse Review Screening and Safety Exclusion Questionnaire (continued)

| Screening and Safety Exclusion Questionnaire | | | |
|---|-----------|--|---|
| Question | Age Range | Response | Exclusion Criteria |
| 11. Since the interview in your home on {date of household interview}, is (<u>SP NAME</u>) taking any additional prescription medications? | 6–15 | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If Yes, enter all new medications using the prescription medication module. If a new medication is flagged in the module, exclude the participant from the treadmill component. Otherwise, if Yes, Refused, or Don't Know, see below: |
| <p>The nurse will review the list of medications taken by the participant with the parent/guardian to determine if the participant should be excluded from the treadmill or other components. The list of exclusionary medications for the treadmill test is provided in Section 2.2. Enter the medication in this screen; if a new medication is listed that meets the treadmill blocking criteria, this will be reflected on the Component Status Review Screen.</p> | | | |
| 12. Does (<u>SP NAME</u>) have a bone or joint problem that could be made worse by walking? | 6–15 | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If Yes, Refused, or Don't Know, exclude from: <ul style="list-style-type: none"> ➤ Treadmill component. |
| 13. Do you know of any reason why (<u>SP NAME</u>) should not walk or run on a treadmill? | 6–15 | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If Yes, Refused, or Don't Know, exclude from: <ul style="list-style-type: none"> ➤ Treadmill component. |
| 14. Has (<u>SP NAME</u>) had any surgery on {his/her} arms or shoulders in the past three months? | 3–15 | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If Yes, Refused, or Don't Know, exclude from: <ul style="list-style-type: none"> ➤ Modified pull-up, ➤ Plank, and ➤ Gross motor skills. |
| 15. Has (<u>SP NAME</u>) had any surgery on {his/her} hands or wrist in the past three months? | 3–15 | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If Yes, ask 15a. If Refused, or Don't Know, exclude from: <ul style="list-style-type: none"> ➤ Modified pull-up, ➤ Plank, ➤ Gross motor skills, and ➤ Grip Strength. |

Table 2-1. Nurse Review Screening and Safety Exclusion Questionnaire (continued)

| Screening and Safety Exclusion Questionnaire | | | |
|---|-----------|---|--|
| Question | Age Range | Response | Exclusion Criteria |
| 15a. Which hand or wrist was the surgery on? | 6–15 | <input type="checkbox"/> Shoulder/Arm <input type="checkbox"/> Right Hand/Wrist <input type="checkbox"/> Left Hand/Wrist <input type="checkbox"/> Both Hands/Wrists <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If surgery was conducted on both hands or both wrists exclude from: ➤ Grip strength. |
| 16. Does (SP) have any paralysis of {his/her} hands, wrists, or arms? | 3–15 | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If Yes, Refused, or Don't Know, exclude from: ➤ Modified pull-up, ➤ Plank, and ➤ Gross motor skills components. If Yes, go to 16a. |
| 16a. Which hand, wrist, or arm is the paralysis on? | | <input type="checkbox"/> Right Hand/Wrist/Arm <input type="checkbox"/> Left Hand/Wrist/Arm <input type="checkbox"/> Both Hands/Wrists/Arms <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If both hands, wrists, or arms are paralyzed, exclude from: ➤ Grip strength, and ➤ Physical activity monitor. |
| 17. We will be asking (<u>SP NAME</u>) to pull {himself/herself} up off the ground using {his/her} arms and holding the position. Do you know of any reason why (<u>SP NAME</u>) should not do this test? | 3–15 | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If Yes, Refused, or Don't Know, exclude from: ➤ Modified pull-up, and ➤ Plank. |
| 18. We will be asking (<u>SP NAME</u>) to push {his/her} legs as hard as {he/she} can against an object. Do you know of any reason why (<u>SP NAME</u>) should not do this test? | 6–15 | <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If Yes, Refused, or Don't Know, exclude from: ➤ Lower body muscle strength component. |

Table 2-1. Nurse Review Screening and Safety Exclusion Questionnaire (continued)

| Screening and Safety Exclusion Questionnaire | | | |
|--|-----------|--|--|
| Question | Age Range | Response | Exclusion Criteria |
| 19. During one of the tests, we will be asking (<u> </u>) to squeeze both of {his/her} hands as hard as {he/she} can. Do you know of any reason why (<u> </u>) should not do the test? | 6–15 | <input type="checkbox"/> No <input type="checkbox"/> Yes, don't test right <input type="checkbox"/> Yes, don't test left <input type="checkbox"/> Yes, don't test either <input type="checkbox"/> Don't Know <input type="checkbox"/> Refused | If “Yes, don't test either,” Refused, or Don't Know, exclude from: ➤ Grip strength component. |
| 20. Body weight of 500 pounds or more as measured in the Body Measurements component | 6–15 | | Exclude from: ➤ Treadmill. |
| 21. Body weight of 350 pounds or more as measured in the Body Measurements component | 6–15 | | Exclude from: ➤ Modified pull-up. |

2.3 Prescription Medications Review

This segment of the Nurse Review questionnaire allows the nurse to ask about any prescription medications that have not been recorded during the home interview. The SP may have been prescribed a medication between the home interview and NYFS appointment day, and it is important to ascertain that information due to the medication safety exclusion blocking for the treadmill exam.

If it is reported during the home interview and Nurse Review Questionnaire that any of the following medications are currently prescribed, the SP will be automatically excluded from the TGMD and treadmill (Table 2-2). Multum is a proprietary database with comprehensive drug product and disease information. This database includes drug names, drug product information, disease names, coding systems such as ICD-9-CM and NDC, generic names, brand names and common abbreviations. Multum Class Codes are used by ISIS to identify protocol-driven medication exclusions.

Table 2-2. Medications that exclude participant from treadmill

| Generic | Trade |
|---|---|
| Anti-Arrhythmics | |
| Class Codes 350500, 351000, 352000, 353000, 354000, 355000 | |
| Amiodarone | Cordarone |
| Bretylum | Bretylol |
| Disopyramide | Norpace |
| Encainide | Enkaid |
| Ethmozine | Moricizine |
| Flecainide | Tambocor |
| Lidocaine | Xylocaine, Xylocard |
| Meiletine | Mexitil |
| Moricizine | Ethmozine |
| Posicor | Mibefradil |
| Procainamide | Pronestyl, Procan SR |
| Propafenone | Rhythmol |
| Quinidine | Quinora, Quinalan, Cardioquin, Quinidex, Quinaglute |
| Beta Blockers | |
| Class Codes 331000, 332000, 333000 | |
| Acebutolol | Sectral |
| Atenolol | Tenormin |
| Betaxolol | Kerlone |
| Bisoprolol | Zebeta |
| Carteolol | Cartrol |
| Esmolol | Brevibloc |
| Labetalol | Normodyne, Trandate |
| Levobunolol | Betagan |
| Metoprolol Succinate | Toprol-XL |
| Metoprolol Tartrate | Lopressor |
| Nadolol | Corgard |
| Oxprenolol | Trasicor, Slow Trasicor |
| Penbutolol | Levatol |
| Pindolol | Visken |
| Propranolol | Inderal |
| Sotolol | Betapace |
| Timolol | Blocadren |
| Beta Blockers/Diuretic Combinations | |
| Class Code 369920 | |
| Bendroflumethiazide + Nadolol | Corzide |
| Hydrochlorothiazide + Propranolol | Inderide |
| Metoprolol + Hydrochlorothiazide | Lopressor HCT |
| Atenolol + Chlorthalidone | Tenoretic |
| Timolol + Hydrochlorothiazide | Timolide |
| Bisoprolol + Hydrochlorothiazide | Ziac |

Table 2-2. Medications that exclude participant from treadmill (continued)

| Generic | Trade |
|--|---|
| Cardiac Glycoside Class Code 312000 | |
| Digitalis | Crystodigin |
| Digoxin | Lanoxin |
| Eye Drops/ Beta Blockers Class Codes 862500, 862599 | |
| Levobunolol Eye Drops | Betagen Eye Drops |
| Betaxolol | Betoptic Eye Drops |
| Metipranolol | Optipranolol |
| Timolol | Timoptic Eye Drops |
| Nitrates and Nitroglycerin Class Code 321000 | |
| Isosorbide Dinitrate | Isordil, Diltrate |
| Isosorbide Mononitrate | Ismo, Monoket |
| Nitroglycerin, Translingual | Nitrostat, Nitrolingual Spray |
| Nitroglycerin, Transmucosal | Nitrogard |
| Nitroglycerin, Topical | Nitrol, Nitro-Bid, Transderm Nitro, Nitro-Dur II, Nitrodisc, Minitran, Deponit, Nitroderm |
| Nitroglycerin, Sustained Release | Nitrong, Nitrocine, Nitroglyn |
| Pentaerythritol Tetranitrate | Cardilate |

The following exhibits (2-2 to 2-10) describe the prescription medication data entry screens. The data entry screens display the instructions needed to retrieve and enter a prescription medication. The information collected about prescribed medication includes the name, if the container was observed, length of time the SP has been using the product, and the main reason for taking it.

Exhibit 2-2. Medication data entry screen 1

Blaise 4.8 Data Entry - C:\isis\EXCL291\EXCL

Forms Answer Navigate Options Help

AKSHAR PATEL (12, M) Yr13.s291.v1

HELP AVAILABLE

Now I would like to talk about **prescription medication** AKSHAR PATEL has used in the **past 30 days**. Again, these are products prescribed by a health professional such as a doctor or dentist.

[First I will record some information about the medication, then I will ask you some questions about it.]

**REFER TO PRODUCT LABEL(S) OR ASK RESPONDENT FOR NAME(S) OF PRESCRIPTION MEDICATIONS USED.
ENTER MEDICATION NAME.**

**The field RXQ231 begins the medication lookup.
Enter the product name. To access the medication
lookup function, press the backspace key.**

| | | | | | | | |
|---------------------|----------------------|----------------------|--------|---------|---------|--------|----------------------|
| | RXQ231 | RXQ240S | RXQ250 | RXQ260Q | RXQ260U | RXQ290 | RXQ294 |
| PrscriptnMedList[1] | <input type="text"/> | <input type="text"/> | | | | | <input type="text"/> |

Exhibit 2-3. Medication data entry screen 2 – Lookup function

Blaise 4.8 Data Entry - C:\isis\EXCL291\EXCL

Forms Answer Navigate Options Help

M3 BARONE (3, M) Yr13.s291.v1

PRESS BS TO START THE LOOKUP.

SELECT MEDICATION FROM LIST.

IF MEDICATION NOT ON LIST - PRESS BS TO DELETE ENTRY.

TYPE *.**

PRESS ENTER TO SELECT.

C:\isis\EXCL291\external\alldrugs - Blaise 4.8 Database Browser

| drugname | drugtype | generic_id | generic |
|-----------------------------------|----------|------------|------------------------|
| MUCINEX | OTC | d00797 | GUAIFENESIN |
| MUCINEX D | Rx | d03879 | GUAIFENESIN-PSEUDOEPHI |
| MUCINEX DM | OTC | d03400 | DEXTROMETHORPHAN-GUA |
| MUCINEX CHILDRENS | OTC | d00797 | GUAIFENESIN |
| MUCINEX FULL FORCE | OTC | d00772 | OXYMETAZOLINE NASAL |
| MUCINEX MAX STRENGTH | OTC | d00797 | GUAIFENESIN |
| MUCINEX D MAX STRENGTH | OTC | d03879 | GUAIFENESIN-PSEUDOEPHI |
| MUCINEX MOISTURE SMART | OTC | d00772 | OXYMETAZOLINE NASAL |
| MUCINEX CHILDREN'S COLD | OTC | d03881 | GUAIFENESIN-PHENYLEPHF |
| MUCINEX CHILDREN'S COUGH | OTC | d03400 | DEXTROMETHORPHAN-GUA |
| MUCINEX KIDS' MINI-MELTS | OTC | d00797 | GUAIFENESIN |
| MUCINEX DM MAXIMUM STRENGTH | OTC | d03400 | DEXTROMETHORPHAN-GUA |
| MUCINEX CHILDRENS MINI-MELTS | OTC | d00797 | GUAIFENESIN |
| MUCINEX JUNIOR STRENGTH MINI-M | OTC | d00797 | GUAIFENESIN |
| MUCINEX CHILDREN'S COUGH MINI-OTC | OTC | d03400 | DEXTROMETHORPHAN-GUA |
| MUCINEX CHILDREN'S MULTI-SYMP | OTC | d03408 | DEXTROMETHORPHAN/GUA |

Search: mucinex

| | | | | | | | |
|----------------------|--------------------------------------|--|--|--|--|--|--|
| | RXQ231 | | | | | | |
| PrscriptnMedList[1] | <input type="text" value="mucinex"/> | | | | | | |
| PrscriptnMedList[2] | | | | | | | |
| PrscriptnMedList[3] | | | | | | | |
| PrscriptnMedList[4] | | | | | | | |
| PrscriptnMedList[5] | | | | | | | |
| PrscriptnMedList[6] | | | | | | | |
| PrscriptnMedList[7] | | | | | | | |
| PrscriptnMedList[8] | | | | | | | |
| PrscriptnMedList[9] | | | | | | | |
| PrscriptnMedList[10] | | | | | | | |

Exhibit 2-4. Medication data entry screen 3 – Selected medication

Blaise 4.8 Data Entry - C:\isis\EXCL291\EXCL

M3 BARONE (3, M) Yr13.s291.v1

PRESS BS TO START THE LOOKUP.

SELECT MEDICATION FROM LIST.

IF MEDICATION NOT ON LIST - PRESS BS TO DELETE ENTRY.

TYPE ***.

PRESS ENTER TO SELECT.

The field RXQ240S displays the medication selected from the lookup table.

| | RXQ231 | RXQ240S | RXQ250 | RXQ260Q | RXQ260U | RXQ290 | RXQ294 |
|---------------------|---------|-----------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| PrscriptnMedList{1} | mucinex | MUCINEX D | <input type="checkbox"/> |
| PrscriptnMedList{2} | | | | | | | |
| PrscriptnMedList{3} | | | | | | | |
| PrscriptnMedList{4} | | | | | | | |

Exhibit 2-5. Medication data entry screen 4 – Medication container seen/not seen

Blaise 4.8 Data Entry - C:\isis\EXCL291\EXCL

M3 BARONE (3, M) Yr13.s291.v1

MUCINEX D

INTERVIEWER: ENTER 1 RESPONSE

This field is typically used during the home interview. It is not necessary to see the container. Enter the appropriate response and press enter to the next field.

1. CONTAINER SEEN
 2. CONTAINER NOT SEEN

| | RXQ231 | RXQ240S | RXQ250 | RXQ260Q | RXQ260U | RXQ290 | RXQ294 |
|---------------------|---------|-----------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| PrscriptnMedList{1} | mucinex | MUCINEX D | <input type="checkbox"/> |
| PrscriptnMedList{2} | | | | | | | |

Exhibit 2-6. Medication data entry screen 5 – How long SP prescribed the medication

Blaise 4.8 Data Entry - C:\isis\EXCL291\EXCL

Forms Answer Navigate Options Help

M3 BARONE (3. M) Y13.s291.v1

For how long has M3 BARONE been using or taking MUCINEX D?

ENTER NUMBER (OF DAYS, WEEKS, MONTHS OR YEARS)

Ask respondent how long the participant has been on the medication and enter the duration as a numeral and press enter to advance to the field where the user selects Days, Weeks, Months, or Years.

| | RXQ231 | RXQ240S | RXQ250 | RXQ260Q | RXQ260U | RXQ290 | RXQ294 |
|---------------------|---------|-----------|--------|---------|---------|--------|--------|
| PrscriptnMedList[1] | mucinex | MUCINEX D | 1 | | | | |
| PrscriptnMedList[0] | | | | | | | |

Exhibit 2-7. Medication data entry screen 6 – Part 2–How long SP taking medication

Blaise 4.8 Data Entry - C:\isis\EXCL291\EXCL

Forms Answer Navigate Options Help

ENTER UNIT

Select Days, Weeks, Months, or Years.

C 1. DAYS
C 2. WEEKS
C 3. MONTHS
C 4. YEARS

| | RXQ231 | RXQ240S | RXQ250 | RXQ260Q | RXQ260U | RXQ290 | RXQ294 |
|---------------------|---------|-----------|--------|---------|---------|--------|--------|
| PrscriptnMedList[1] | mucinex | MUCINEX D | 1 | 4.0 | | | |
| PrscriptnMedList[0] | | | | | | | |

Exhibit 2-8. Enter the reason for medication

Blaise 4.8 Data Entry - C:\isis\EXCL291\EXCL

M3 BARONE (3, M) Yr13.s291.v1

What is the **main** reason for which M3 BARONE uses MUCINEX D?

ENTER TEXT

Enter a brief one or two word explanation for the respondent's understanding of the reason for the medication.

| | RXQ231 | RXQ240S | RXQ250 | RXQ260Q | RXQ260U | RXQ290 | RXQ294 |
|---------------------|---------|-----------|--------|---------|---------|------------|--------|
| PrscriptnMedList{1} | mucihex | MUCINEX D | 1 | 4.0 | 1 | congestion | |
| PrscriptnMedList{2} | | | | | | | |
| PrscriptnMedList{3} | | | | | | | |

Exhibit 2-9. Option to add more prescription medications

Blaise 4.8 Data Entry - C:\isis\EXCL291\EXCL

M3 BARONE (3, M) Yr13.s291.v1

HELP AVAILABLE

CHECK CONTAINERS. ARE THERE ANY OTHER PRESCRIPTION MEDICATIONS?

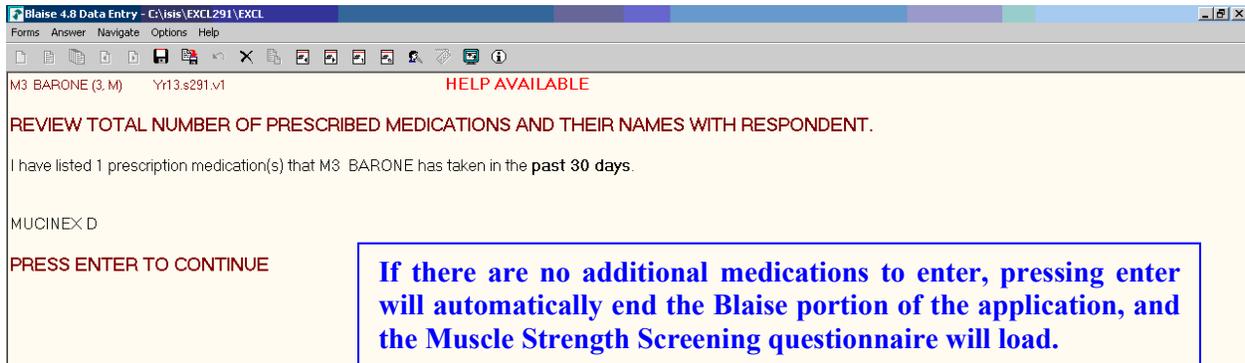
OR ASK RESPONDENT:
[Are there any other prescription medications that M3 BARONE used in the past 30 days?]

Selecting "No" will end the prescription medication section. Selecting "Yes" will enable a second field on the next line.

1. YES
 2. NO

| | RXQ231 | RXQ240S | RXQ250 | RXQ260Q | RXQ260U | RXQ290 | RXQ294 |
|---------------------|---------|-----------|--------|---------|---------|------------|--------|
| PrscriptnMedList{1} | mucihex | MUCINEX D | 1 | 4.0 | 1 | congestion | |
| PrscriptnMedList{2} | | | | | | | |
| PrscriptnMedList{3} | | | | | | | |

Exhibit 2-10. Review total number of prescribed medications with respondent and exit Blaise questionnaire



Blaise 4.8 Data Entry - C:\visis\EXCL291\EXCL

Forms Answer Navigate Options Help

M3 BARONE (3, M) Yr13.s291.v1 HELP AVAILABLE

REVIEW TOTAL NUMBER OF PRESCRIBED MEDICATIONS AND THEIR NAMES WITH RESPONDENT.

I have listed 1 prescription medication(s) that M3 BARONE has taken in the past 30 days.

MUCINEX D

PRESS ENTER TO CONTINUE

If there are no additional medications to enter, pressing enter will automatically end the Blaise portion of the application, and the Muscle Strength Screening questionnaire will load.

2.4 Muscle Strength (Grip Strength) Pretest Questionnaire

The respondent is asked a series of questions to determine if the SP should be excluded from parts of the exam and to collect information on items that may influence the results. In most cases, responses are entered from drop-down menus. These responses are uploaded and displayed in a read-only format in the muscle strength application.

Ask the questions exactly as they appear on the screen (Exhibit 2-11). Do not omit or add anything. If the SP is unsure how to answer, use the explanations in the manual below each question to help the SP determine the answer. Listen carefully to the SP's responses, and make certain he or she is providing the information the question is asking. If you think the SP has misunderstood the question, probe to clarify by repeating the question with a preface such as "Just to make sure I have this correct"

Exhibit 2-11. Pretest Questionnaire screen 1

1. May I see your hands? ARE THERE ANY VISIBLE LIMITATIONS FOR EITHER HAND?
 - Yes
 - No
 - Refused

- a. Visible limitations on the right hand (CODE ALL THAT APPLY.)
 - Missing arm, hand, or thumb
 - Hand paralysis
 - Wearing a cast on wrist or hand
 - Most of hand covered by bandages (See Figure 2-1 for examples.)
 - Missing fingers other than thumb or broken fingers
 - Other (specify)
 - No visible limitation for right hand

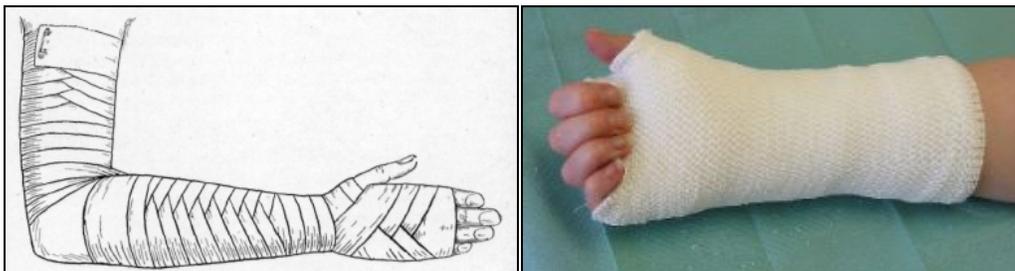


Figure 2-1. Example of hand mostly covered by bandages

- b. Visible limitations on the left hand (CODE ALL THAT APPLY.)
- Missing arm, hand, or thumb
 - Hand paralysis
 - Wearing a cast on wrist or hand
 - Most of hand covered by bandages (See Figure 3-1 for examples.)
 - Missing fingers other than thumb or broken fingers
 - Other (specify)
 - No visible limitation for left hand

Examine the SP's hands. If you determine that one or both hands have visible limitation(s), the system will prompt you to answer the followup questions to identify the observed limitations. Code **all** visible physical limitations that will affect the test. Once you chose "Yes" for the first question, you are not allowed to mark "no visible limitation" for both hands in the followup portions. In this case, an error message will be displayed to prompt you to change your response(s) in questions 1, 1a, or 1b.

Only use the "Other (specify)" code if you observed an unlisted reason on the SP's hand(s) that will definitely prevent him or her from holding or squeezing the dynamometer. Do not record minor abnormalities such as a minor paper cut in this field because this code will trigger the hand indicated to be excluded.

If one of the SP's hands is coded as "Missing arm, hand, or thumb," "Hand paralysis," "Wearing a cast on wrist or hand," "Most hand covered by bandages," or "Other (specify)," he or she will be excluded from testing that specific hand. If an SP is missing fingers other than the thumb on the right or left hand, he or she is still eligible to complete the exam. If there is a visible physical limitation that excludes both hands or if the SP refuses to let you see his or her hands, the exam will end.

2. Have you had any surgery on your hands or wrists **in the past three months**?

- Yes
 - No
 - Refused
 - Don't know
- a. Which hand or wrist was the surgery on?
- Right hand/wrist
 - Left hand/wrist
 - Both hands/wrist
 - Refused
 - Don't know

If the SP has had surgery on his or her hands or wrists in the past 3 months, ISIS will prompt you to ask which hand(s) or wrist(s). This is a safety exclusion question. The hand(s) or wrist(s) indicated will be excluded from the exam. If the SP has had any other surgeries that will affect his or her ability to complete the test, it will be recorded in question 3.

3. In this test, we will be asking you to squeeze this instrument as hard as you can. Do you know of any reason why you should not do the test? (DO NOT INCLUDE EXCLUSIONS PREVIOUSLY RECORDED.)

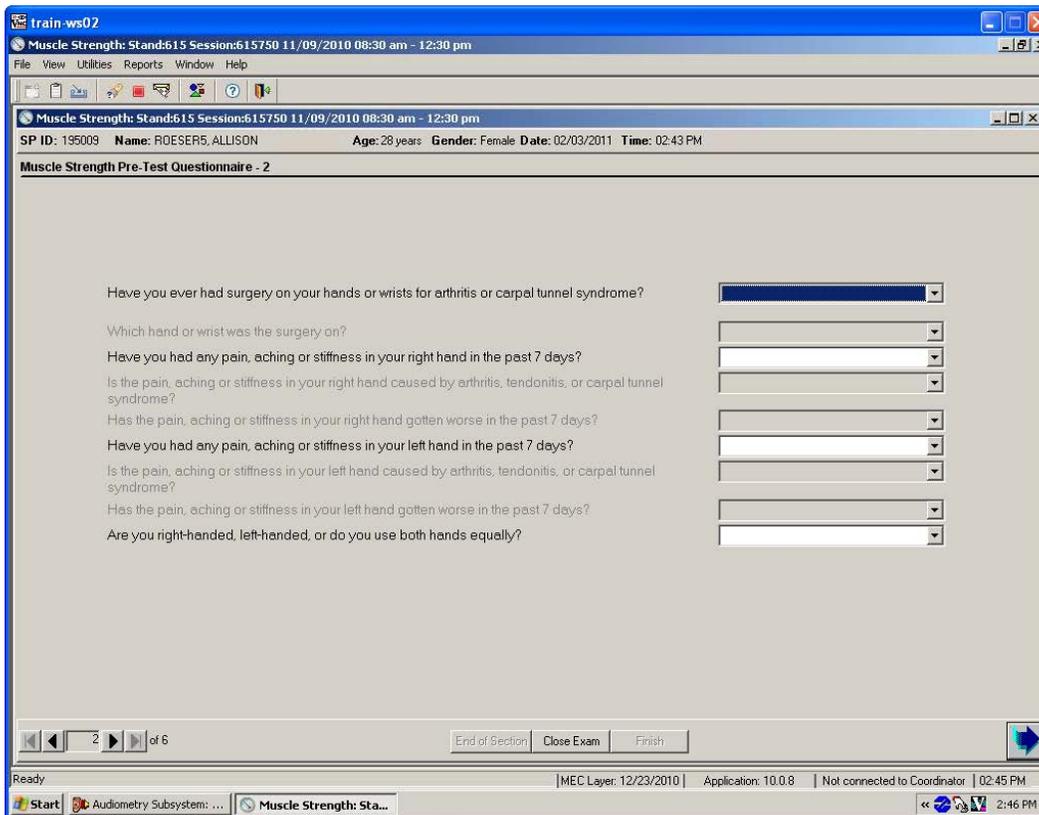
- No
- Yes; should not test right hand
- Yes; should not test left hand
- Yes; should not test either hand
- Refused
- Don't know

a. Specify reason: _____

This is the last exclusion question. Only record exclusions that were not recorded in the two previous questions. If the SP indicates that one or both hands should not be tested, you will be prompted to specify a reason. Type the reason the SP gives into the computer.

Based on the responses given to the safety exclusion questions, ISIS will determine which hand(s) should be tested. The remaining questions will be used to help interpret the data (Exhibit 2-12). Responses to these questions will not exclude an SP from the test.

Exhibit 2-12. Pretest Questionnaire screen 2



4. Have you **ever** had surgery on your hands or wrists for **arthritis** or **carpal tunnel syndrome**?
 - Yes
 - No
 - Refused
 - Don't know
 - a. Which hand or wrist was the surgery on?
 - Right hand/wrist
 - Left hand/wrist
 - Both hands/wrist
 - Refused
 - Don't know

If the SP has had surgery on his or her hands or wrists for arthritis or carpal tunnel syndrome, ISIS will prompt you to ask which hand(s) or wrist(s).

5. Have you had any pain, aching or stiffness in your **right** hand in the **past 7 days**?
- Yes
 - No
 - Refused
 - Don't know
- a. Is the pain, aching or stiffness in your **right** hand caused by **arthritis, tendonitis, or carpal tunnel syndrome**?
- Yes
 - No
 - Refused
 - Don't know
- b. Has the pain, aching or stiffness in your **right** hand **gotten worse** in the past 7 days?
- Yes
 - No
 - Refused
 - Don't know

This set of questions is only asked to the SP if his or her right hand has been determined as eligible for the grip test. If the SP's right hand is excluded from the test, the system will block these questions and the entry fields will be grayed out on the screen.

If the SP has had pain, aching or stiffness in his or her right hand in the past 7 days, ISIS will prompt you to ask two followup questions. The first followup question asks whether the pain, aching, or stiffness is caused by arthritis, tendonitis, or carpal tunnel syndrome. The second question is used to ascertain whether there is any acute flare-up on the SP's right hand.

6. Have you had any pain, aching, or stiffness in your **left** hand in the **past 7 days**?
- Yes
 - No
 - Refused
 - Don't know
- a. Is the pain, aching, or stiffness in your **left** hand caused by **arthritis, tendonitis, or carpal tunnel syndrome**?
- Yes
 - No
 - Refused
 - Don't know

- b. Has the pain, aching, or stiffness in your **left hand gotten worse** in the past 7 days?
- Yes
 - No
 - Refused
 - Don't know

The same questions are repeated here for the left hand. Similar to the previous set of questions, these questions are only asked to the SP if his or her left hand has been determined as eligible for the grip test. If the SP's left hand is excluded from the test, the system will block these questions and the entry fields will be grayed out on the screen.

7. Are you right-handed, left-handed, or do you use both hands equally?
- Right-handed
 - Left-handed
 - Use both hands equally
 - Refused
 - Don't know

This question is used to identify the SP's dominant hand. This information will be used to determine which hand the test will start with. If the SP has trouble identifying his or her dominant hand, probe for his or her writing hand.

2.5 Nurse Component Status Review

The purpose of this screen is to summarize the results of the questionnaires, and display all of the exams the SP is eligible to receive based on age, and the status, i.e., if excluded/not excluded, of the physical activity components based on the responses to the safety and screening questionnaires. The following screen (Exhibit 2-13) displays the Nurse Component Status Review Screen for an 11-year-old female who has no safety exclusions.

Exhibit 2-13. Nurse Component Status Review: No Safety Exclusions

Nurse Review: Stand:617 Session:617017 09/18/2011 08:30 am - 09:00 pm

File View Utilities Reports Review Window Help

Nurse Review: Stand:617 Session:617018 09/19/2011 08:30 am - 09:00 pm

SP ID: 751547 Name: PATTY, TERENCE Age: 11 years Gender: Male Date: 02/21/2012 Time: 10:24 AM

Nurse Component Status Review

eczema on hands

"If a doctor says a child 6 - 15 should not participate in sports or other physical activities for a specific condition, and the following is listed in "other, specify" they should be excluded from the treadmill for:

a. Any health condition that is systemic or involves a major organ system, example: diabetes, cystic fibrosis, cancer, juvenile rheumatoid arthritis, or kidney failure

b. Any mental health condition: depression, ADHD, generalized anxiety disorder, panic disorder, or autism spectrum disorder.

c. Any recent acute infection, recent surgeries, or significant trauma, i.e., head injury (recent = past month)

If the "other, specify" condition is a dermatologic condition, minor soft tissue contusion, or minor orthopedic issue, and does not in any way hinder a youth from walking safely on the treadmill- including being able to grasp the handrail, they will be allowed to proceed with the treadmill test."

| Component: | Reason for exclusion: |
|---|-----------------------|
| <input type="checkbox"/> Treadmill | <input type="text"/> |
| <input type="checkbox"/> Modified Pull Up | <input type="text"/> |
| <input type="checkbox"/> Plank | <input type="text"/> |
| <input type="checkbox"/> Muscle Strength | <input type="text"/> |
| <input type="checkbox"/> Lower Body Muscle Strength | <input type="text"/> |

Comment:

A "Comments" field with free text entry (about 240 characters) appears at the bottom of the Nurse Component Status Review Screen. These comments will print out on the Nurse Review section of the Study Participant Information Sheet.

3 of 7

End of Section Close Exam Finish

Ready | MEC Layer: 2/8/2012 | Application: 10.0.7 | Not connected to Coordinator | 10:26 AM

Start Pull-Up: Stand:616 Sessi... Nurse Review: Stand:...

10:27 AM

The nurse will not be able to unblock exams from this screen, but will have the discretion to exclude/block other applications as deemed appropriate. If the nurse chooses to block another exam, a comment must accompany this decision; a hard edit stop will prevent the user from advancing from this screen (Exhibit 2-14) if the comment field has not been completed. The status of the exam will display the reason, "Blocked based on nurse review." The screen also contains a "Comment" field that allows free-text entries that will be exported to the Nurse Review section of the Study Participant Information Sheet. The comments field is to be used judiciously and is primarily designed for the nurse to document if the SP needs to take an asthma medication, and when the SP self-administered the medication. Another use for the comments section is for the nurse to communicate to the other examination staff any pertinent medical information that was discovered during the nurse review interview.

Exhibit 2-14. Exclusion based on nurse discretion at the Nurse Component Status Review screen

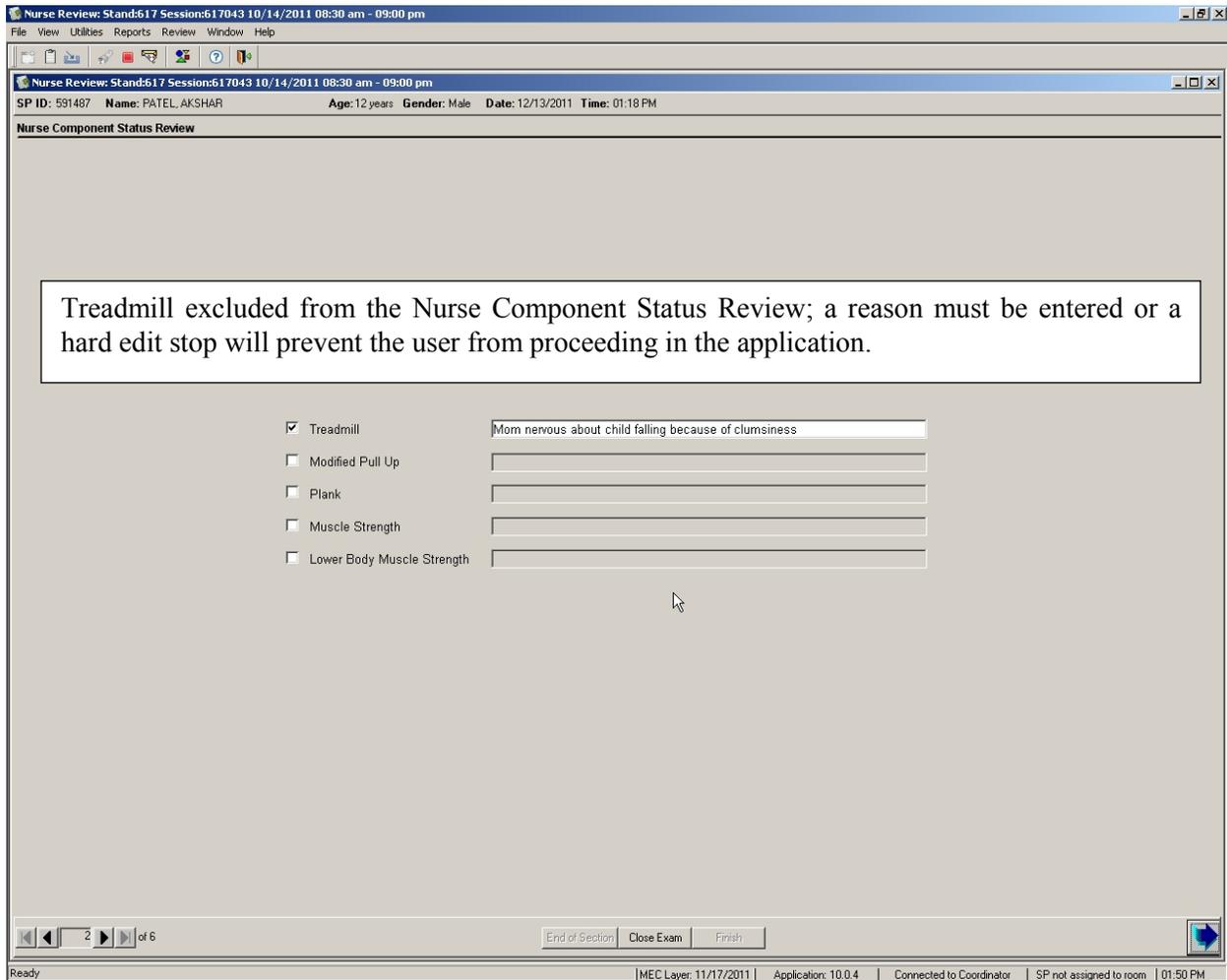


Exhibit 2-15 shows the component exclusions as a result of the questionnaires; note that these appear in grey, and so the user is unable to change, i.e., unblock these exams from this screen.

Exhibit 2-15. Component and reason for exclusion

The screenshot displays a software interface for a "Nurse Component Status Review". At the top, a blue header bar contains the text "Nurse Review: Stand:617 Session:617043 10/14/2011 08:30 am - 09:00 pm". Below this, a grey bar shows "SP ID: 931938 Name: TRAINING27, SARAHMC Age: 13 years Gender: Female Date: 12/30/2011 Time: 10:32 AM". The main content area is titled "Nurse Component Status Review" and features two columns: "Component:" and "Reason for exclusion:". Under "Component:", there are five items with checkboxes: "Treadmill" (checked), "Modified Pull Up" (checked), "Plank" (checked), "Muscle Strength" (unchecked), and "Lower Body Muscle Strength" (unchecked). Corresponding text boxes in the "Reason for exclusion:" column contain "Safety Exclusion" for the first three items, and are empty for the last two. At the bottom left, there are navigation arrows and the text "2 of 6". At the bottom right, there are three buttons: "End of Section", "Close Exam", and "Finish".

| Component: | Reason for exclusion: |
|--|-----------------------|
| <input checked="" type="checkbox"/> Treadmill | Safety Exclusion |
| <input checked="" type="checkbox"/> Modified Pull Up | Safety Exclusion |
| <input checked="" type="checkbox"/> Plank | Safety Exclusion |
| <input type="checkbox"/> Muscle Strength | |
| <input type="checkbox"/> Lower Body Muscle Strength | |

2.5.1 Health Condition Evaluation

If the response to the question, “Has a doctor said {sp_name} *CURRENTLY* should not participate in sports or other physical activities because of a health condition?” is YES, and the reason is not a heart condition, the full response to the followup question, “What condition is it? _____” will appear at the top of the screen as the first item to be

reviewed. This response will be accompanied by clinical guidance text provided by NCHS medical officers; the following guidance text will appear:

“If a doctor says a child 6-15 should not participate in sports or other physical activities for a specific condition, and the following is listed in “other, specify” they should be excluded from the treadmill for:

- a. Any health condition that is systemic or involves a major organ system, example: diabetes, cystic fibrosis, cancer, juvenile rheumatoid arthritis, or kidney failure.*
- b. Any mental health condition: depression, ADHD, generalized anxiety disorder, panic disorder, or autism spectrum disorder.*
- c. Any recent acute infection, recent surgeries, or significant trauma, i.e., head injury (recent = past month)*

If the “other, specify” condition is a dermatologic condition, minor soft tissue contusion, or minor orthopedic issue , and does not in any way hinder a youth from walking safely on the treadmill—including being able to grasp the handrail—they will be allowed to proceed with the treadmill test.”

In the example below, the parent reported that the SP has epilepsy; this answer was transmitted to the Nurse Component Status Review screen as the first item to be reviewed in Exhibit 2-16. The nurse would exclude the SP from the treadmill component based on the presence of a medical condition for which a physician recommended a physical limitation. If the nurse selects a component to exclude based on the assessment of the reported health condition, the exam will be grayed-out, and “Safety Exclusion” automatically populates the “Reason for Exclusion” field.

Exhibit 2-16. Health condition evaluation and exclusion from treadmill

Nurse Review: Stand:291 Session:291045 10/16/2011 08:30 am - 09:00 pm

SP ID: 632461 Name: HOPE, ANDY Age: 8 years Gender: Male Date: 12/20/2011 Time: 11:54 AM

Nurse Component Status Review

Epilepsy

"If a doctor says a child 6 - 15 should not participate in sports or other physical activities for a specific condition, and the following is listed in "other, specify" they should be excluded from the treadmill for:

a. Any health condition that is systemic or involves a major organ system, example: diabetes, cystic fibrosis, cancer, juvenile rheumatoid arthritis, or kidney failure

b. Any mental health condition: depression, ADHD, generalized anxiety disorder, panic disorder, or autism spectrum disorder.

c. Any recent acute infection, recent surgeries, or significant trauma, i.e., head injury (recent = past month)

If the "other, specify" condition is a dermatologic condition, minor soft tissue contusion, or minor orthopedic issue, and does not in any way hinder a youth from walking safely on the treadmill- including being able to grasp the handrail, they will be allowed to proceed with the treadmill test."

| Component: | Reason for exclusion: |
|---|-----------------------|
| <input checked="" type="checkbox"/> Treadmill | Safety Exclusion |
| <input type="checkbox"/> Modified Pull Up | |
| <input type="checkbox"/> Plank | |
| <input type="checkbox"/> Muscle Strength | |
| <input type="checkbox"/> Lower Body Muscle Strength | |

2.5.2 Exercise Induced Asthma

If the SP is reported to have exercise induced asthma, and should take inhalant asthma medication prior to taking part in tests that include running, this information is also transferred to this screen (Exhibit 2-17). It will appear at the top of the screen as:

"You indicated that you want [SP Name] to take the inhalant before participating in tests that include running. Would you like to ask [SP Name] to take her/his medication now?"

Exhibit 2-17. SP needs to take asthma medication screen

Nurse Review: Stand:617 Session:617017 09/18/2011 08:30 am - 09:00 pm

File View Utilities Reports Review Window Help

Nurse Review: Stand:617 Session:617017 09/18/2011 08:30 am - 09:00 pm

SP ID: 454051 Name: DEEGAN, DOUG S Age: 12 years Gender: Male Date: 02/21/2012 Time: 01:49 PM

Nurse Component Status Review

YOU INDICATED THAT YOU WANT DOUG TO TAKE THE INHALANT BEFORE PARTICIPATING IN TESTS THAT INCLUDE RUNNING. WOULD YOU LIKE TO ASK DOUG TO TAKE HER/HIS MEDICATION NOW?

| Component: | Reason for exclusion: |
|---|-----------------------|
| <input type="checkbox"/> Treadmill | <input type="text"/> |
| <input type="checkbox"/> Modified Pull Up | <input type="text"/> |
| <input type="checkbox"/> Plank | <input type="text"/> |
| <input type="checkbox"/> Muscle Strength | <input type="text"/> |
| <input type="checkbox"/> Lower Body Muscle Strength | <input type="text"/> |

Comment:

3 of 7

End of Section Close Exam Finish

Ready | MEC Layer: 2/8/2012 | Application: 10.0.7 | Not connected to Coordinator | 01:49 PM

Start Pull-Up: Stand:616 Sessi... Nurse Review: Stand:...

1:49 PM

The nurse will advise the SP to take a dose of their inhalant at that time, or prior to the completion of the Nurse Review exam before the SP leaves the room to begin his or her physical activities. *The essential point for the treadmill protocol is that the asthma medication must have been taken at least 30 minutes prior to the beginning of the treadmill test; at no time is the SP to wait until just before the treadmill test to take his or her inhaler.* The nurse will document the time the medication was self-administered in the “Comments” section (Exhibit 2-18).

Exhibit 2-18. SP needs to take medication screen with time of administration

Nurse Review: Stand:617 Session:617017 09/18/2011 08:30 am - 09:00 pm

File View Utilities Reports Review Window Help

Nurse Review: Stand:617 Session:617017 09/18/2011 08:30 am - 09:00 pm

SP ID: 401839 Name: MAYER, SON1 S Age: 15 years Gender: Male Date: 02/21/2012 Time: 01:51 PM

Nurse Component Status Review

YOU INDICATED THAT YOU WANT SON1 TO TAKE THE INHALANT BEFORE PARTICIPATING IN TESTS THAT INCLUDE RUNNING. WOULD YOU LIKE TO ASK SON1 TO TAKE HER/HIS MEDICATION NOW?

| Component: | Reason for exclusion: |
|---|-----------------------|
| <input type="checkbox"/> Treadmill | <input type="text"/> |
| <input type="checkbox"/> Modified Pull Up | <input type="text"/> |
| <input type="checkbox"/> Plank | <input type="text"/> |
| <input type="checkbox"/> Muscle Strength | <input type="text"/> |
| <input type="checkbox"/> Lower Body Muscle Strength | <input type="text"/> |

Comment:
Asthma medication-Albuterol 2 puffs taken at 2:20 PM.

3 of 7

End of Section Close Exam Finish

Ready | MEC Layer: 2/8/2012 | Application: 10.0.7 | Not connected to Coordinator | 01:52 PM

Start | Pull-Up: Stand:616 Sessi... | Nurse Review: Stand:...

1:53 PM

Exhibit 2-19 shows a screenshot where the asthma medication reminder is displayed when the treadmill exam was excluded due to asthma during the Nurse Review questionnaire. While it is no longer necessary to require the child take the asthma medication because she or he will not be going to the treadmill exam, the nurse should still document that the child is asthmatic in the Comment field so that it prints out in the Nurse Review Field of the Study Participant Information Sheet to alert all the NYFS examiners.

Exhibit 2-19. Asthma medication reminder when treadmill is excluded

The screenshot displays a web-based form titled "Nurse Review: Stand:617 Session:617043 10/14/2011 08:30 am - 09:00 pm". The patient information at the top includes "SP ID: 622837", "Name: BEST, KEVDN", "Age: 13 years", "Gender: Male", "Date: 12/30/2011", and "Time: 10:39 AM". The main heading is "Nurse Component Status Review".

The central text reads: "YOU INDICATED THAT YOU WANT KEVDN TO TAKE THE INHALANT BEFORE PARTICIPATING IN TESTS THAT INCLUDE RUNNING. WOULD YOU LIKE TO ASK KEVDN TO TAKE HER/HIS MEDICATION NOW?"

| Component: | Reason for exclusion: |
|---|-----------------------|
| <input checked="" type="checkbox"/> Treadmill | Safety Exclusion |
| <input type="checkbox"/> Modified Pull Up | |
| <input type="checkbox"/> Plank | |
| <input type="checkbox"/> Muscle Strength | |
| <input type="checkbox"/> Lower Body Muscle Strength | |

If the nurse is satisfied with the exclusion status of the components from this screen, the screen will be advanced using the lower right corner arrow (Exhibit 2-20).

Exhibit 2-20. Status review of excluded components

The screenshot shows a software window titled "Nurse Review: Stand:291 Session:291045 10/16/2011 08:30 am - 09:00 pm". Below the title bar, it displays "SP ID: 376386 Name: FANG, PETER LI Age: 4 years Gender: Male Date: 12/20/2011 Time: 11:34 AM". The main content area is titled "Nurse Component Status Review" and contains the following text:

severe exercise induced asthma, reactive airway disease

"If a doctor says a child 6 - 15 should not participate in sports or other physical activities for a specific condition, and the following is listed in "other, specify" they should be excluded from the treadmill for:

- a. Any health condition that is systemic or involves a major organ system, example: diabetes, cystic fibrosis, cancer, juvenile rheumatoid arthritis, or kidney failure
- b. Any mental health condition: depression, ADHD, generalized anxiety disorder, panic disorder, or autism spectrum disorder.
- c. Any recent acute infection, recent surgeries, or significant trauma, i.e., head injury (recent = past month)

If the "other, specify" condition is a dermatologic condition, minor soft tissue contusion, or minor orthopedic issue, and does not in any way hinder a youth from walking safely on the treadmill- including being able to grasp the handrail, they will be allowed to proceed with the treadmill test."

| Component: | Reason for exclusion: |
|--|-----------------------|
| <input checked="" type="checkbox"/> Gross Motor Skills | Safety Exclusion |
| <input checked="" type="checkbox"/> Plank | Safety Exclusion |
| <input type="checkbox"/> Lower Body Muscle Strength | |

2.5.3 Verify Street Address and Phone

The following two screens (Exhibits 2-21 and 2-22) allow the nurse to confirm the address and phone number of the participant. These data are asked to ensure that the information is correct for the purpose of following up with the physical activity monitor.

Exhibit 2-21. Verify Street Address

Nurse Review: Stand:617 Session:617043 10/14/2011 08:30 am - 09:00 pm
SP ID: 531487 Name: PATEL, AKSHAR Age: 12 years Gender: Male Date: 12/13/2011 Time: 01:18 PM

Verify Street Address

I would like to verify your address. Please give me your complete address.

Additional Address Line

| Street # | Dir Pre | Street Name | St/Rd/Ave | Dir Post |
|----------|----------------------|-------------|-----------|----------------------|
| 552 | <input type="text"/> | BELVEDERE | ST | <input type="text"/> |

| Unit/Apt/Bldg | Unit # | PO Box | RRHC # | RRHC Box |
|----------------------|----------------------|----------------------|----------------------|----------------------|
| <input type="text"/> |

| City | State | Zip |
|---------|-------|-------|
| Houston | TX | 73301 |

Is your mailing address the same as your street address?

Did you live at this address on 10/5/2011?

Make corrections as required and advance to the next screen.

Exhibit 2-22. Verify Phone Numbers

Nurse Review: Stand617 Session617043 10/14/2011 08:30 am - 09:00 pm

File View Utilities Reports Review Window Help

Nurse Review: Stand617 Session617043 10/14/2011 08:30 am - 09:00 pm

SP ID: 591487 Name: PATEL, AKSHAR Age: 12 years Gender: Male Date: 12/13/2011 Time: 01:18 PM

Verify Phone numbers

Please give me your home telephone number.

IF NO HOME PHONE:
Is there another number where you can be reached? Where is that phone located?

| Phone Type | Phone No | Ext. | Refused | Don't Know |
|------------|--------------|-------|------------|------------|
| Home | 301-251-2262 | 00000 | Refused | Don't Know |
| | | | Don't Have | |
| Home | 301-279-4570 | 00000 | Refused | Don't Know |
| | | | Don't Have | |

Insert

5 of 6

End of Section Close Exam Finish

Ready | MEC Layer: 11/17/2011 | Application: 10.0.4 | Connected to Coordinator | SP not assigned to room | 01:52 PM

Make corrections as needed and advance to the next screen.

This is the final screen (Exhibit 2-23) that indicates the status, or completion description, of the nurse review application. For any “Partial” or “Not Done” status, the nurse must select from an option that best describes why the exam is not complete; if this is not done, the nurse will not be able to close the exam. Pressing the “Finish” button ends the exam and the Study Participant Information Sheet will automatically print at the coordinator desk.

Exhibit 2-23. Proxy Status

The screenshot shows a software window titled "Nurse Review: Stand517 Sessions617043 10/14/2011 08:30 am - 09:00 pm". The window has a menu bar with "File", "View", "Utilities", "Reports", "Review", "Window", and "Help". Below the menu bar, there is a header area with the following information: "Nurse Review: Stand517 Sessions617043 10/14/2011 08:30 am - 09:00 pm", "SP ID: 591487", "Name: PATEL, AKSHAR", "Age: 12 years", "Gender: Male", "Date: 12/13/2011", and "Time: 01:18 PM". The main content area is titled "Proxy Status" and contains a form with the following elements: a "Status" section with three radio buttons labeled "Complete", "Partial", and "Not Done"; a "Comments" section with a dropdown menu; and an "Other text" section with a text input field. At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish". The status bar at the very bottom of the window displays "Ready", "MEC Layer: 11/17/2011", "Application: 10.0.4", "Connected to Coordinator", "SP not assigned to room", and "01:53 PM".

3. NYFS NURSE PRACTITIONER REFERRALS

3.1 Background

Although the primary purpose of the mobile center (MC) examination is data collection, not diagnosis or treatment, the examination may produce findings that warrant further medical attention. There is an obligation to inform SPs of any abnormal results from the examinations and to refer SPs to appropriate providers for treatment. MC nurse practitioners are responsible for reviewing exam data and generating referrals to a health care provider. Risks from the NYFS components are minimal, but may include tiredness, soreness, and possible injuries to joints or muscles. All components included in the survey have been used with children and adolescents previously. A nurse practitioner (NP) will be present during all examination center sessions. Tests will be stopped immediately with any complaint of discomfort or pain. All tests also will be stopped immediately if the participant is not able to follow instructions.

The referrals are made to the SP's primary care practitioner or to provider or clinic that was located in the geographical region. These community referrals are informal in that NHANES/NYFS has no formal relationship with these provider(s); the advance team researches and identifies community providers and clinic information and conveys this information to the physicians and NPs for the purpose of making a referral. Whenever possible, the NP should make the referral to the attention of the SP's own primary care provider.

3.2 Referral Types

Two types of referrals can be generated from the NYFS: (1) Specific examination observations made during the treadmill exam whenever a stopping criteria condition was encountered; and (2) general observations made by a MC examiner that the NP feels should be brought to the attention of a health care provider. In the referral comments, the NPs will indicate whether the medical follow-up is urgent or non-urgent.

3.2.1 Urgent Referral Parameters

The parent/guardian will be advised to have the SP see the child's health care provider within the next 5 days for an urgent referral.

The treadmill exam has protocol-driven urgent referral criteria. The parent/guardian will be advised to have the SP see the child's health care provider within the next 5 days if the following symptoms occurred during the treadmill exam:

- Pain or pressure in the chest;
- Pain in neck, jaw, or teeth;
- Pain in the shoulder or between the shoulder blades;
- Pain radiating down one or both arms;
- Moderate/severe leg pain or cramping; or
- Severe shortness of breath/wheezing.

In the case of general observations, an urgent observation referral would be generated if the NP is discharging the SP from the MC for an injury that requires immediate medical attention, or if a medical issue is discovered during the exams.

3.2.2 Non-Urgent Referral Parameters

The parent/guardian will be advised to see the child's health care provider within the next 5 days for a non-urgent referral.

For treadmill observations, the parent/guardian will be advised to inform the child's health care provider at the child's next appointment of symptoms such as:

- Change in skin color to bluish/grayish;
- Severe headache;
- Confusion or agitation;

- Nausea;
- Unstable gait; or
- Visual problems.

All other observation referrals will be considered non-urgent unless deemed otherwise by the NP.

3.3 Reporting Child Abuse

If a minor reports that he or she has been abused, the MC nurse practitioner should document the nature of the abuse. If warranted, the MC NP should call **Child Protective Services at the number provided by the NHANES Advance Arrangements Team**. If the NP is unsure whether or not to refer, he or she should discuss the case with a social worker at Child Protective Services (CPS). When presenting the case, the MC NP should not use the child's name or any other identifier. If the social worker and NP agree that the referral to CPS should be made, the NP may provide the name and address of the child.

3.4 Nurse Practitioner Referral Protocol

Throughout each session, and prior to an SP's departure from the MC, the nurse should periodically check the referral review screen for any observation or treadmill referrals. The review toolbar selection (Exhibit 3-1) has two review options: SP History and Referral Review. Use this drop-down list to select the Referral Review (Exhibit 3-2).

Exhibit 3-1. Review menu for selecting Referral Review

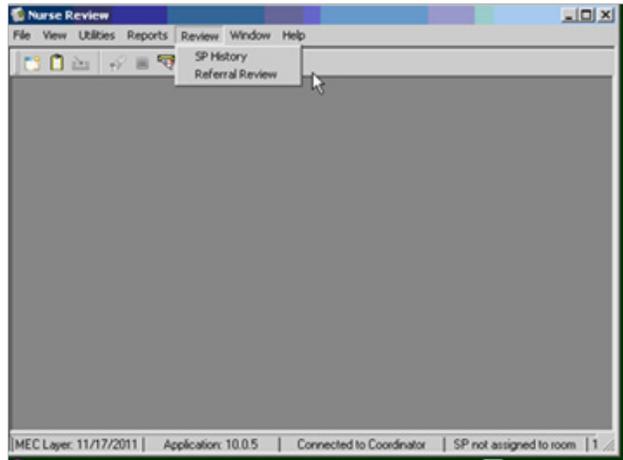
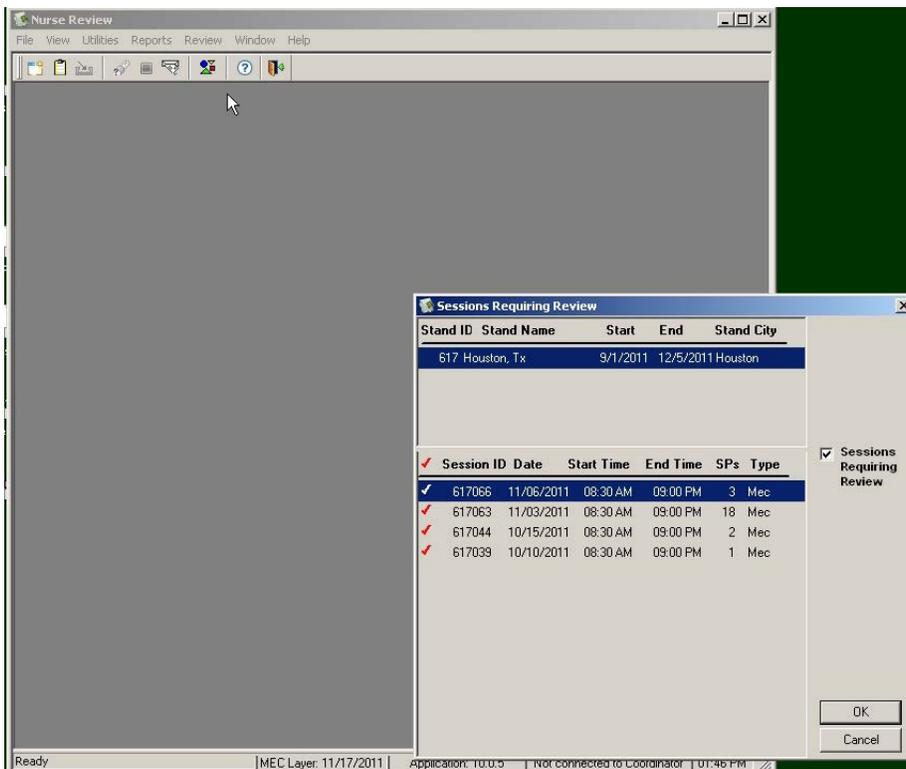


Exhibit 3-2. Referral Review session picklist

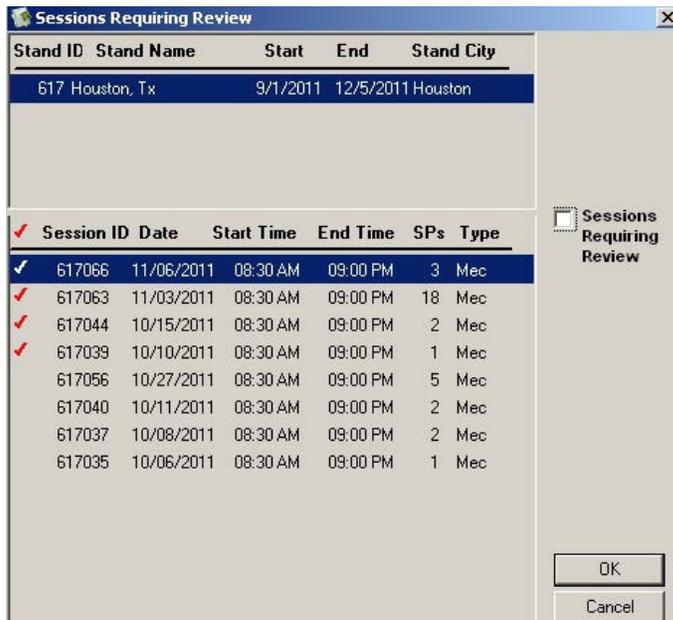


3.4.1 Sessions Requiring Review

The next screen that appears is the “Sessions Requiring Review” screen (Exhibit 3-3) which displays the current stand location and number. The bottom part of the screen displays various sessions in the stand, depending on how they are selected by the NP.

- When the “Sessions Requiring Review” box is checked, all MC sessions that require review are displayed.
- Referrals posted in the “Review Box” that the NP has not reviewed causes the application screen to display a **red checkmark beside the session indicating that the session requires review.**
- The **red checkmark remains** beside this session until the NP reviews all referrals in the session. When all referrals are completed or reviewed, the system removes the red checkmark.
- The upper section of the screen displays the current stand.
- The lower section of the screen displays the sessions to select to review.
- All sessions that have not yet been reviewed and closed out by the NP will appear with a red checkmark in the far left column.

Exhibit 3-3. Referral Review session picklist, sessions requiring review box not checked



The sessions that still require reviewing appear in addition to the sessions for which the NP has completed reviews.

Checkmarks that fail to disappear when the NPs have been closely monitoring a session most likely remain because the user forgets to check the “Save” button before closing the Referral Review screen.

- A checkmark in the “Sessions Requiring Review” tells the application only to display those sessions that have not been reviewed. It is not acceptable to have as many sessions that require review as in the above screenshot; every session should be monitored for the appearance of referral observations throughout the course of a session, prior to discharging an SP from the MC, and before closing the Nurse Review application at the end of the day.
- To view all sessions in the current stand, remove the checkmark from the “Sessions Requiring Review”; all sessions in the current stand will be displayed.
- To review a specific session, highlight and double-click on that session and that session will be displayed.
- Click “Cancel” to exit without viewing any sessions.

3.4.2 Review Box

- The Referral Review screen (Exhibit 3-4) lists all SPs in the current session; any participant who requires a referral assessment is marked with a white box in the column. There are two types of referrals to review: the first column is “Observ.,” and the second is “TM” (Treadmill).
- A box at the bottom left of the screen is checked if the session requires review. The box is unchecked if no review is required.
- To select the SP for review, move the cursor over the desired name.
- Highlight the name of the SP to be reviewed.
- Double-click on the SP name, or, click the “Details” radio button.

Exhibit 3-4. Referral Review selection screen with information to review

Referral Review Stand:291 Session: 291043 10/14/2011 08:30 am - 09:00 pm

| SP | | | | Return | Observ. | TM |
|-----------|--------|-----|--------|-------------|-------------|----|
| Name | ID | Age | Gender | Rev. Status | Rev. Status | |
| B. CHEN | 223755 | 10 | Female | 1 | | |
| A. CHEN | 657326 | 15 | Male | 2 | | |
| F. BARONE | 344840 | 8 | Female | 3 | | |
| F. BARONE | 554033 | 15 | Female | 4 | | |
| F. BARONE | 470553 | 14 | Female | 5 | | |
| T. JONES | 857615 | 10 | Female | 1 | | |
| F. BARONE | 415617 | 3 | Female | 2 | | |
| M. BARONE | 315453 | 6 | Male | 3 | | |
| F. BARONE | 517362 | 12 | Female | 4 | | |
| F. BARONE | 607997 | 4 | Female | 5 | | |
| M. BELL | 461188 | 13 | Female | 1 | | |
| M. BARONE | 578358 | 12 | Male | 2 | | |

Rev. Status Codes: 1 - Reviewed, referral NDT required
 2 - Reviewed, referral required
 3 - Reviewed, referral complete
 4 - Reviewed, actions required
 5 - Referral required - SP signed release

Session Requires Review

Back Message Referral Save Details Cancel

White boxes indicate that the nurse must open the referral information by double-clicking on the row of the SP.

The following Exhibit 3-5 shows that all boxes are greyed-out if there is no referral information for the nurse to review.

Exhibit 3-5. Referral Review selection screen with NO information to review

Referral Review Stand:291 Session: 291042 10/13/2011 08:30 am - 09:00 pm

| SP | | | | Return | Observ. | TM |
|---------|--------|-----|--------|-------------|-------------|----|
| Name | ID | Age | Gender | Rev. Status | Rev. Status | |
| S. MA | 348873 | 6 | Female | | | |
| S. MA | 762397 | 12 | Male | | | |
| S. DEMO | 342181 | 3 | Female | | | |
| S. T4 | 362452 | 5 | Male | | | |
| S. T1 | 671246 | 15 | Female | | | |
| S. HILL | 982703 | 11 | Female | | | |

Rev. Status Codes: 1 - Reviewed, referral NDT required
 2 - Reviewed, referral required
 3 - Reviewed, referral complete
 4 - Reviewed, actions required
 5 - Referral required - SP signed release

Session Requires Review

Back Message Referral Save Details Cancel

Here, neither of the two columns contains referral data. This indicates that there were no referrals generated during the session. This can change throughout a session, so it is advisable to check this screen periodically. At the end of a session, if there are no referrals, the NP still must select "Save" before closing the referral review screen; if this is not done, the session will continue to appear in the "Sessions Requiring Review" screens.

When a row is selected, a screen will appear that contains two tabs as shown below in Exhibit 3-6. Move between the two tabs to access and review the information. In the case below, this indicates Priority 1 treadmill stopping criteria.

Exhibit 3-6. Priority 1 urgent treadmill generated referral

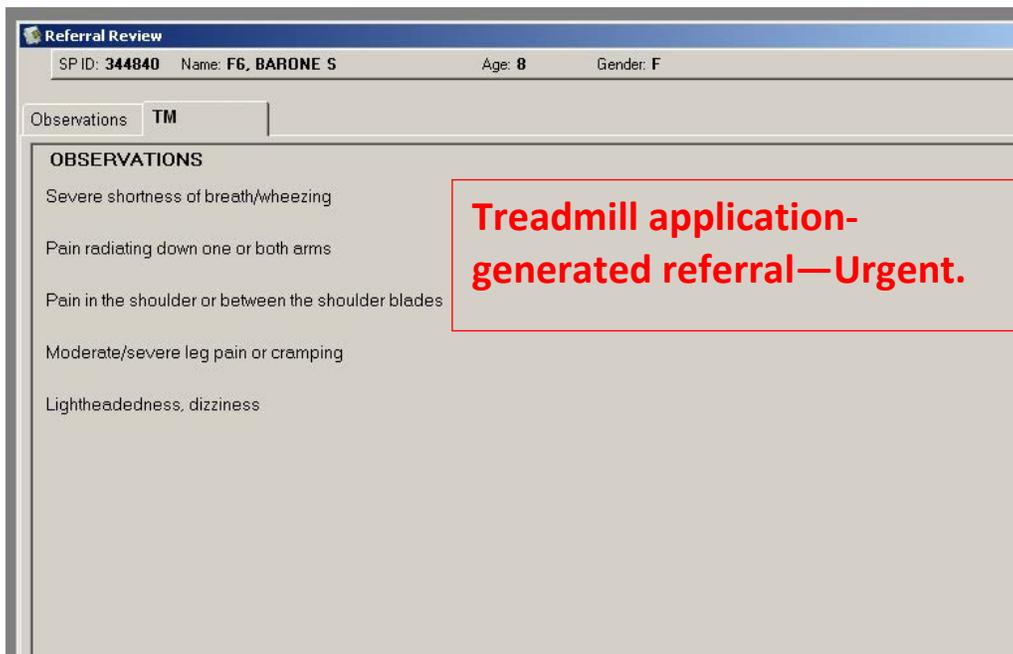
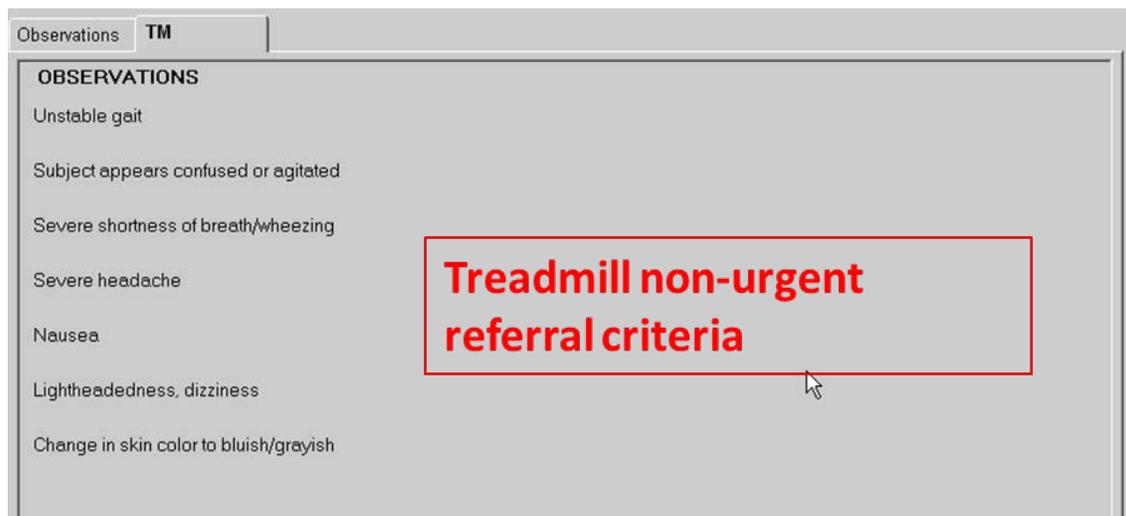


Exhibit 3-7. Screen indicating treadmill non-urgent referral criteria



3.5 Observation Referrals

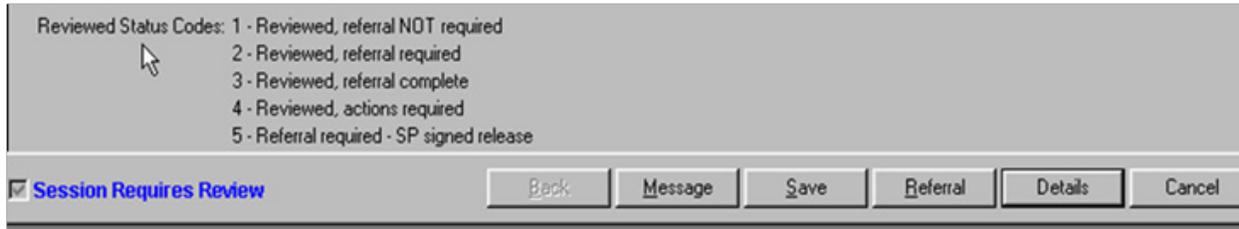
An observation referral can be generated from any component on the MC for any concern that the examiners identify throughout the SP's visit. Examples of concerns include head lice, upper respiratory infection, a skin lesion/rash, or any condition that has not been diagnosed or has been untreated. The NP will hold a discussion with the parent/guardian to determine if the SP is currently under treatment for the observed condition and whether or not a referral should be made.

3.5.1 Referral Decisionmaking

After reviewing the information, the NP will make a determination on the action to take based on the options presented in the drop-down menu options explained below. See Exhibit 3-8.

1. **Reviewed, referral not required.** The NP reviews either an observation or treadmill referral message, and determines there is no need for a referral. After consulting with the parent/guardian, the NP is comfortable that the parent and the SP's primary care provider are aware of the issue.
2. **Reviewed, referral required.** This indicates that the NP has reviewed the data in the inbox, and determined that a referral is necessary, but has not yet generated the referral. A checkmark in the "Return" column reminds the user that the referral still needs to be completed.
3. **Reviewed, referral complete.** The NP has generated the referral, printed the letter, and saved the data.
4. **Reviewed, actions required.** This is similar but not the same as Code 2. Use this code when the SP has been reviewed and you have completed the referral, however, the NP wants to take further action. An example may be if the NP needs to telephone a health care provider but has been unable to complete the process, or wishes to follow up with the SP. This may be carried over to the next day, or the next session. When Code 4 is checked, the SP may be checked out of the MC, but this session continues to be flagged, requiring review until this and other referrals are coded as 1 or 3.
5. **Referral Required, SP signed Release.** The NP has reviewed a concern with the parent or guardian, recommends that the SP be evaluated by a physician, but the SP refuses to do this. An example would be if the SP falls and has a laceration of some type, and should be sutured. A release form is available in the Blank Forms folder. The NP may seek the assistance of the MEC physician in this case. It is extremely rare.

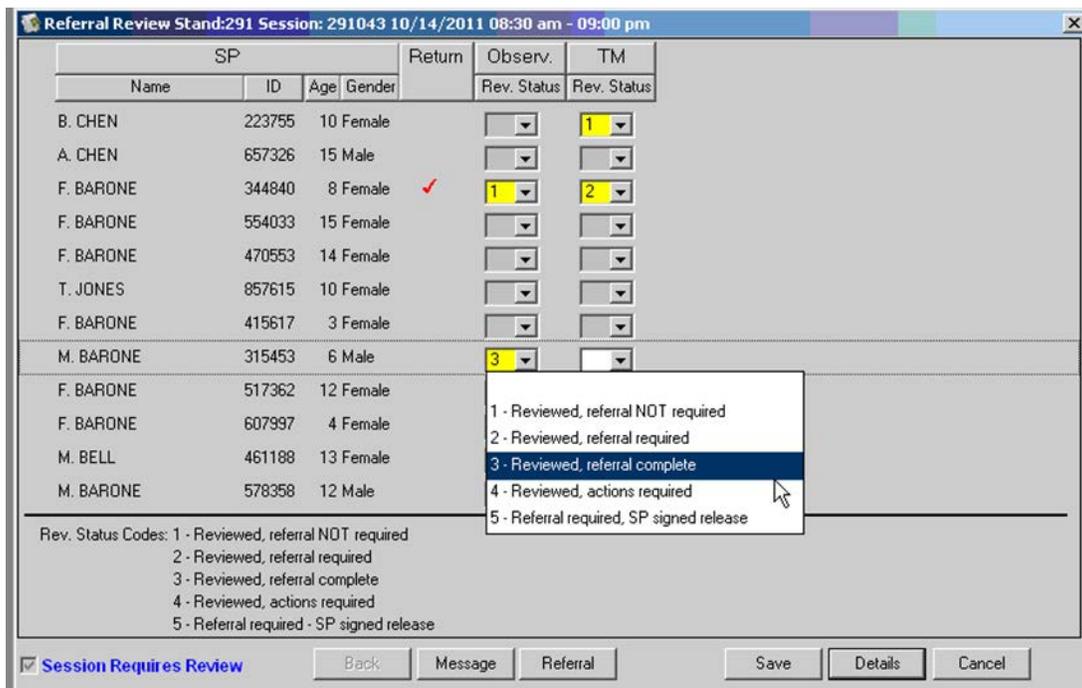
Exhibit 3-8. Reviewed status codes



The referral legend is located at the bottom left of the referral review screen for the users' reference.

In Exhibit 3-9, F. Barone, the 8-year-old female, has two different referral dispositions. The Observation referral was reviewed by the NP and after discussing the findings with the parent, made a determination that a referral was not necessary. The treadmill referral information was reviewed by the NP, and after discussing the findings with the parent made a determination that a referral was necessary, but has not yet generated the referral. M. Barone, the 6-year-old male, was evaluated by the NP, and a referral was completed.

Exhibit 3-9. Referral review status codes



3.5.2 The Referral Screen and Generating a Referral Letter

If a referral is required, select “Referral” and the following screen (Exhibit 3-10) will appear.

Exhibit 3-10. Referral screen with print option for letter

The screenshot shows a software window titled "SP Referral Information". The form is divided into several sections:

- Header:** "SP Referral Information" with a close button (X).
- Form Fields:**
 - Clinic/Physician Name: [Text Box]
 - Addr. 1: [Text Box]
 - Addr. 2: [Text Box]
 - City, State, Zip: [Text Box] [Dropdown] [Text Box]
 - Contact Name: [Text Box]
 - Phone: () - [Text Box]
 - Fax: () - [Text Box]
- medical referral Section:**
 - Print Referral
 - Clinic (with "Clinic Pickup" button)
 - Physician
 - Explained to SP
 - Explained to Guardian
 - Explanation declined
- Language Selection:** English (selected), Spanish
- Description of Explanation:** [Large Text Area]
- SP Response:** [Large Text Area]
- Referral Comments:** [Large Text Area]
- Buttons:** Print, Preview, Save, Close

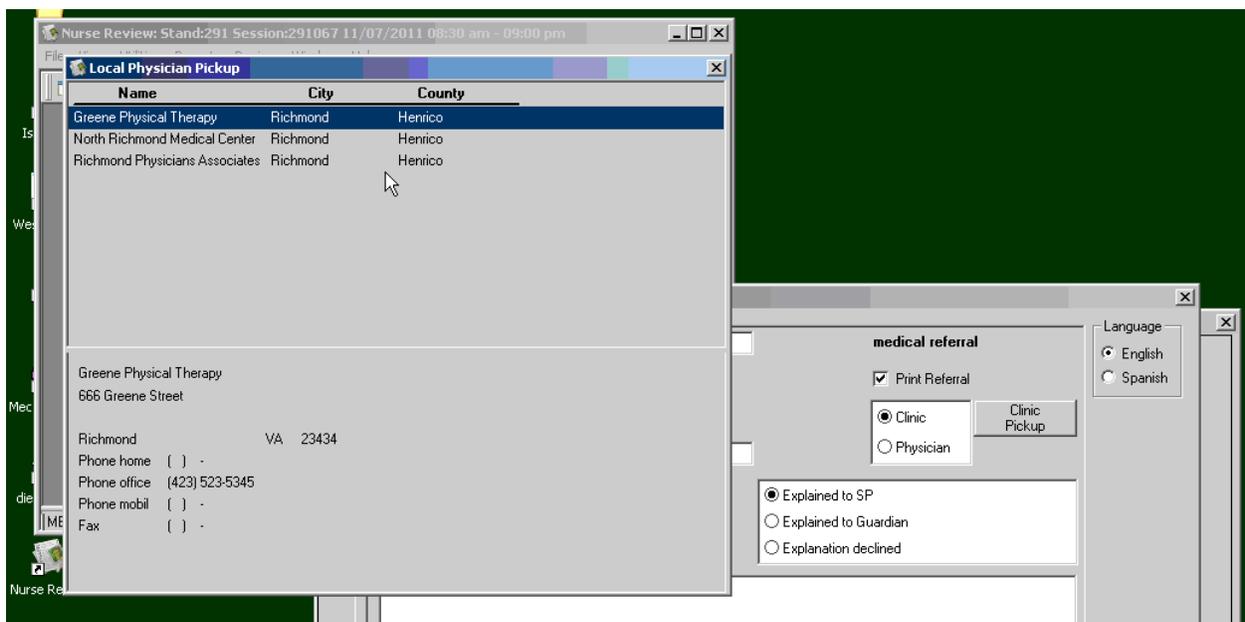
3.5.3 Select a Provider

The NP will discuss the need for a referral with the parent/guardian and then select a provider. Ideally, the family will have a primary care practitioner, and the nurse will enter as much information as the parent can recall. It is not necessary to complete all fields for the address and phone number to generate the referral letter. If the parent/guardian does not have a primary care practitioner, the

NP will use the “Clinic Pickup” to access the local providers entered into the database by the advance arrangements (AA) team. Select either clinic or physician.

- When the “Referral” button is clicked, Exhibit 3-11 is displayed. Click on “Clinic Pickup” to view a list of local clinics. Click on “NP” to see a list of local providers.
- The address and phone number will appear in the appropriate boxes.
- Select the name of the clinic or health care provider (Exhibit 3-12).

Exhibit 3-11. Screen with local physician pick-up clinics



The screenshot shows a software interface with a window titled "Local Physician Pickup". The window contains a table with the following data:

| Name | City | County |
|--------------------------------|----------|---------|
| Greene Physical Therapy | Richmond | Henrico |
| North Richmond Medical Center | Richmond | Henrico |
| Richmond Physicians Associates | Richmond | Henrico |

Below the table, the details for "Greene Physical Therapy" are displayed:

Greene Physical Therapy
666 Greene Street
Richmond VA 23434
Phone home () -
Phone office (423) 523-5345
Phone mobil () -
Fax () -

To the right of the table is a "medical referral" form with the following options:

- Print Referral
- Clinic (with a "Clinic Pickup" button)
- Physician
- Explained to SP
- Explained to Guardian
- Explanation declined

Language options: English, Spanish

Using Local Physician Pickup

1. Review the selections with the SP for geographical proximity
2. Double Click on the selection, and the fields will be populated with the name, address and phone number of that clinic.

Exhibit 3-12. Local physician and clinic pickup referral letter addresses

| Local Physician Pickup | | |
|--------------------------------|-----------------|-------------|
| Name | City | County |
| Chicago Dept. of Public Health | Chicago | COOK |
| Englewood Clinic | Chicago | COOK |
| Lower West Side Clinic | Chicago | COOK |
| North District Office | Rolling Meadows | COOK |
| Roseland Clinic | Chicago | COOK |
| South District Office | Markham | COOK |
| Southwest District Office | Bridgeview | COOK |
| Uptown Clinic | Chicago | COOK |
| West District Office | Maywood | COOK |
| West Town Clinic | Chicago | COOK |

| | |
|--------------------------------|----------------|
| Uptown Clinic | |
| Chicago Dept. of Public Health | |
| 845 West Wilson | |
| Chicago | IL |
| Phone home | () - |
| Phone office | (312) 744-1938 |
| Phone mobil | () - |
| Fax | () - |

3.5.4 Referral Letter Review

The NP must complete three fields when generating a referral: description of explanation, SP response and referral comments (Exhibit 3-13). Please bear in mind that the only information from the following fields that is uploaded into the referral letter is from the referral comments. The other two are for internal use only for quality control and recordkeeping.

1. Description of Explanation: The documentation in this field.
2. SP Response.
3. Referral Comments. These are the only comments that are uploaded to the referral letter. In this field, briefly describe the reason you want the SP to have a provider referral. There is no need to attempt an extensive medical history review, assessment or plan; just state the facts of the observation and any precipitating factors you may want to convey to the provider.

Exhibit 3-13. SP referral information

SP Referral Information

Clinic/Physician Name:

Addr. 1:

Addr. 2:

City, State, Zip:

Contact Name:

Phone:

Fax:

medical referral

Print Referral

Clinic Physician

Explained to SP
 Explained to Guardian
 Explanation declined

Language

English
 Spanish

Description of Explanation:

Document your description of the reason for the referral; this is for our records, and is not printed in the referral letter. Keep description brief-there is a character limit in this field.

SP Response:

This is where you would document your encounter with the SP/parent, i.e. whether they are aware of the issue, if there is no hx of the observation that has triggered the referral etc. There is a character limit, so indicate if SP/parent agreed or not.

Referral Comments:

This is where the observation and reason for the referral is documented but only in as much detail as necessary. This will be printed on a separate page following the referral letter. For example:
"Please evaluate (SP NAME) for shortness of breath during a treadmill test."

There is no need to attempt an extensive medical history review, assessment or plan; just state the facts of the observation and any precipitating factors you may want to convey to the physician. |

Click “Yes” to save and close this box. If all status codes are 1 and 3, the “Session Requires Review” box will be unchecked and the red checkmark will be removed from the session requiring review list. See Exhibit 3-14.

Exhibit 3-14. Example of an Observation Referral

The screenshot shows a software window titled "SP Referral Information" with a close button (X) in the top right corner. The form is divided into several sections:

- Clinic/Physician Name:** A text field containing "Dr. (Name of SP's Pediatrician)".
- Address:** Three text fields for "Addr. 1:", "Addr. 2:", and "City, State, Zip:". The "City, State, Zip" field is split into three sub-fields.
- Contact Information:** Text fields for "Contact Name:", "Phone:", and "Fax:", each with a dropdown menu for area code selection.
- Referral Type:** A section titled "medical referral" containing:
 - A checked checkbox for "Print Referral".
 - Radio buttons for "Clinic" (unchecked) and "Physician" (checked).
 - A "Clinic Pickup" button.
 - Radio buttons for "Explained to SP" (unchecked), "Explained to Guardian" (checked), and "Explanation declined" (unchecked).
- Language:** Radio buttons for "English" (selected) and "Spanish".
- Description of Explanation:** A text area containing "General observation: SP has head lice".
- SP Response:** A text area containing "Parent aware, has been ongoing issue at the school."
- Referral Comments:** A text area containing "Please evaluate for the management and control of head lice; this is the third infestation in 3 months. The problem is well known in the school SP attends."

On the right side of the window, there are four stacked buttons: "Print", "Preview", "Save", and "Close". A mouse cursor is pointing at the "Close" button.

Exhibit 3-15. Warning to save changes

Closing without saving loses all data! Each time a review is performed, save the data.

Be sure to check the scroll bar for additional rows of SPs; the maximum number of rows that can be displayed is 11.

| Name | SP | Return | Preg. | CBC | BP | Observ. | MH | SP |
|------------|--------|-----------|-------------|-------------|-------------|-------------|-------------|-------------|
| | | | Rev. Status |
| M. HOGAN | 597319 | Female | | | | | | |
| D. HOGAN | 622136 | Female | | | | | | |
| S. MURRAY | 623543 | 35 Female | | | | | | |
| T. HOGAN | 691151 | 50 Male | | | | | | |
| K. HOGAN | 736050 | 53 Male | | | | 2 | | |
| E. HOGAN | 871293 | 4 Female | | | | | | |
| A. SMITH | 228518 | 16 Female | | | | | | |
| A. SMITH | 230557 | 37 Female | | | | | | |
| C. JANE | 274843 | 8 Female | | | | | | |
| A. GREGORY | 295351 | 36 Female | | | | | | |
| C. SMITH | 361548 | 50 Female | | | | | | |

Rev. Status Codes: 1 - Reviewed, referral NOT required
2 - Reviewed, referral required
3 - Reviewed, referral complete
4 - Reviewed, actions required
5 - Referral required - SP signed release

Physician

Do you want to save changes?

Yes No Cancel

Session Requires Review

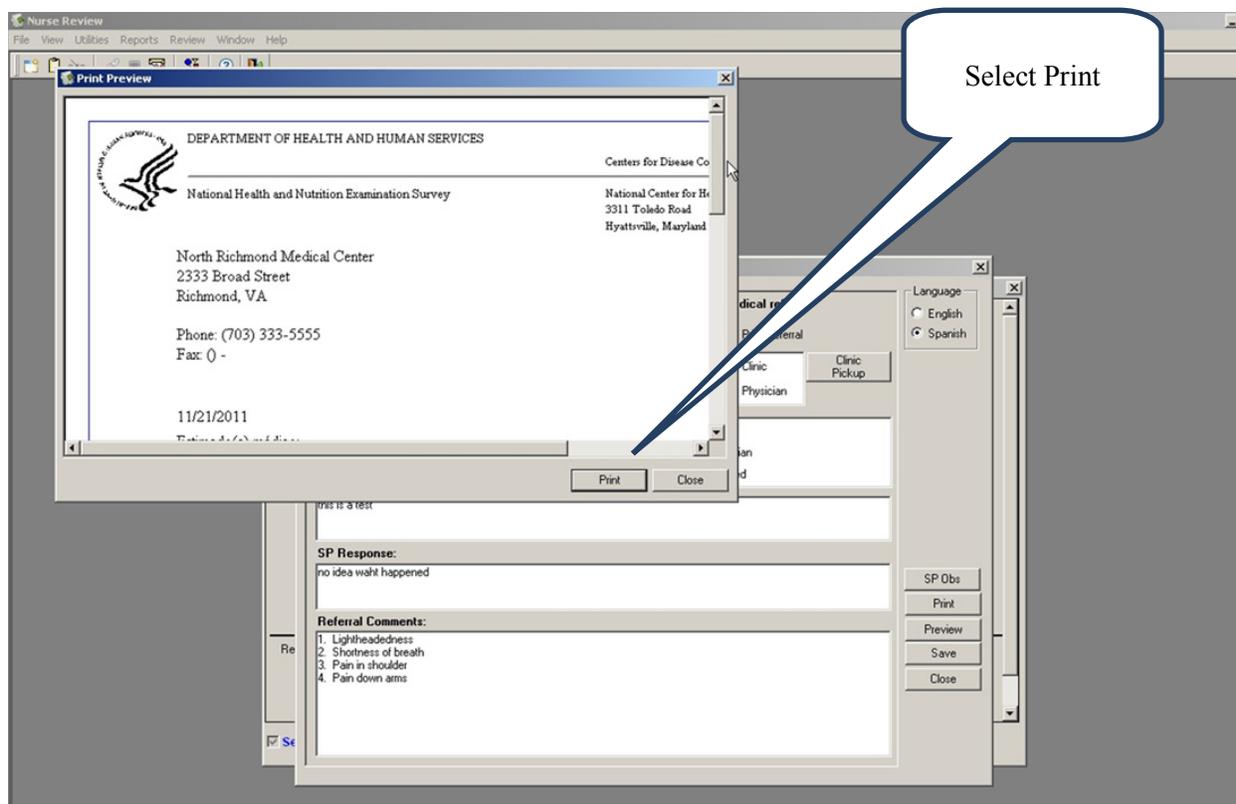
Back Message Referral MH Referral Save Details Cancel

One of the most common causes of data loss in the referral system occurs when the user fails to save the data. The application has been enhanced with a hard edit stop to remind the user to save the data if the application is closed without saving.

Printing the Referral Letter

When the letter is printed, the first page contains the form letter followed by a separate page that is printed with the entry from the “Referral Comments” page (Exhibit 3-16).

Exhibit 3-16. Print preview of referral letter



The following Exhibit 3-17 shows the letter that will be printed from the referral screen. The second page of the letter (Exhibit 3-18) prints only the comments from the “Referral Comments” field for the physician to review. Place both documents into a business envelope, write the provider’s name on the envelope, and give to the parent.

Exhibit 3-17. Letter printed from referral screen

| | | |
|---|---|--|
|  | DEPARTMENT OF HEALTH AND HUMAN SERVICES | Centers for Disease Control and Prevention |
| National Health and Nutrition Examination Survey | | National Center for Health Statistics 3311 Toledo Road Hyattsville, Maryland 20782 |
| <p>My Doctor</p> | | |
| <p>Phone: Fax:</p> | | |
| <p>2/21/2012</p> | | |
| <p>Dear Practitioner:</p> | | |
| <p>On November 06, 2011, Carl Macy was among those who participated in the National Health and Nutrition Examination Survey - National Youth Fitness Survey, conducted by National Center for Health Statistics, part of the Center for Disease Control and Prevention. The objective of the survey is to obtain information on physical activity and fitness in children. During the testing, an incident occurred that requires medical follow-up. This incident is described on the attached Referral Comments page.</p> | | |
| <p>This study is intended to collect health measures for research. It is not a physical exam. No attempt has been made to diagnose or treat medical conditions of the participants. If you have any questions, you may contact me at the Mobile Exam Center. The phone number is (555) 666-7777 until November 27, 2011. After that date you may contact Dr. Kathryn Porter at the National Center for Health Statistics, Monday through Friday 8:30 AM to 6:00 PM, EST. The toll free number is 1-800-452-6115.</p> | | |
| <p>Cordially,</p> | | |
| <p>Whitney Block, N.P.</p> | | |
| <p>Carl Macy, 453190, 2/21/2012. Exam Date: November 06, 2011. National Center For Health Statistics, 3311 Toledo Road, Hyattsville, Maryland 20782.</p> | | <p>Page 1 of 2</p> |

Exhibit 3-18. Second page of referral letter

Referral Comments for Carl Macy

Physician Comments
Please evaluate and treat for head lice.

Carl Macy, 453190, 2/21/2012. Exam Date: November 06, 2011.
National Center For Health Statistics, 3311 Toledo Road, Hyattsville, Maryland 20782.

Page 2 of 2

3.6 NHANES Release Form for SPs Refusing Referrals

- SPs who decline or refuse a medical referral, are asked to sign the NHANES Release Form (Exhibit 3-19). The date and stand number must be completed. The form is available in English and Spanish.
- This form is available for printing in the “Forms” directory.
- Ask the SP to place a checkmark next to the correct ending for the reference sentence:
 - “This is to certify that against the advice of the staff doctor, I.”
 - am leaving the Mobile Exam Center.
 - am removing (name of sample person).
 - choose no further medical referral or immediate follow-up.
- Ask the SP to sign this form.
- Obtain a witness signature for the form.

Exhibit 3-19. NHANES release form



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
6525 Belcrest Road
Hyattsville, Maryland 20782

**NHANES
RELEASE FORM**

Date: _____

Stand: _____

This is to certify that against the advice of the staff doctor I:

(Check one)

- am leaving the Mobile Exam Center
- am removing _____
(name of sample person)
from the Mobile Exam Center
- choose no further medical referral or immediate follow-up.

By so doing, I assume all responsibilities for my act.

Signed _____

Relationship _____

Witness _____

4. EMERGENCIES AND INCIDENTS IN THE MOBILE CENTER

4.1 Safety in the Mobile Center

The best approach to emergency situations in the mobile center (MC) is to prevent problems from developing into emergencies whenever possible, and to be well prepared for those emergencies that cannot be avoided. It is the responsibility of all examination staff members to participate in maintaining safety in the MC by staying alert for potentially unsafe conditions or unusual sample person (SP) behavior, and by being thoroughly familiar with the current NHANES procedures for emergencies.

4.1.1 Sample Persons in Wheelchairs

Some SPs or their family members may arrive in wheelchairs, and the exam staff will have to facilitate the SPs' entry into the MC and their progress through the examination. The NYFS nurse practitioners will be notified when a participant uses a wheelchair for mobility so that the handicap lift can be prepared. If the SP can bear sufficient weight on at least one leg or can otherwise support himself or herself during the transfer, the nurse practitioner and another exam staff member should assist him or her into the MC wheelchair to facilitate movement throughout the MC.

Sample persons who cannot bear most of their weight on one leg and need assistance in transferring to the MC chair should not be lifted or moved out of their wheelchairs. Lifting or moving SPs without their assistance could result in injury to a SP or staff member, and is unwarranted. SPs should remain in their wheelchairs and receive the exams that can be conducted in that position. When the transfer of an SP raises questions, the nurse practitioner should make the decision of whether or not to transfer an SP.

4.1.2 Children in the MC

Children in the MC should be monitored at all times when not participating in an exam component. Young children should not be permitted to walk through the MC unescorted, and should not

interfere with the performance of any examinations. When waiting for an exam, young or unruly children should remain in the reception area under supervision.

4.2 Safety Precautions in the MC

A number of precautions have been taken to promote safety in the mobile center:

- All examination staff members are certified in cardiopulmonary resuscitation, Course Level C, and recertified biannually.
- A nurse practitioner is required to be present when SPs are in the MC.
- At least one of the nurse practitioners must be present whenever SPs are in the MC.
- All staff are required to be thoroughly familiar with the safety issues and emergency procedures.
- Mock emergency drills will be held periodically in the MC to simulate a medical emergency and permit practice of emergency procedures.

Standard first aid approaches will be followed for common problems such as faints, minor seizures, falls, and other minor injuries. The nurse practitioner will be notified immediately of any situation involving a participant whose safety is of concern. The nurse practitioners are expected to manage minor incidents or adverse events that occur in the National Youth Fitness Survey (NYFS) on their own. In the case of a medical emergency, the nurse practitioner will call 911 and attend to the emergency while other NYFS staff will engage the NHANES MEC physician when available.

Equipment and supplies are available for use in the management of a participant in distress. The nurse practitioner can be provided with a list of medications that the participant is taking and that was obtained during the home interview. If EMS is called, transfer of care occurs when trained ambulance personnel arrive to transport a participant in distress. If the child was not accompanied to the examination center by a parent or guardian, the nurse practitioner/physician or field office will contact the participant's family as soon as possible to inform them of the incident and the medical facility to which the participant was taken. Medical emergencies are rare and not expected for the NYFS.

4.2.1 Safety Equipment

The following safety equipment is available in the MC:

- Two fire extinguishers have been placed on the MC to allow rapid response to fire.
- A drug kit, an automated external defibrillator, one portable size D oxygen tank, and portable blood pressure equipment are kept in the MC. All staff must be able to recognize and locate this equipment without delay.
- Pocket masks for CPR are located in each room of the MC.

The following safety procedures will be used in the MC:

- The phone number “911” is to be used to activate emergency medical services (EMS) if applicable for the MC location. The telephone number and address of the local fire and rescue squad will be posted at the coordinator’s station by the telephone.
- The address of the MC will be posted in the coordinator’s station so that the location can be reported correctly to EMS.
- The MC is a “NO SMOKING” facility. Neither staff nor SPs may smoke in the exam center. Should a staff member or SP have the need to smoke, she or he must step outside the MC.

4.2.2 Oxygen Cylinders and Supplies

There is one size D aluminum oxygen cylinder on the mobile center (MC), which is the backup oxygen cylinder on the NHANES mobile exam center. The nurse practitioner will obtain the cylinder from the MEC physician during setup, and will return the cylinder to the physician during tear down. The cylinders are 14.27” long by 4.38” diameter with an oxygen capacity of 415 liters; a full cylinder will vary in clinically effective usage time, but an estimate of usage time is approximately 25 minutes when running at 8L/min.

The oxygen cylinder is attached to the wall of the short corridor. The regulator must be attached at all times. The cylinder and regulator are encased in a soft nylon padded carrying bag with a shoulder strap for ease of carrying during an emergency.

Oxygen administration supplies include: one pediatric nasal cannula, one adult nasal cannula, one non-rebreather oxygen mask with tubing, and one oxygen extension tubing. The MC carries its own oxygen administration supplies and are accounted for on the MC inventory. Staff must remember not to take the MC's oxygen supplies to the MEC when returning the oxygen cylinder to the MEC physician. The nurse practitioner is responsible for conducting an inventory of all oxygen administration supplies at stand setup and teardown, and ordering replacements through the inventory management system.

Oxygen is regarded as a medication and should only be administered by or with the direction of a qualified health care provider. On the MC, the nurse practitioner is the staff member designated to determine the necessity of oxygen administration, and will provide other MC staff with instructions regarding method of administration and the flow rate. Whenever oxygen is administered *for any length of time*, the NP is responsible for recording all information regarding the oxygen administration on the Oxygen Usage Log. Any administration of oxygen constitutes an emergency or incident, and the NP must also complete the emergency forms on the MC.

Oxygen Cylinder Monitoring. The nurse practitioners are responsible for monitoring oxygen cylinders. Regulator readings should be recorded on the Oxygen Cylinder Monitoring Log at the following times throughout each stand: on setup day, **every Monday** during the afternoon or evening session, and at teardown. If the team is not working on Monday, then the supply level should be checked the next session worked. The nurse is responsible for signing the form when the oxygen level is checked. The completed forms are returned to the MEC physician at the end of the NYFS exams, and the MEC physician will use this form until the end of the stand. The MEC physician returns the form to Jim Covell at the Westat home office.

Oxygen Tank Refilling/Replacement. When either cylinder is less than half full, the facility and equipment specialist (FES) is responsible for refilling the cylinder. During SP sessions, one cylinder must be present on the MC, even if only half full. Dr. Porter from NCHS provides Westat with a prescription letter to be kept with the FES, and a copy of the letter will be retained at the Westat home office with Jim Covell. Oxygen suppliers almost always require a prescription for oxygen, although this depends on the laws of individual states.

Table 4-1 lists the contents of the MC emergency kits.

Table 4-1. Emergency kit supply items

| Emergency kit supply items | Quantity |
|--------------------------------|----------|
| Medications: glucose tube | 1 |
| Pocket aneroid BP cuff – child | 1 |
| Pocket aneroid BP cuff – adult | 1 |
| Stethoscope – pediatric | 1 |
| Stethoscope – adult | 1 |
| Bandage scissors | 1 pair |
| Pen light | 1 |
| Sterile gloves: medium | 2 pair |
| Transpore tape 1/2” | 1 roll |
| Surgilube packets | 10 |
| Tongue depressor | 5 |
| Oral airway – small | 1 |
| Oral airway – medium | 1 |
| Oral airway – large | 1 |
| Nasal cannula – pediatric | 1 |
| Nasal cannula – adult | 1 |
| Oxygen mask (non-rebreather) | 1 |
| Oxygen extension tubing | 1 |

Table 4-2 lists the contents of the first aid kit.

Table 4-2. First aid kit

| First Aid Kit | Quantity |
|--|---------------|
| Alcohol wipes | 1 box |
| Ammonia ampoules | 1 box (5) |
| Air sickness bags | 12 |
| Antiseptic wipes | 20 packets |
| Band-Aids (3/4" x 3" flex adhesive) – Coverlet | 1 box |
| Gauze pads (2" x 2") – sterile | 1 box |
| Gauze pads (4" x 4") – sterile | 1 box |
| Hand soap-waterless (Purell) | As you desire |
| Hydrocortisone cream | 1 box |
| Hydrogen peroxide | 1 bottle |
| Instant cold pack | 3 |
| Odor perception inhibitor – 50 packets per box | 1 box |
| Tape, first aid adhesive 1" transpore | 1 roll |
| Triple Antibiotic Ointment | 1 box |
| Tweezers | 1 |
| Bandage scissors | 1 |
| Thermometer (mercury). (We do not measure temps on the participants even if they appear to have a fever—it is strictly for the staff.) | 1 |

4.2.3 On-Site Preparations at Each Stand

The field office or the advance arrangements team will contact and meet with local fire and rescue representatives to orient them to the location and structure of the MC.

The field office will provide advance notice to the MC of any SPs who require assistance entering or moving through the exam center. The nurse practitioner will inform the MC staff and coordinate the necessary preparations of the MC to accommodate the SP.

The nurse practitioner will review the medication history from the household interview for each SP prior to the examination session in which the SP's appointment is scheduled. The SP medication information can be accessed by the nurse practitioner in the nurse review application.

4.3 Reporting SP Problems to the MC Nurse Practitioner

SPs who report feeling ill or who appear to feel ill should be reported to the MC nurse practitioner at the earliest opportunity. At times SPs may have nonspecific complaints such as viral illnesses, joint pain, or fatigue that do not appear to warrant an emergency response. Exam staff members should offer to have the nurse practitioner speak with an SP who has a particular complaint. If the SP is reluctant or refuses to discuss his or her complaints with the nurse practitioner, and there is any question about the health or safety of the SP, staff members should consult the nurse practitioner for recommendations on how to proceed through the exam. The nurse practitioner may consult with the MEC physician at any time that the MEC is in session.

4.4 Medical Management on the Mobile Center

The following sections describe some medical scenarios that may occur during the MC examination and actions to be taken by the MC nurse practitioner. The section also provides guidance in determining the level of referral for a participant.

First Aid for Choking

Infants, children, and adults who are choking as a result of a foreign body obstruction should be treated according to the guidelines recommended in basic life support courses.

For adults and children older than 1 year, the abdominal thrust maneuver is the treatment of choice. A series of 6 to 10 rapid, upward abdominal thrusts can be performed until the foreign body is expelled. If the obstruction is not relieved using the abdominal thrust maneuver, the victim's airway should be opened using the tongue-jaw lift. If the object is visible, it can be removed with a finger sweep. If the object is not visible, blind finger sweeps can cause further airway obstruction and should never be done on children.

For choking infants, place the infant face down on the rescuer's forearm in a 60-degree head-down position with the head and neck stabilized. A series of back blows and chest thrusts should be performed until the airway obstruction is relieved.

Seizures

Participants who experience a seizure while in the MC should receive immediate attention from the nurse practitioner. The following steps should be taken to secure the safety of the participant:

- Step 1. Position the participant on the ground.
- Step 2. Insert an oral airway if the jaw is relaxed. (Do not **force** any object into the mouth.)
- Step 3. Remove glasses and loosen collar.
- Step 4. Remove objects from vicinity of participant to prevent injury.
- Step 5. Monitor vital signs.

The MC nurse practitioner must use his or her clinical judgment based on the participant's past medical history, the type and duration of the seizure, the cause of the seizure, and current seizure medication to determine whether or not the person needs emergency medical care or can be sent home. The MC nurse practitioner is also responsible for maintaining an airway, giving any indicated medications, and directing care of a seizing participant until an ambulance arrives or the seizure is over.

Hypoglycemia

Most conditions of hypoglycemia can be treated while the subject is conscious with the simple administration of juice and other first aid measures. If hypoglycemia is suspected in the case of an unconscious participant, the following steps may be taken after emergency assistance is summoned:

- Step 1. Recognition of hypoglycemia based on available history:

Bizarre behavior and other clinical signs of possible glucose insufficiency should lead the nurse practitioner to think of hypoglycemia. Hypoglycemia may develop in both diabetic and nondiabetic individuals.

Step 2. Basic life support:

- Immediate management includes positioning (supine), airway maintenance, oxygen administration, and monitoring of vital signs. The hypoglycemic participant will not regain consciousness until the blood glucose level is elevated.

Step 3. Definitive management:

- An unconscious person with a prior history of diabetes mellitus is always presumed to be hypoglycemic unless other causes of unconsciousness are present. Definitive management of the unconscious diabetic usually entails the administration of a carbohydrate by the most effective route available. The most effective route is usually intravenous administration of 50 percent dextrose solution. The unconscious participant must **never** be given anything by mouth, since this may add to the possibility of airway obstruction or pulmonary aspiration. In the absence of intravenous fluids, definitive management must await the arrival of local emergency assistance.

Use of Oxygen

When the oxygen tank is used in the MC, the flow rate should be set between 3-6 liters/minute unless the person has chronic obstructive pulmonary disease (COPD). With the use of the nasal cannula, a flow range of 3-6 liters/minute produces a forced inspiratory oxygen of 40 to 50 percent. If the SP self-reported COPD, the flow rate should be set at 2 liters per minute. At this rate, there is little to no danger of interfering with the hypoxic-breathing stimulus present in COPD.

4.5 Emergency Procedures

4.5.1 Medical Emergencies Overview

The MC examinations are designed to be safe for participants. To ensure maximal safety, the nurse practitioner must be able to handle the initial management of an participant in distress. The response of the nurse practitioner is limited by a number of factors. There are no respiratory therapists or other specialized staff that are necessary for a high level emergency response. The MC is not a diagnostic or treatment center, and the liability insurance obtained for Westat nurse practitioners does not cover any type of treatment procedure (except emergency stabilization). Within these restrictions, the appropriate

response of the nurse practitioner should be, as previously stated, to stabilize the participant in distress and facilitate a safe and expedited transfer to the nearest medical facility.

Before examinations begin at a stand, the facility and equipment specialist (FES) will have obtained information from the advance team about the types and availability of emergency medical services in the area where the MC is located. The FES will also invite the emergency medical service to tour the MC prior to the start day of SP examinations. Emergency medical services can include those available at nearby hospitals, hospital ambulance services, and emergency services available from police and fire rescue squads as well as from other county or local rescue squads. The phone number “911” is to be used if applicable for the MC location. However, the telephone numbers of the nearest police, fire, and rescue squads will also be posted. Execution of emergency procedures and the proper use of all emergency equipment will be the responsibility of the MC nurse practitioner.

The nurse practitioner is responsible for directing the care of a participant in the event of an emergency. Staff members are responsible for the tasks assigned to them under the direction of the nurse practitioner.

The best overall approach to medical emergencies is prevention. The nurse practitioner may be called upon to decide if some procedures should not be administered to certain participants to avoid potential medical problems if the participant does not fit easily into the preexisting medical exclusion categories for that procedure. The examining nurse practitioner can at his or her discretion proscribe certain procedures such as respiratory health and other tests if he or she believes the test may endanger a participant’s health. The specific reasons for excluding the participant should be recorded in the system in the comment drop-down list.

Standard first aid approaches are to be followed for common problems such as faints, minor seizures, falls, and other minor injuries. The MC nurse practitioner will determine the level of treatment and referral based on the circumstances of each case. Caution should be exercised, and there should be no hesitation to send a participant to an emergency room when circumstances warrant.

The nurse practitioner is to be notified immediately of any situation involving a participant whose safety is of concern. Any questionable situation should be considered an emergency and evaluated by the nurse practitioner. In addition to the equipment and supplies that are in the MC at the time of the emergency, a list of the medications (prescription and nonprescription) that the participant is currently

taking will be available. The medication list may provide pertinent medical history information to the nurse practitioner so that a more accurate assessment of the participant can be made and the appropriate emergency treatment given. The medication list is the one obtained by the interviewer in the household questionnaire, and is available in the nurse review application.

When ambulance personnel trained in emergency medical care arrive to transport a participant in distress (Level I referral) the nurse practitioner should make an assessment of whether he or she should accompany the participant to the emergency room. The decision should be based on maximizing safety for the participant. The field office will contact the participant's family as soon as possible to inform them of the incident and the medical facility to which the participant was taken. The nurse practitioner may also contact the participant's designated primary health care providers as soon as possible to inform them of the occurrence and name of the medical facility to which the participant was taken.

4.5.2 Procedures for Handling Unexpected or Adverse Events

Risks from the NYFS components are minimal, but may include tiredness, soreness, and possible injuries to joints or muscles. All components included in the survey have been used with children and adolescents previously. A nurse practitioner will be present during all examination center sessions. Tests will be stopped immediately with any complaint of discomfort or pain. All tests also will be stopped immediately if the participant is not able to follow instructions. The nurse should generate an incident form for staff as well as SPs, parents, and guests.

The following guidance is intended to support the NPs in the event of the following situations that may arise: nosebleeds, syncope, head injury, and laceration.

Nosebleeds. Nosebleeds are common. Most often they are a nuisance and not a true medical problem. But they can be both. Among children and young adults, nosebleeds usually originate from the septum, just inside the nose.

If a nosebleed occurs in a NYFS participant:

- Have the youth sit upright and or lean forward.
- **Have the participant pinch his or her nose with his or her thumb and index finger.** Instruct the participant to breathe through his or her mouth. Continue to pinch for 5 to 10 minutes. This maneuver sends pressure to the bleeding point on the nasal septum and often stops the flow of blood.
- After bleeding has stopped, instruct the participant to not pick or blow his or her nose, and suggest that he or she not bend down until several hours after the bleeding episode. If any subsequent examinations require bending over where the head is lower than the heart, exclude the participant for these maneuvers.
- If the **bleeding lasts for more than 20 minutes**, have the parent/guardian seek immediate care for the youth.

Syncope. Syncope (fainting) is a partial or complete loss of consciousness due to a reduced supply of blood to the brain for a short time. Since NYFS participants will be under continuous observation, either in an examination setting or being escorted from one component to another, staff should be on the alert for signs and symptoms of syncope. These include:

- Sweating.
- Coldness of the skin.
- Dizziness.
- Numbness and tingling of the hands and feet.
- Extreme paleness.
- Nausea.
- Possible disturbance of vision.

If the study participant exhibits any of the manifestations listed above during the NYFS examination, **stop the assessment immediately** and do the following:

- Have the participant **sit and bend over** with his or her head at the level of the knees. If the symptoms are severe and loss of consciousness is imminent, **assist the participant to a supine position** on the floor.
- Loosen any tight clothing.

- Be on the alert for vomiting; if vomiting occurs while the participant is supine, roll the participant onto his or her side.
- Maintain an open airway.
- If there was loss of consciousness, obtain vital signs immediately and every 5 minutes until the blood pressure is normalized.
- Provide a cool wet cloth to the forehead.
- **Do not** give any liquid unless the participant has fully recovered.
- If the participant loses consciousness, is unresponsive and cannot be aroused, engage the emergency medical system. Do not leave the participant unattended. If no pulse is detected, administer CPR.

Head Injury. Head injury is a broad term that refers to the vast array of injuries to the scalp, skull, brain and the underlying tissue and blood vessels in a child's head. This could be as mild as a bump or bruise or severe as a concussion or fractured skull.

Mild or moderate head injuries:

- To control bleeding, apply clean dressings directly to scalp or facial cuts.
- To control swelling, apply ice for 20 to 30 minutes.

Provide a referral if the participant experiences:

- Increased drowsiness.
- Irritability or restlessness.
- Loss of strength in the hands or feet.
- Persistent vomiting.
- Worsening headache.

Call 911 if the person has any of the following symptoms:

- Blood or clear fluids coming from the ears or nose.
- Slurred speech.
- Unconsciousness, confusion, dizziness, or drowsiness.

- Unequal pupil size or blurred or double vision.
- Do not move the participant until a medical team arrives and checks for spinal cord injury (unless the airway is blocked).

Lacerations. Lacerations are characterized as torn or ragged wounds.

- Most bleeding from a cut or laceration can be stopped with direct pressure and time (rest and elevation are also helpful).
- Cleaning with a gentle soap and water will help reduce the chance of bacterial infection.
- Apply a sterile gauze bandage to protect the wound.
- Participants who require sutures should be referred to the emergency room immediately.

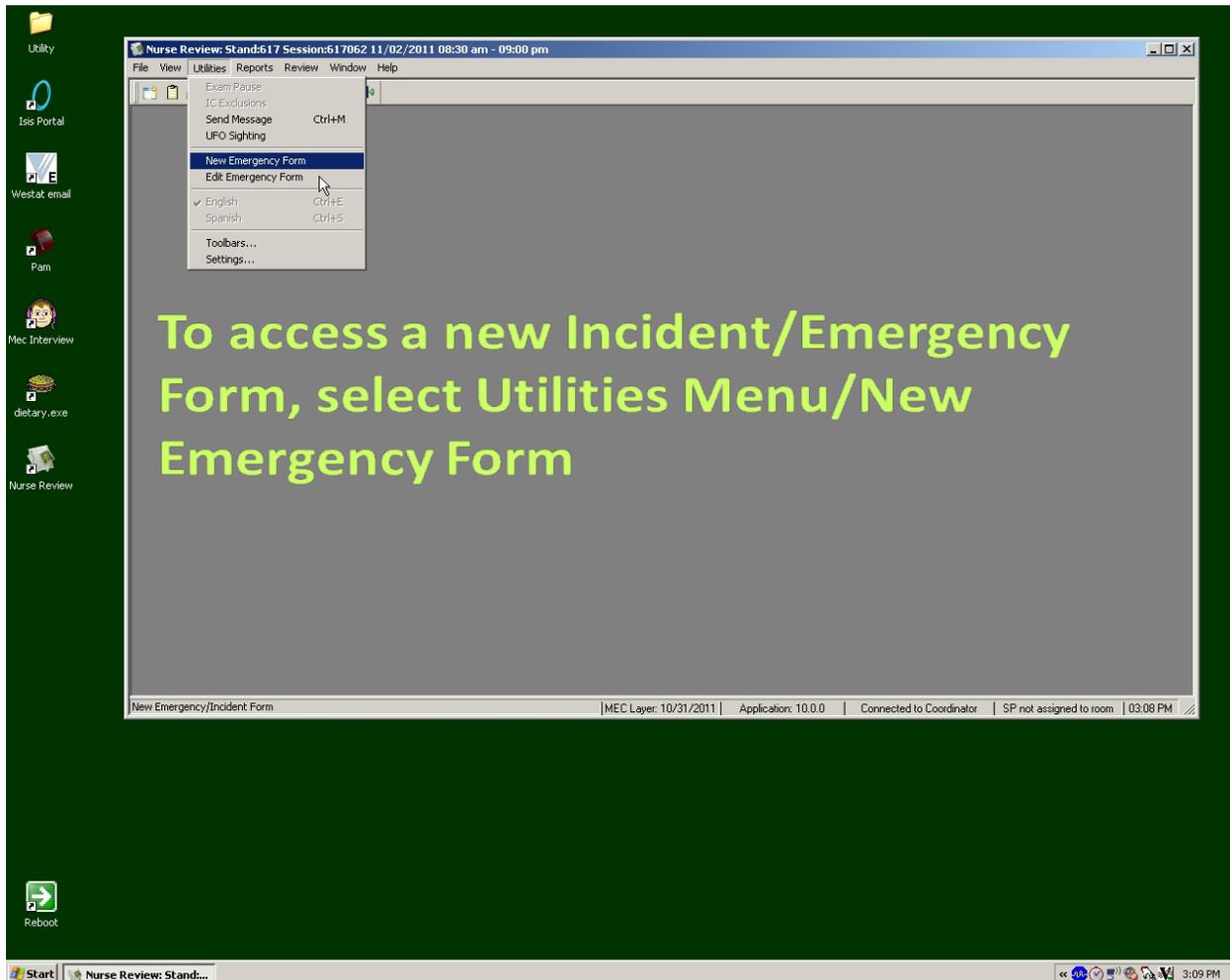
4.6 Documentation of Incidents and Emergencies

4.6.1 Completing the Incident/Emergency Form

The Incident/Emergency Form is electronically generated from the nurse review application. The form should be completed as soon as possible after the event, and the home office notified of any emergencies that required the participant to be released from the MC. In the case of staff injuries, the nurse practitioner should document the event in this system, (see Exhibit 4-1) and notify home office staff as soon as possible. The incident form can be edited at any time after saving it, so if the user is interrupted while documenting, it can be re-accessed at any time to complete.

The following screenshots, Exhibits 4-1 to 4-4, depict the procedures for documenting an incident in the nurse review application.

Exhibit 4-1. New emergency form



The emergency form is located in the utilities menu; select “New Emergency Form.”

- Select “Incident.” See Exhibit 4-2.
- Select the “Person Type.” The choices are “SP,” “Staff,” or “Other.” “Other” may include visitors or guests.
- The “Date” is automatically entered as the current date. If the incident occurred on an earlier date, the date entered should be the date the incident occurred. The date is a required field.

- The “Start Time” is automatically entered as the time the form was opened. If the incident occurred at an earlier time, the time entered should be the time the incident started. The start time is a required field. Please pay careful attention to this field in order to document the incident/emergency accurately. Data entry errors occur most commonly in this field.
- **NOTE:** “AM” is changed to “PM” by pressing “P” and “PM” is changed to “AM” by pressing “A”.

Exhibit 4-2. Select incident or emergency

- Select Incident or Emergency
- Select Person Type
- Select Referral NP

The emergency form differs from the incident form only in the three tabs that are enabled: treatment, urgent care, and notification. Only select Emergency if the SP had to be discharged from the mobile center. If it was an emergency, document Recorder Name, Runner Name, Who Called 911, and Who Found the person.

Exhibit 4-3. Incident/emergency form

The screenshot shows a software window titled "Incident/Emergency Form". At the top, there are two tabs: "Incident" and "Emergency", with "Emergency" selected. Below the tabs are radio buttons for "Person Type" with options "SP", "Tech", and "Other". The form contains several input fields: "Referral NP", "Recorder Name", "Emergency Date" (02/06/2012), "Runner Name(s)", "Start Time" (03:25 PM), "End Time" (00:00 AM), "Who Called 911", "Location", "Who Found", and a "Description" text area. A "Personal Info" section includes fields for "Person ID", "Age", "Gender", "Last name", "First name", and "Middle name". At the bottom, there are tabs for "Vitals", "Symptoms", "Observation", "Assessment", "Plan", "Misc.", "Treatment", "Urgent Care", and "Notification". The "Vitals" tab is active, showing a table with columns for "Time", "Heart Rate", "Systolic", "Diastolic", "Respiratory Rate", and "Comments". Below the table are "Insert" and "Delete" buttons. At the very bottom of the window are "Print", "Close", and "Save" buttons.

The Emergency Form enables the tabs of Treatment, Urgent Care, and Notification that are disabled in the Incident Form.

Complete the Referral Nurse Practitioner (NP) and Personal Info fields. Then move down to the tabbed fields at the bottom of the screen to document findings. The format is the traditional “SOAP” documentation:

- Vitals;
- Symptoms;
- Observation;
- Assessment; and
- Plan.

Exhibit 4-4. Incident/emergency form enabled for incident

Incident/Emergency Form

Incident/Emergency
 Incident Emergency

Person Type
 SP Tech Other

Referral NP: Whitney Block
Recorder Name: [Empty]
Emergency Date: 02/06/2012
Runner Name(s): [Empty]
Start Time: 02:19 PM **End Time:** 02:20 PM
Who Called 911: [Empty]
Location: Treadmill room
Who Found: [Empty]
Description: Syo SP tripped and fell off of the treadmill.

Personal Info
Person ID: 999999 **Age:** 5 **Gender:** Female
Last name: Smith **First name:** Smafhue **Middle name:** Smafhon

Vitals | Symptoms | Observation | Assessment | Plan | Misc. | Treatment | Urgent Care | Notification

| Time | Heart Rate | Systolic | Diastolic | Respiratory Rate | Comments |
|----------|------------|----------|-----------|------------------|---|
| 02:19 PM | 98 | 102 | 48 | 26 | SP in no acute distress, denies pain or discomfort. |

Buttons: Print, Close, Save, Insert, Delete

Exhibits 4-5 to 4-8 list instructions for entering vital signs on the Incidents/Emergency Form.

Exhibit 4-5. Recording vital signs (1)

The Vitals Sign Tab

Vitals | Symptoms | Observation | Assessment | Plan | Misc. | Treatment | Urgent Care | Notification

| Time | Heart Rate | Systolic | Diastolic | Respiratory Rate | Comments |
|------|------------|----------|-----------|------------------|----------|
|------|------------|----------|-----------|------------------|----------|

Buttons: Print, Close, Save, Insert, Delete

To add a line to enter “Vitals” information, select “Insert.” This may also be used to delete a line entered in error.

Exhibit 4-6. Recording vital signs (2)

| Vitals | | | | | | Symptoms | Observation | Assessment | Plan | Misc. | Treatment | Urgent Care | Notification |
|----------|-------------|-----------|------------|-------------------|-----------|----------|-------------|------------|------|-------|-----------|-------------|--------------|
| Time: | Heart Rate: | Systolic: | Diastolic: | Respiratory Rate: | Comments: | | | | | | | | |
| 12:00 AM | | | | | | | | | | | | | |

The default time that appears on each new line is 12:00 AM. The user must remember to change the time in each row.

Exhibit 4-7. Recording vital signs (3)

| Vitals | | | | | | Symptoms | Observation | Assessment | Plan | Misc. | Treatment | Urgent Care | Notification |
|----------|-------------|-----------|------------|-------------------|---|----------|-------------|------------|------|-------|-----------|-------------|--------------|
| Time: | Heart Rate: | Systolic: | Diastolic: | Respiratory Rate: | Comments: | | | | | | | | |
| 02:19 PM | 98 | 102 | 48 | 26 | SP in no acute distress, denies pain or discomfort. | | | | | | | | |

Enter the time the vital signs were taken and then enter the heart rate/minute, systolic and diastolic blood pressure, and respiratory rate/minute.

Exhibit 4-8. Recording vital signs (4)

| Vitals | | | | | | Symptoms | Observation | Assessment | Plan | Misc. | Treatment | Urgent Care | Notification |
|----------|-------------|-----------|------------|-------------------|---|----------|-------------|------------|------|-------|-----------|-------------|--------------|
| Time: | Heart Rate: | Systolic: | Diastolic: | Respiratory Rate: | Comments: | | | | | | | | |
| 02:19 PM | 98 | 102 | 48 | 26 | SP in no acute distress, denies pain or discomfort. | | | | | | | | |
| 12:00 AM | | | | | | | | | | | | | |

Enter a comment to describe the SP's condition at the time the vital signs were taken. Add additional lines as necessary using the "Insert" button.

Continue to document the “SOAP” note by making entries into each of the Symptoms, Observation, Assessment, and Plan tabs. The miscellaneous tab can be used at the user’s discretion—this tab is often useful to document employee incidents.

The Incident/Emergency form may be saved, closed, and then re-opened for additional documentation. The system has built-in edits that remind the user to save the data first before pressing the close button (Exhibit 4-9).

Exhibit 4-9. Saving and closing the incident/emergency form (1)

The screenshot shows a software window titled "Incident/Emergency Form". At the top, there are radio buttons for "Incident" (selected) and "Emergency", and a "Person Type" section with radio buttons for "SP" (selected), "Tech", and "Other". Below this are several input fields: "Referral NP:" (dropdown), "Recorder Name:" (dropdown), "Emergency Date:" (calendar icon), "Runner Name(s):" (dropdown), "Start Time:" (10:22 AM), "End Time:" (00:00 AM), "Who Called 911:" (dropdown), "Location:" (dropdown), "Who Found:" (dropdown), and a "Description:" text area. A "Personal Info" section contains fields for "Person ID:", "Age:", "Gender:", "Last name:", "First name:", and "Middle name:". Below the form are tabs for "Vitals", "Symptoms", "Observation", "Assessment", "Plan", "Misc.", "Treatment", "Urgent Care", and "Notification". The "Vitals" tab is active, showing a table with columns for "Time:", "Heart Rate:", "Systolic:", "Diastolic:", "Respiratory Rate:", and "Comments:". A "Physician" dropdown menu is open, showing a warning icon and the text "Do you want to close without save changes?". At the bottom of the window are "Print", "Close", and "Save" buttons.

Hard Edit reminder to save changes

Exhibit 4-10. Saving and closing the incident/emergency form (2)

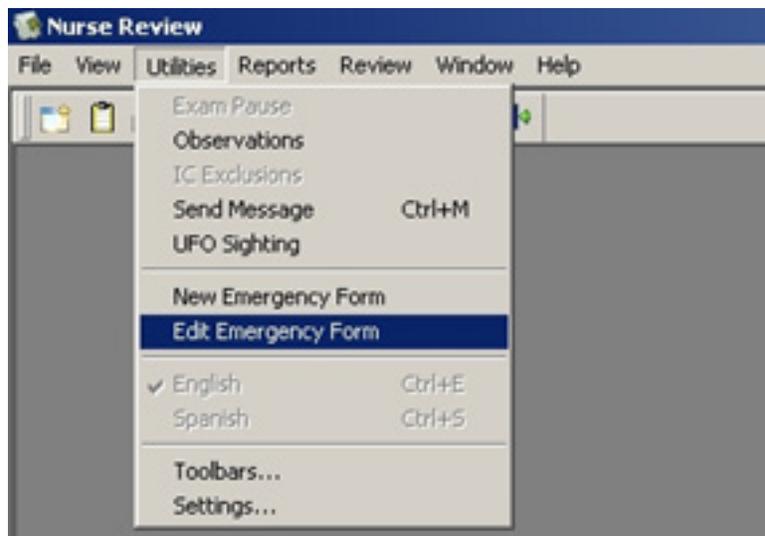


Hard Edit reminder to enter a valid time in the “End” field.

If you try to close the form without entering an “End Time,” a message will be displayed “Please enter a valid time.” Click “OK” and enter the time the incident/emergency was resolved.

To re-open and add to or edit an Incident/Emergency Form, go to the Utilities menu and select “Edit Emergency Form.” See Exhibit 4-11.

Exhibit 4-11. Editing the emergency form



When “Edit Emergency Form” is selected, the next screen that appears is the “Emergency Pickup,” which displays all Incident/Emergency Forms created at that stand. The form can be edited and saved again (Exhibit 4-12).

Exhibit 4-12. Emergency pickup

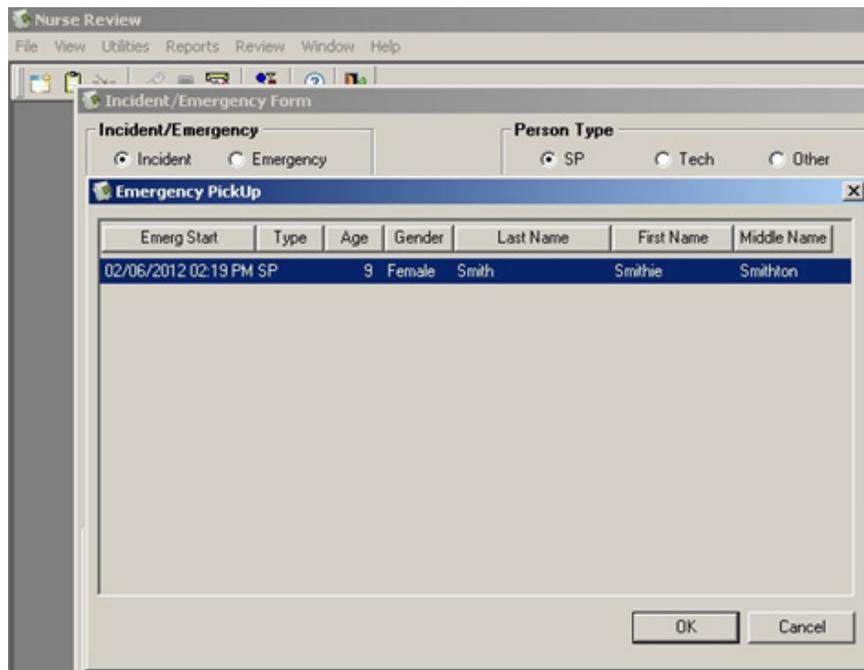


Exhibit 4-13. Completed emergency form

Nurse Review: Stand:617 Session:617062 11/02/2011 08:30 am - 09:00 pm

Incident/Emergency Form

Incident/Emergency
 Incident Emergency

Person Type
 SP Tech Other

Phys. ID: 2500 Recorder Name: J'appelle Whozit
 Emergency Date: 11/02/2011 Runner Name(s): J'appelle Whatzit
 Start Time: 03:12 PM End Time: 03:25 PM Who Called 911: N/A
 Location: MC Trailer in Treadmill Room Who Found: J'appelle Moi
 Description: After 3 minutes on treadmill , SP began to look pale and weak.

Personal Info
 Person ID: 0 Age: 9 Gender: Female
 Last name: Participant First name: Palty Middle name:

Vitals | Symptoms | Observation | Assessment | Plan | Misc. | Treatment | Urgent Care | Notification

| Time | Heart Rate | Systolic | Diastolic | Respiratory Rate | Comments |
|----------|------------|----------|-----------|------------------|---|
| 12:22 PM | 108 | 84 | 40 | 24 | C/O Nausea and dizziness after 3 minutes on treadmill; lying prone on floor with feet elevated. |
| 12:00 AM | | | | | |
| 12:00 AM | | | | | |
| 12:00 AM | | | | | |

Print Close Save Insert Delete

The Incident Report can be printed by selecting the “Print” button at the bottom of the electronic form; the printout appears as follows (Exhibit 4-14).

Exhibit 4-14. Incident report

Incident Report for Smithie S. Smith

02/06/2012

General Information

Person Type: SP **Recorder Name:**
Emergency Date: 02/06/2012 **Runner Name(s):**
Start Time: 02:19 PM **End Time:** 02:20 PM **Who Called 911:**
Location: Treadmill room **Who Found:**
Description: 9 yo SP tripped and fell off of the treadmill.

Personal Info

Person ID: 999999 **Age:** 9 **Gender:** Female
Last name: Smith **First name:** Smithie **Middle name:** Smithton

Symptoms

Vitals

| Time: | Heart Rate: | Systolic: | Diastolic: | Respiratory Rate: | Comments: |
|----------|-------------|-----------|------------|-------------------|---|
| 02:19 PM | 98 | 102 | 48 | 26 | SP in no acute distress, denies pain or discomfort. |

Observations

While walking on the treadmill, SP tripped and fell to knees, and rode the treadmill backwards and landed on the floor on buttocks. SP is awake, alert, in no apparent distress. Examined knees, superficial abrasions noted to both knees, skin intact. Examined bac and buttocks area, no bruising evident, no pain on palpation to lower back.

Assessment

S/P fall on treadmill, no obvious injury.

Plan

Wash knees with soap and water while at the Mobile Center. Advise parent to observe lower back and buttocks for bruising or pain

Miscellaneous

Appendix A

The Management of Minor Closed Head Injury in Children

The Management of Minor Closed Head Injury in Children

Committee on Quality Improvement, American Academy of Pediatrics

Commission on Clinical Policies and Research, American Academy of Family Physicians

ABSTRACT. The American Academy of Pediatrics (AAP) and its Committee on Quality Improvement in collaboration with the American Academy of Family Physicians (AAFP) and its Commission on Clinical Policies and Research, and in conjunction with experts in neurology, emergency medicine and critical care, research methodologists, and practicing physicians have developed this practice parameter. This parameter provides recommendations for the management of a previously neurologically healthy child with a minor closed head injury who, at the time of injury, may have experienced temporary loss of consciousness, experienced an impact seizure, vomited, or experienced other signs and symptoms. These recommendations derive from a thorough review of the literature and expert consensus. The methods and results of the literature review and data analyses including evidence tables can be found in the technical report. This practice parameter is not intended as a sole source of guidance for the management of children with minor closed head injuries. Rather, it is designed to assist physicians by providing an analytic framework for the evaluation and management of this condition. It is not intended to replace clinical judgment or establish a protocol for all patients with a minor head injury, and rarely will provide the only appropriate approach to the problem.

The practice parameter, "The Management of Minor Closed Head Injury in Children," was reviewed by the AAFP Commission on Clinical Policies and Research and individuals appointed by the AAFP and appropriate committees and sections of the AAP including the Chapter Review Group, a focus group of office-based pediatricians representing each AAP District: Gene R. Adams, MD; Robert M. Corwin, MD; Diane Fuquay, MD; Barbara M. Harley, MD; Thomas J. Herr, MD, Chair; Kenneth E. Matthews, MD; Robert D. Mines, MD; Lawrence C. Pakula, MD; Howard B. Weinblatt, MD; and Delosa A. Young, MD.

The supporting data are contained in a technical report available at <http://www.pediatrics.org/cgi/content/full/104/6/e78>.

ABBREVIATIONS. AAP, American Academy of Pediatrics; AAFP, American Academy of Family Physicians; CT, cranial computed tomography; MRI, magnetic resonance imaging.

The recommendations in this statement do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.
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Minor closed head injury is one of the most frequent reasons for visits to a physician.¹ Although >95 000 children experience a traumatic brain injury each year in the United States,² consensus is lacking about the acute care of children with minor closed head injury. The evaluation and management of injured children may be influenced by local practice customs, settings where children are evaluated, the type and extent of financial coverage, and the availability of technology and medical staffing.

Because of the magnitude of the problem and the potential seriousness of closed head injury among children, the AAP and the American Academy of Family Physicians (AAFP) undertook the development of an evidence-based parameter for health care professionals who care for children with minor closed head injury. In this document, the term Subcommittee is used to denote the Subcommittee on Minor Closed Head Injury, which reports to the AAP Committee on Quality Improvement, and the AAFP Commission on Clinical Policies, Research, and Scientific Affairs.

While developing this practice parameter, the Subcommittee attempted to find evidence of benefits resulting from 1 or more patient management options. However, at many points, adequate data were not available from the medical literature to provide guidance for the management of children with mild head injury. When such data were unavailable, we did not make specific recommendations for physicians and other professionals but instead we presented a range of practice options deemed acceptable by the Subcommittee.

An algorithm at the end of this parameter presents recommendations and options in the context of direct patient care. Management is discussed for the initial evaluation of a child with minor closed head injury, and the disposition after evaluation. These recommendations and options may be modified to fit the needs of individual patients.

PURPOSE AND SCOPE

This practice parameter is specifically intended for previously neurologically healthy children of either sex 2 through 20 years of age, with isolated minor closed head injury.

The parameter defines children with minor closed head injury as those who have normal mental status at the initial examination, who have no abnormal or focal findings on neurologic (including fundoscopic) examination, and who have no physical evidence of

skull fracture (such as hemotympanum, Battle's sign, or palpable bone depression).

This parameter also is intended to address children who may have experienced temporary loss of consciousness (duration <1 minute) with injury, may have had a seizure immediately after injury, may have vomited after injury, or may have exhibited signs and symptoms such as headache and lethargy. The treatment of these children is addressed by this parameter, provided that they seem to be normal as described in the preceding paragraph at the time of evaluation.

This parameter is not intended for victims of multiple trauma, for children with unobserved loss of consciousness, or for patients with known or suspected cervical spine injury. Children who may otherwise fulfill the criteria for minor closed head injury, but for whom this parameter is not intended include patients with a history of bleeding diatheses or neurologic disorders potentially aggravated by trauma (such as arteriovenous malformations or shunts), patients with suspected intentional head trauma (eg, suspected child abuse), or patients with a language barrier.

The term brief loss of consciousness in this parameter refers to a duration of loss of consciousness of 1 minute or less. This parameter does not make any inference that the risk for intracranial injury changes with any specific length of unconsciousness lasting <1 minute. The treatment of children with loss of consciousness of longer duration is not addressed by this parameter.

Finally, this parameter refers only to the management of children evaluated by a health care professional immediately or shortly after (within 24 hours) injury. This parameter is not intended for the management of children who are initially evaluated >24 hours after injury.

METHODS FOR PARAMETER DEVELOPMENT

The literature review encompassed original research on minor closed head trauma in children, including studies on the prevalence of intracranial injury, the sensitivity and specificity of different imaging modalities, the utility of early diagnosis of intracranial injury, the effectiveness of various patient management strategies, and the impact of minor closed head injury on subsequent child health. Research was included if it had data exclusively on children or identifiable child-specific data, if cases were comparable with the case definition in the parameter, and if the data were published in a peer-reviewed journal. Review articles and articles based solely on expert opinion were excluded.

An initial search was performed on several computerized databases including Medline (1966–1993) using the terms head trauma and head injury. The search was restricted to infants, children, and adolescents, and to English-language articles published after 1966. A total of 422 articles were identified. Titles and abstracts were reviewed by the Subcommittee and articles were reviewed if any reviewer considered the title relevant. This process identified 168 articles that were sent to Subcommittee members

with a literature review form to categorize study design, identify study questions, and abstract pertinent data. In addition, reference lists in the articles were reviewed for additional sources, and 125 additional articles were identified. After excluding review articles and other studies not meeting entry criteria, a total of 64 articles were included for review. All articles were reabstracted by the methodologists and the data summarized on evidence tables. Differences in case definition, outcome definition, and study samples precluded pooling of data among studies.

The published data proved extremely limited for a number of study questions, and direct queries were placed to several authors for child-specific data. Because these data have not been formally published, the Subcommittee does not rest strong conclusions on them; however, they are included in the Technical Report. The Technical Report produced along with this practice parameter contains supporting scientific data and analysis including evidence tables and is available at <http://www.pediatrics.org/cgi/content/full/104/6/e78>.

SUMMARY

Initial Evaluation and Management of the Child With Minor Closed Head Injury and No Loss of Consciousness

Observation

For children with minor closed head injury and no loss of consciousness, a thorough history and appropriate physical and neurologic examination should be performed. Observation in the clinic, office, emergency department, or at home, under the care of a competent caregiver is recommended for children with minor closed head injury and no loss of consciousness. Observation implies regular monitoring by a competent adult who would be able to recognize abnormalities and to seek appropriate assistance. The use of cranial computed tomography (CT) scan, skull radiograph, or magnetic resonance imaging (MRI) is not recommended for the initial evaluation and management of the child with minor closed head injury and no loss of consciousness.

Initial Evaluation of the Child With Minor Closed Head Injury With Brief Loss of Consciousness

Observation or Cranial CT Scan

For children with minor closed head injury and brief loss of consciousness (<1 minute), a thorough history and an appropriate physical and neurologic examination should be performed. Observation, in the office, clinic, emergency department, hospital, or home under the care of a competent caregiver, may be used to evaluate children with minor closed head injury with brief loss of consciousness. Cranial CT scanning may also be used, in addition to observation, in the initial evaluation and management of children with minor closed head injury with loss of consciousness.

The use of skull radiographs or MRI in the initial management of children with minor closed head injury and loss of consciousness is not recom-

mended. However, there are limited situations in which MRI and skull radiography are options (see sections on skull radiographs and on MRI).

Patient Management Considerations

Many factors may influence how management strategies influence outcomes for children with minor closed head injury. These factors include: 1) the prevalence of intracranial injury, 2) the percentage of intracranial injuries that need medical or neurosurgical intervention (ie, the percentage of these injuries that, if left undiagnosed or untreated, leads to disability or death), 3) the relative accuracy of clinical examination, skull radiographs, and CT scans as diagnostic tools to detect such intracranial injuries that benefit from medical or neurosurgical intervention, 4) the efficacy of treatment for intracranial injuries, and 5) the detrimental effect on outcome, if any, of delay from the time of injury to the time of diagnosis and intervention.

This last factor, delay of diagnosis and intervention, is particularly relevant when trying to decide between a clinical strategy of immediate CT scanning of all patients as opposed to a strategy that relies primarily on patient observation, with CT scanning reserved for rare patients whose conditions change. To our knowledge, no published studies were available for review that compared clinically meaningful outcomes (ie, morbidity or mortality) between children receiving different management regimens such as immediate neuroimaging, or observation. Although some studies were able to demonstrate the presence of intracranial abnormalities on CT scans or MRIs among children with minor head injury, no known evidence suggested that immediate neuroimaging of asymptomatic children improved outcomes for these children, compared with the outcomes for children managed primarily with examination and observation.

Initial Management of the Child With Minor Closed Head Injury and No Loss of Consciousness

Minor closed head injury without loss of consciousness is a common occurrence in childhood. Available data suggest that the risk of intracranial injury is negligible in this situation. Population-based studies have found that fewer than 1 in 5000 patients with minor closed head injury and no loss of consciousness have intracranial injuries that require medical or neurosurgical intervention. In 1 study of 5252 low-risk patients, mostly adults, none were found to have an intracranial injury after minor head injury.³ Comparably sized studies do not exist for children. In 2 much smaller studies of children with minor head injury, among those with normal neurologic examination findings and no loss of consciousness, amnesia, vomiting, headache, or mental status abnormalities, no children had abnormal CT scan findings.^{4,5}

Observation

Among children with minor closed head injury and no loss of consciousness, a thorough history and appropriate physical and neurologic examination

should be performed. Subcommittee consensus was that observation, in the clinic, office, emergency department, or home under the care of a competent observer, be used as the primary management strategy. If on examination the patient's condition appears normal (as outlined earlier), no additional tests are needed and the child can be safely discharged to the care of a responsible caregiver. The recommended duration of observation is discussed in the section titled "Disposition of the Child With Minor Head Injury."

CT Scan/MRI

With such a low prevalence of intracranial injury, the Subcommittee believed that the marginal benefits of early detection of intracranial injury afforded by routine brain imaging studies such as CT or MRI were outweighed by considerations of cost, inconvenience, resource allocation, and possible side effects attributable to sedation or inappropriate interventions (eg, medical, surgical, or other interventions based on incidental CT findings in asymptomatic children).

Skull Radiographs

Skull radiographs have only a very limited role in the evaluation of children with minor closed head injury, no loss of consciousness, and no signs of skull fracture (ie, no palpable depression, hemotympanum, or Battle's sign). The substantial rate of false-positive results provided by skull radiographs (ie, a skull fracture detected on skull radiographs in the absence of intracranial injury) along with the low prevalence of intracranial injury among this specific subset of patients, leads to a low predictive value of skull radiographs. Most children with abnormal skull radiographs will not harbor significant intracranial lesions and conversely intracranial injury occurs in the absence of a skull fracture detected on skull radiographs.

There may be some clinical scenarios in which a practitioner desires imaging such as the case of a child with a scalp hematoma over the course of the meningeal artery. In situations such as these, the Subcommittee believes that clinical judgment should prevail. However, given the relatively low predictive value of skull radiographs, the Subcommittee believes that, if imaging is desired, cranial CT scan is the more satisfactory imaging modality.

Initial Management of the Child With Minor Closed Head Injury and Brief Loss of Consciousness

Among children with minor closed head injury, loss of consciousness is uncommon but is associated with an increased risk for intracranial injury. Studies performed since the advent of CT scanning suggest that children with loss of consciousness, or who demonstrate amnesia at the time of evaluation, or who have headache or vomiting at the time of evaluation, have a prevalence of intracranial injury detectable on CT that ranges from 0% to 7%.⁵⁻⁸ Although most of these intracranial lesions will remain clinically insignificant, a substantial proportion of children, between 2% and 5% of those with minor

head injury and loss of consciousness, may require neurosurgical intervention.⁶⁻⁸ The differences in findings among studies are likely attributable to differences in selection criteria, along with random variation among studies with limited sample size. Although these findings might have been biased somewhat if more seriously injured patients were preferentially selected for CT scans, even studies in which patients were explicitly stated to be neurologically normal and asymptomatic found children with clinically significant injuries that required intervention.⁶

In past studies of children with minor head injury, patient selection may have led to overestimates of the prevalence of intracranial injury. Many of these studies looked at patients referred to emergency departments or trauma centers, patients brought to emergency departments after examination in the field by emergency personnel, or patients for whom the reason for obtaining CT scans was not clearly stated. These factors may have led to the selection of a patient population at higher risk for intracranial injury than the patients specifically addressed in this practice parameter.

As evidence of this, population-based studies before the widespread availability of CT scanning found the prevalence of clinically significant intracranial injury after minor closed head injury to be far less than estimated by the aforementioned studies. One study found a prevalence of intracranial injury that required neurosurgery to be as low as .02%.⁹ This discrepancy is consistent also with the fact that many lesions currently identified with cranial CT were not recognized before the availability of this technology. Because most of these lesions do not progress or require neurosurgical intervention, most would not have been diagnosed in studies before the availability of CT scan.

Observation

As discussed earlier, the Subcommittee did not find evidence to show that immediate neuroimaging of asymptomatic children produced demonstrable benefits compared with a management strategy of initial observation alone. In light of these considerations, there was Subcommittee consensus based on limited evidence that for children who are neurologically normal after minor closed head injury with loss of consciousness, patient observation was an acceptable management option.

If the health care practitioner chooses observation alone, it may be performed in the clinic, office, emergency department, hospital, or at home under the care of a competent observer, typically a parent or suitable guardian. If the observer seems unable to follow or comply with the instructions for home observation, observation under the supervision of a health care practitioner is to be considered.

CT Scan

Data that support the routine use of CT scanning of children with minor head injury and loss of consciousness indicate that children with intracranial lesions after minor closed head injury are not easily

distinguishable clinically from the large majority with no intracranial injury.^{10,11} Children with nonspecific signs such as headache, vomiting, or lethargy after minor closed head injury may be more likely to have intracranial injury than children without such signs. However, these clinical signs are of limited predictive value, and most children with headache, lethargy, or vomiting after minor closed head injury do not have demonstrable intracranial injury. In addition, some children with intracranial injury do not have any signs or symptoms. Because of these findings, many investigators have concluded that the physical and neurologic examination are inadequate predictors of intracranial injury, and that cranial CT is more sensitive than physical and neurologic examinations for the diagnosis of intracranial injury.

The most accurate and rapid means of detecting intracranial injury would be with a clinical protocol that routinely obtained intracranial imaging for all children after head injury. Rapid diagnosis and treatment of subdural hematomas was found in 1 study to significantly reduce morbidity and mortality among severely injured adults.¹² However, this result was not replicated in other studies of subdural or epidural hematomas¹³⁻¹⁵ and similar studies have not addressed less severely head injured children, or children with minor closed head injury.

CT itself is a safe procedure. However, some healthy children require sedation or anesthesia, and the benefits gained from cranial CT should be carefully weighed against the possible harm of sedating and/or anesthetizing a large number of children. In addition, CT scans obtained for asymptomatic children may show incidental findings that lead to subsequent unnecessary medical or surgical interventions. To our knowledge, no data are available that demonstrate that children who undergo CT scanning early after minor closed head injury with loss of consciousness have different outcomes compared with children who receive observation alone after injury. A clinical trial comparing the risks and benefits of immediate CT scanning with simple monitored observation for children with minor closed head injury has not been performed, primarily because intracranial injury after minor closed head injury is so rare that the cost and logistics of such a study would be prohibitive. As a result, the risk-benefit ratio for the evaluation and management modalities of CT scanning or observation is unknown.

Simple observation by a reliable parent or guardian is the management option with the least initial costs, while CT scans typically cost less than observation performed in the hospital. A study that compares costs of CT and observation strategies would need data on the cost of following up children with positive CT scans, as well as the potential costs associated with late detection and emergency therapy among those managed by observation alone.

Because of these considerations, there was Subcommittee consensus based on limited evidence that for children who are neurologically normal after minor closed head injury with loss of consciousness, cranial CT scanning along with observation was also an acceptable management option.

Skull Radiographs

Before the availability of CT imaging, skull radiographs were a common means to evaluate children with head injury. Skull radiographs may identify skull fractures, but they do not directly show brain injury or other intracranial trauma. Although intracranial injury is more common in the presence of a skull fracture, many studies have demonstrated that intracranial lesions are not always associated with skull fractures and that skull fractures do not always indicate an underlying intracranial lesion.^{7,8,16}

Large studies of children and adults have shown that the sensitivity of skull radiographs for identifying intracranial injury in children is quite low (~25% in some studies). More recent studies limited to children have reported sensitivities between 50% and 100%, with the latter higher figure reported from studies of adolescent patients.^{7,8,15,16} The specificity of skull radiographs for intracranial injury (the proportion of patients without intracranial injury who have normal radiographs) has been reported as between 53% and 97% in these same studies. Given the limited specificity of skull radiographs and the low prevalence of intracranial injury, the skull radiographs would likely be interpreted as abnormal for a substantial proportion of patients without intracranial injury. Furthermore, the low sensitivity of the radiographs will result in the interpretation of skull radiographs as normal for some patients with intracranial injury.

The Subcommittee consensus was that skull radiographs have only a limited role in the management of the child with loss of consciousness. If imaging is desired by the health care practitioner and if CT and skull radiographs are available, the Subcommittee believes that CT scanning is the imaging modality of choice, based on the increased sensitivity and specificity of CT scans. When CT scanning is not readily available, skull radiographs may assist the practitioner to define the extent of injury and risk for intracranial injury. In this situation, there was Subcommittee consensus that, for a child who has suffered minor closed head injury with loss of consciousness, skull radiographs are an acceptable management option. However, as noted, skull fractures may be detected on skull radiographs in the absence of intracranial injury, and intracranial injury may be present when no skull fracture is detected on skull radiographs. These limitations should be considered carefully by physicians who elect to use skull radiographs. Regardless of findings on skull films (should the physician elect to obtain them) close observation, as described previously, remains a cornerstone of patient management.

MRI

MRI is another available modality for neuroimaging. Although MRI has been shown to be more sensitive than cranial CT in detecting certain types of intracranial abnormalities, CT is more sensitive for hyperacute and acute intracranial hemorrhage (especially subarachnoid hemorrhage). CT is more quickly and easily performed than MRI, and costs for CT

scans generally are less than those for MRI. The consensus of the Subcommittee was that cranial CT offered substantial advantages over MRI in the acute care of children with minor closed head injury.

As is the case with skull radiographs, there may be situations in which CT scanning is not readily available and the health care professional desires to obtain imaging studies. There was Subcommittee consensus that, for a child who has experienced minor closed head injury with loss of consciousness, MRI to evaluate the intracranial status of the child was an acceptable management option.

Disposition of Children With Minor Closed Head Injury

Children Managed by Observation Alone

Children who appear neurologically normal after minor closed head injury are at very low risk for subsequent deterioration in their condition and are unlikely to require medical intervention. Therefore, although observation is recommended for patients after the initial evaluation is completed, such observation may take place in many different settings. The strategy chosen by the health care practitioner may depend on the resources available for observation. Other factors, such as the distance and time it would take to reach appropriate care if the patient's clinical status worsened, may influence where observation occurs.

Historically, when hospitalization has been used to observe children after head injury, the length of stay averaged 12 to 48 hours. This practice was based on the reasoning that most life-threatening complications occur within 24 hours after head injury. The Subcommittee believes that a prudent duration of observation would extend at least 24 hours, and could be accomplished in any combination of locations, including the emergency department, hospital, clinic, office, or home. However, it is important for physicians, parents, and other guardians to have a high index of suspicion about any change in the patient's clinical status for several days after the injury. Parents or guardians require careful instruction to seek medical attention if the patient's condition worsens at any time during the first several days after injury.

In all cases, the health care professional is to make a careful assessment of the parent or guardian's anticipated compliance with the instructions to monitor the patient. If the caregiver is incompetent, unavailable, intoxicated, or otherwise incapacitated, other provisions must be made to ensure adequate observation of the child. These provisions may differ based on the characteristics of each case.

The physician has an important role in educating the parents or guardians of children with minor closed head injury. Understandable, printed instructions should be given to the parent or guardian detailing how to monitor the patient and including information on how and when to seek medical attention if necessary. All children discharged should be released to the care of a reliable parent or guardian who has adequate transportation and who has the

capability to seek medical attention if the child's condition worsens.

Children Evaluated by Cranial CT

Neurologically normal patients with normal cranial CT scans are at extremely low risk for subsequent problems. Although there are many reports of patients with head injuries in whom extradural or intracerebral bleeding developed after an initial stable clinical period,¹⁸⁻²² there are only a few reports of patients in whom extradural or intracerebral bleeding developed after a postinjury CT scan was interpreted as normal.²³⁻²⁵ Most often when such cases have been described, the patients had sustained a more severe initial head injury than the patient for whom this parameter is intended, and the neurologic status of the patients was not intact at the initial examination following the injury. A number of studies have demonstrated the safety of using cranial CT as a triage instrument for neurologically normal and clinically stable patients after minor closed head injury.²⁶⁻³¹

Patients may be discharged from the hospital for observation by a reliable observer if the postinjury CT scan is interpreted as normal. The length of observation should be similar to that described in the preceding section. If the cranial CT reveals abnormalities, proper disposition depends on a thorough consideration of the abnormalities and, when warranted, consultations with appropriate subspecialists.

Research Issues

Classification of Head Injury in Children and Prognostic Features

Much remains to be learned about minor closed head injury in children. The implications of clinical events such as loss of consciousness and signs or symptoms such as seizures, nausea, vomiting, and headache remain unclear. Data on patients with low-risk head injuries but with loss of consciousness, such as the data provided on a primarily adult population, are not available for children. Moreover, this practice parameter deals with clinically normal patients who did not lose consciousness at the time of injury and with patients who did lose consciousness with injury. Children with minor head injury, who have experienced loss of consciousness, vomiting or seizures have been found to have a prevalence of intracranial injury ranging from 2% to 5%. Questions remain about the selection of patients for many of these studies, and there is considerable uncertainty about the generalizability of these results to patients within this parameter.

Future studies on minor closed head injury should assess the relationship between characteristics such as these and the risk for intracranial injury among children who are clinically asymptomatic. Specifically, studies should address the question of whether such a history of loss of consciousness is associated with an increased risk for clinically significant intracranial abnormalities. Such studies should not be limited to patients seen in referral settings, but in-

stead should cover patients from a wide range of settings, including those managed in clinics and offices, and if possible, those managed over the phone.

These studies should also address the independent prognostic value of other signs and symptoms for which the clinical significance in children is uncertain. In particular, practitioners are often faced with managing patients who are asymptomatic except for episodes of repeated vomiting or moderate to severe headache. The Subcommittee did not find evidence in the literature that helped differentiate the risk status of children with such symptoms from children without such symptoms. If studies are performed on this population, information should be collected on the presence of signs or symptoms including post-traumatic seizures, nausea with or without vomiting, posttraumatic amnesia, scalp lacerations and hematomas, headache, and dizziness, and their relationship to intracranial injury.

The Benefit of Early Detection of, and Intervention for, Intracranial Lesions in Asymptomatic Children

The outcome for asymptomatic patients found to have intracranial hematomas is of particular interest. Additional studies are needed to determine whether a strategy of immediate CT scan provides measurably improved outcomes for children with minor closed head injury compared with a strategy of observation followed by CT scan for children whose clinical status changes. Although rapid detection and neurosurgical intervention for intracranial injuries such as subdural hematomas has been shown to improve outcome in some studies of patients with more serious head injuries, it is unclear whether the same benefit would accrue to asymptomatic neurologically normal children.

A randomized, controlled trial would provide the most direct information on the risks and benefits of each management strategy. However, such a study would be extremely difficult and expensive to perform because of the rarity of adverse outcomes. Retrospective observational studies among children with minor head injury could be performed more easily and at less cost. However, correct characterization of the patient's clinical status before any treatment strategy or diagnostic procedure would be essential to eliminate bias in the evaluation of the comparison groups.

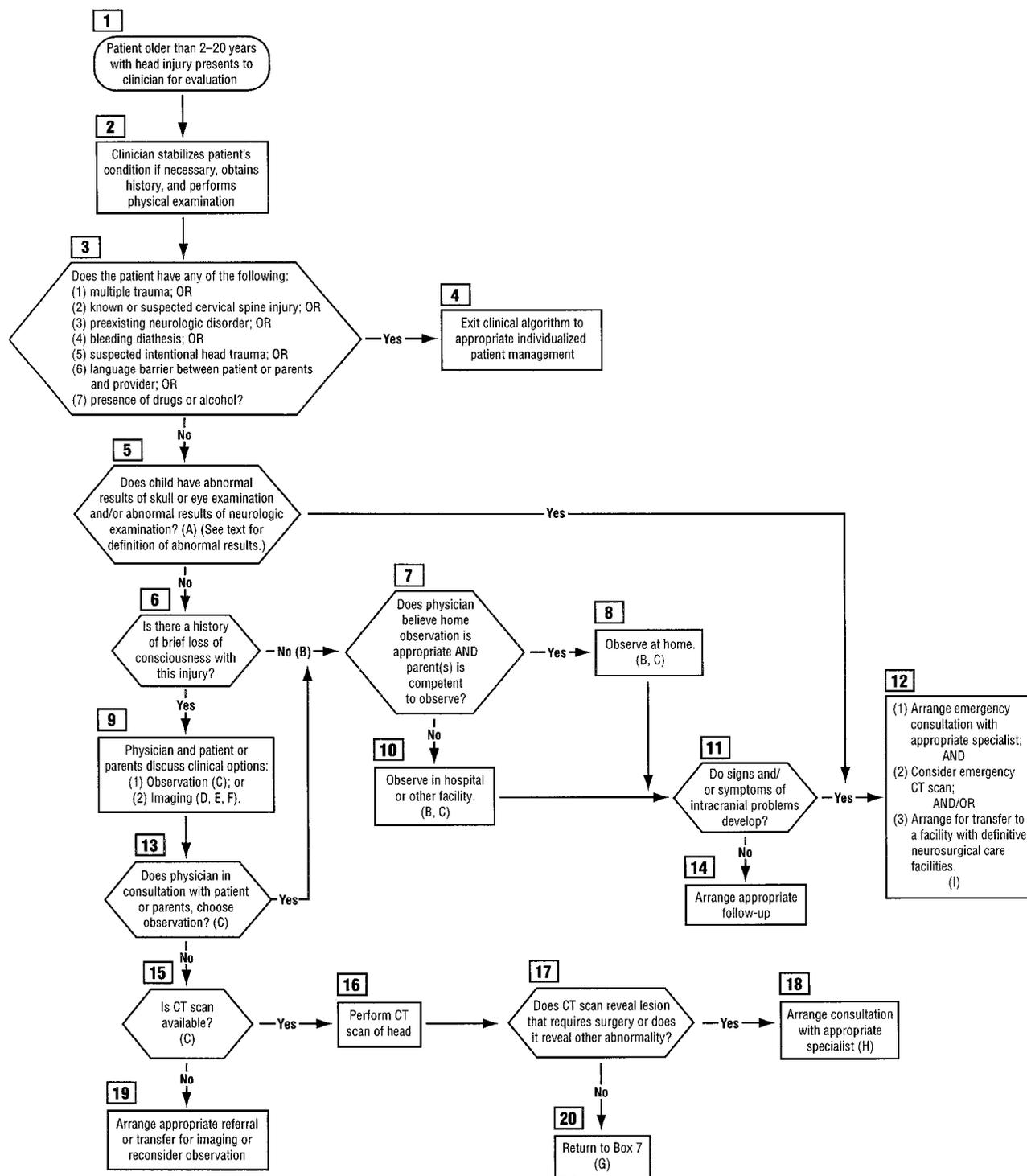
Finally, if such studies are performed to compare different diagnostic and management strategies, the outcomes should include not only mortality and short-term morbidity, but also long-term outcomes such as persistent psychological problems or learning disorders.

The Management of the Asymptomatic Patient With Intracranial Hemorrhage

The optimal management and prognosis for asymptomatic patients with intracranial hemorrhage is unknown. Because surgery is not always indicated or beneficial, some neurosurgeons and neurologists now advocate an expectant approach of close observation for small intracranial and extradural hemato-

Evaluation and Triage of Children and Adolescents With Minor Head Trauma

Algorithm



mas, considering hematoma size, shift of intracranial structures, and other factors.

If all asymptomatic children with minor head injury undergo cranial CT scanning, a substantial number of patients with an abnormal result on CT may undergo surgery that is unnecessary or even harm-

ful. Additional research is needed to determine the proper management of asymptomatic children with intracranial hemorrhage. Outcome measures should include mortality and morbidity outcomes such as seizures, learning disabilities, and behavioral disabilities.

As newer modalities for neuroimaging are developed and disseminated, careful evaluation of their relative utility is necessary before they are used for patients with minor closed head injury. Although such new modalities frequently provide new and different types of information to the health care professional, it is important that they be submitted to scientific study to assess their effect on patient outcome.

Algorithm

The notes below are integral to the algorithm. The letters in parentheses correspond to the algorithm.

A. This parameter addresses the management of previously neurologically healthy children with minor closed head injury who have normal mental status on presentation, no abnormal or focal findings on neurologic (including fundoscopic) examination, and no physical evidence of skull fracture (such as hemotympanum, Battle's sign, or palpable depression).

B. Observation in the clinic, office, emergency department, or home, under the care of a competent caregiver is recommended for children with minor closed head injury and no loss of consciousness.

C. Observation in the office, clinic, emergency department, hospital, or home under the care of a competent caregiver may be used to manage children with minor closed head injury with loss of consciousness.

D. Cranial CT scanning along with observation may also be used in the initial evaluation and management of children with minor closed head injury with brief loss of consciousness.

E. If imaging is desired by the health care practitioner and if both CT and skull radiography are available, CT scanning is the imaging modality of choice, because of its increased sensitivity and specificity. When CT scanning is not readily available, skull radiographs may assist the practitioner to define the risk for intracranial injury. However skull fractures may be detected on skull radiographs in the absence of intracranial injury, and occasionally intracranial injury is present despite the absence of a skull fracture detected on skull radiographs. These limitations should be considered by physicians who elect to use skull radiographs. Whether the changed probabilities for harboring an intracranial injury based on the results of the skull radiographs is sufficient to alter the management strategy may depend on the preferences of the family and physician.

F. In some studies MRI has been shown to be more sensitive than CT in diagnosing certain intracranial lesions. However, there is currently no appreciable difference between CT and MRI in the diagnosis of clinically significant acute intracranial injury and bleeding that requires neurosurgical intervention. CT is more quickly and easily performed than MRI, and the costs for CT scans generally are less than those for MRI. Because of this, the consensus among the Subcommittee was that cranial CT offered advantages over MRI in the acute care of children with minor closed head injury.

G. Neurologically normal patients with a normal cranial CT scan are at very low risk for subsequent deterioration. Patients may be discharged from the hospital for observation by a reliable observer if the postinjury CT scan is normal. The decision to observe at home takes into consideration the delay that would ensue if the child had to return to the hospital as well as the reliability of the parents or other caregivers. Otherwise, depending on the preferences of the patient and physician, observation also may take place in the office, clinic, emergency department, or hospital.

H. If the cranial CT reveals abnormalities, proper disposition depends on a thorough consideration of the abnormalities and, when warranted, consultation with appropriate subspecialists.

I. If the child's neurologic condition worsens during observation, a thorough neurologic examination is to be performed, along with immediate cranial CT after the patient's condition is stabilized. If a repeat CT scan shows new intracranial pathologic abnormalities, consultation with the appropriate subspecialist is warranted.

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