Centers for Disease
Control and Prevention
National Center for
Health Statistics

2022
MEC Clinician Procedures Manual

July 2022

nhanes
The Nation's Mobile Health Survey

National Health and Nutrition Examination Survey

Table of Contents

Table of Contents

Chapter Page

Tables

Figure

Exhibits

Exhibits **Page**

Exhibits **Page**

Exhibits **Page**

1. Overview of Clinician Examination

1.1 The Role of NHANES Clinicians

The NHANES clinicians are key members of the mobile examination center (MEC) team who function in several capacities as required by the survey protocol. These responsibilities may be modified over time as needed. Several responsibilities are completed by the clinician only, while other responsibilities include those where the clinician is cross-trained to complete tasks also performed by other MEC staff.

1.1.1 Responsibilities Specific to the Clinician

Responsibilities completed by the **clinician only** include the following:

- Counsel SPs on obtaining medical care based on survey examination results that fall out of range, including blood pressure;
- Counsel participants regarding abnormal laboratory values including complete blood count (CBC) results;
- Counsel SPs on the interpretation of sexually transmitted diseases (STDs) and communicate the process used for them to obtain results with a personally selected password via a phone call to an 800 number;
- Address SPs with don't know (DK)/refused (RF) response to gender question in Household Interview;
- Counsel SP who reports suicidal ideation and provide a mental health referral;
- Serve as a resource in support of the phlebotomy component. When SPs express concern about the blood draw either for themselves or their children, the clinician can discuss the blood draw procedure with the SP, as well as promote the benefit of the many tests that are reported;
- Serve as a resource to answer questions or concerns regarding the liver genetic testing as described in Chapter 3;
- Respond to SP questions on referrals and report of findings as necessary; and
- Serve as Safety Officer for the exam team.

1.1.2 Cross-Trained Responsibilities for the Clinician

Responsibilities completed by the **clinician and other MEC staff** include the following:

- Complete data collection for anthropometric measures, liver health, balance, and blood pressure;
- Calibrate and maintain the equipment required for the examination tasks and record data and observations in an automated system;
- Provide instruction to study participants on the use of the audio computer-assisted self-interview (audio-CASI);
- Administer informed consent; and
- Administer COVID-19 screening procedures including a short questionnaire and temperature test.

The clinician examination protocol, described in detail in Chapter 3, emphasizes the importance of following the protocol for the purpose of systematic, prioritized survey data collection.

1.1.3 Consultant Physician

The consultant physician has several roles to support and back up the clinicians on the MEC as outlined below. The consulting physician does the following:

- Conducts mock emergency drills **with each team twice a year** on location;
- The drills include several scenarios using the MEC staff in specific roles during a mock emergency. See Section 5.5.1.3 for staff roles in an emergency;
- Works with the clinician and MEC Manager on their role as Safety Officer on the MEC; and
- Works on the MEC in the clinician role as a back-up if the clinician needs to take time off.

1.1.4 Remote Physician

The current MEC schedule includes several 10-12 hour days requiring staff to work staggered shifts. When the clinician is not scheduled to work on the MEC, the role of clinician will be completed by a remote physician. The MECs will work with the remote physician to provide scheduling information on a weekly basis so the remote physician will be available at those times. Each MEC will have a

clinician laptop with video conferencing capability to allow the remote physician to communicate face-to-face with the SPs. One of the MEC staff will set up the video conference for the SP.

1.1.5 Back-Up to Remote Physician

If the remote physician is not able to cover the time needed, the back-up will be a second remote physician or when feasible, the clinician on the other MEC will fill that role.

1.2 Medical Policy Regarding the Examination

The purpose of the NHANES study is to collect data on the health status of the United States population. The MEC is not a medical treatment facility—hence, MEC clinicians do not provide diagnoses or treatment of medical conditions. It is important to emphasize that treatment is **not** within the role of the MEC clinician, and any clinical findings that are of concern to clinicians are documented and included in community practitioner referrals. In most instances, the examining clinician will not be licensed within the state in which the examinations are being conducted. The liability insurance obtained for Westat clinicians does not cover any type of treatment procedure except for medical emergency stabilization while awaiting the arrival of local paramedics.

NHANES survey teams have neither control over, nor connection with, local health care systems. Any clinician involvement beyond routine referral is ineffective and interferes with the purpose of the study. Referral of examinees is included in the MEC procedures for ethical reasons, although referral is not within the purpose of the study. Before SPs depart the MEC, they are provided with a preliminary Report of Findings that becomes available while they are in the MEC. They are provided a final report of all findings approximately 3 months after their MEC examination. These are in the form of written reports and they are mailed to the SPs.

1.2.1 Response to Medical Emergencies

If an SP becomes ill or disabled during the examination session, the clinician renders the level of care necessary to keep the examinee out of immediate danger. Arrangements are made to transport SPs to an appropriate medical facility. An ambulance is called if a potentially life-threatening condition develops for any SP. Further details about medical emergencies are included in Chapter 5.

1.2.2 Maintenance of Emergency Equipment and Supplies

Clinicians maintain emergency equipment and supplies for use in the MEC. They inventory supplies, restock supplies as needed, and ensure that all emergency equipment, medications, and supplies are current and in proper working order. Emergency procedures and supplies are described in detail in Chapter 5, while Chapter 6 presents information on documenting incidents and emergencies.

2. Equipment and Supplies

2.1 Description of Equipment and Supplies

The clinician maintains, tracks, and orders all equipment and supplies necessary for the conduct of all aspects of the clinician component, including the following:

- Emergency management supplies, and
- Office supplies.

2.2 Emergency Management Supplies

For the purposes of inventory management, nearly all types of equipment are designated as nonconsumable items, and supplies are those items that are depleted throughout a stand and used on a daily basis. At the beginning and end of each stand, the clinician will inventory all component-specific equipment and supplies. Supplies ordered from the warehouse by the previous team during teardown should be on site when the next team arrives to set up a new stand. Clinicians will check all newly received supplies against the associated packing lists before incorporating them into the existing inventory. After reconciling the supplies, the clinician will stock the items used for emergency management supplies and any needed items should be noted on the inventory list, reported to the mobile examination center (MEC) Manager, and documented in the Unusual Field Occurrence (UFO) system.

2.2.1 Emergency Supplies

- Oxygen tanks (2) Size D, 415 liters;
- Primary: Secured to wall;
- Backup: Secured to wall under desk;
- Cannulae, mask, and tubing are stored in sleeve;
- Nasal cannula: 1 adult, 1 pediatric;
- Oxygen mask: 1 mask;

- Extension tubing;
- Oral airway—infant, small, medium, large; and
- Automatic External Defibrillator.

2.2.2 Emergency Box—Contents

- Medications:
  - Ammonia ampules;
  - Aspirin, 325 mg tablets;
  - Diphenhydramine liquid, 12.5 mg/5 ml;
  - Diphenhydramine tablets, 25 mg;
  - EpiPen®—junior;
  - EpiPen—adult; and
  - Glucose tube.
- Supplies:
  - Protective eyewear goggles;
  - Tongue depressor;
  - Stethoscope (2)—child and adult;
  - Pocket blood pressure (BP) aneroid cuffs—child, adult, and large adult;
  - Scissors;
  - Pen light;
  - Sterile gloves—two pairs;
  - ½" Transpore tape; and
  - Surgilube packets.

2.3 Office Supplies

The clinician does not have a dedicated room on the MEC. There are five Multipurpose Rooms (MPRs) on the MEC that are used for data collection for multiple components in addition to the clinician data collection and additional tasks. Although no room is dedicated to the clinician tasks, MPR 5 is equipped with a color laser printer, and is stocked with the following office supplies to support the referral process and other clinician-specific tasks:

- Envelopes (plain and National Center for Health Statistics [NCHS] return address);
- NCHS letterhead paper (plain paper is stored in the staff lounge cabinet); and
- Toner cartridges.

2.4 Equipment Setup

Before setting up, the clinicians should verify that all equipment and supplies are in the room. Any pieces of equipment that are missing should be reported to the home office component staff who will notify NCHS staff.

2.5 Teardown Procedure

At the end of each stand, prepare the equipment for transport by packing up and securing all supplies and equipment in the cabinets and drawers.

3. Clinician Protocol

This chapter presents the clinician-specific protocol only. The other roles the clinician fills are presented in Chapters 5 and 6.

The clinician protocol includes the following:

- **3.2.** Shared Safety Exclusion Questions;
- **3.3.** Sexually Transmitted Diseases (STDs) and Human Immunodeficiency Virus (HIV) Testing;
- **3.6.** The Clinician's Role in the Liver Genetics Component;
- **3.7.** The Clinician Application and Utilities; and
- **3.8.** Report Utility.

3.1 Open the Clinician Application

As soon as the sample person (SP) arrives, the SP ID bracelet must be scanned to launch the clinician application.

3.2 Shared Safety Exclusion Questions

The phlebotomy, liver elastography, and body composition (DXA) include questions designed to exclude SPs based on safety reasons. The questions are component-specific and are asked in the component for all SPs aged 16 years and older, but there are two safety exclusion questions that are asked of all SPs for several exams, and these are referred to as shared exclusion questions. They are:

- Do you have a pacemaker or automatic defibrillator?
- Are you currently pregnant?

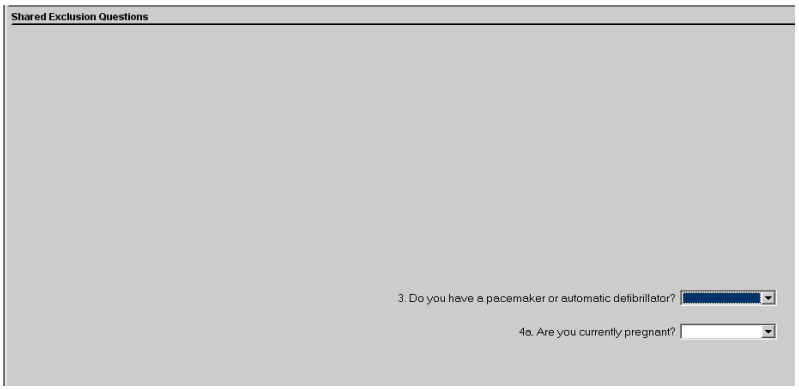
Safety exclusion questions that were not answered during the household interview are asked during the mobile examination center (MEC) examination and at the first opportunity when the SP begins the exam. In the case of children, parents or guardians answer the exclusion questions (Proxy exam) as soon as they arrive at the MEC, with the exception of the pregnancy question. The Proxy exam is

conducted by most MEC, staff including the MEC Manager, clinician, health technologists, phlebotomist, and medical technologists who have been cross-trained on this and other tasks. Each question is asked only once, even when the question is relevant for more than one component—this eliminates wasting time during exams to repeat questions that the SP has already answered. It is important to note that answers to the safety exclusion questions provided during previous components will appear on the screen for the next examiner to see, but the field for data entry is disabled. Once answered, they cannot be changed.

The pregnancy question is administered to all female SPs between the ages of 12 through 59 years. The question is also addressed to SPs aged 8-11 years if they reported during the household interview that menarche had begun. The clinician is the only MEC examiner who asks this question with this age group.

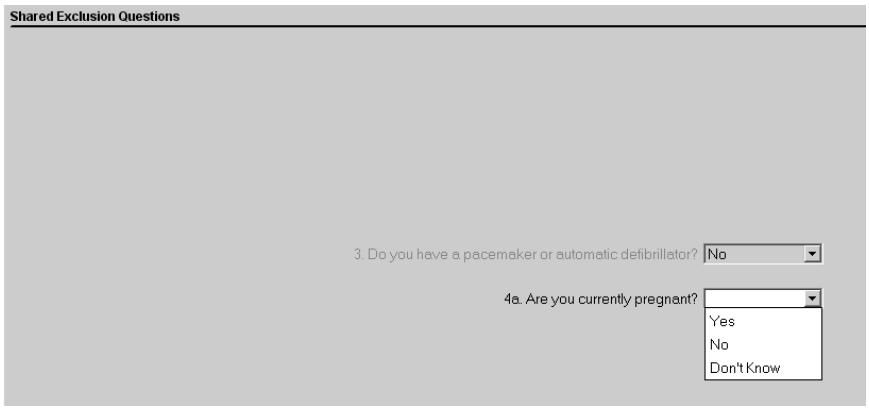
The clinician will see the two shared exclusion questions on the Shared Exclusion screen (Exhibit 3-1).

Exhibit 3-1. Shared exclusion questions for females aged 12-59 years



- If the SP is female, there are shared exclusion questions on self-reported pregnancy.
- If the shared exclusion questions are answered in the household examination, the questions will appear answered and disabled. These responses cannot be changed in the MEC (see Exhibit 3-2).

Exhibit 3-2. Shared exclusion questions answered during a previous exam



- This screen represents the condition in which a parent would have answered the pacemaker or automatic defibrillator question during the Proxy exam, but the pregnancy question is asked by the clinician during the clinician exam.

- If the pregnancy question is answered "Yes," a dialog box will appear with a message that the SP is excluded from DXA. See the following screen (Exhibit 3-3).

Exhibit 3-3. Shared exclusion questions: Exclusion

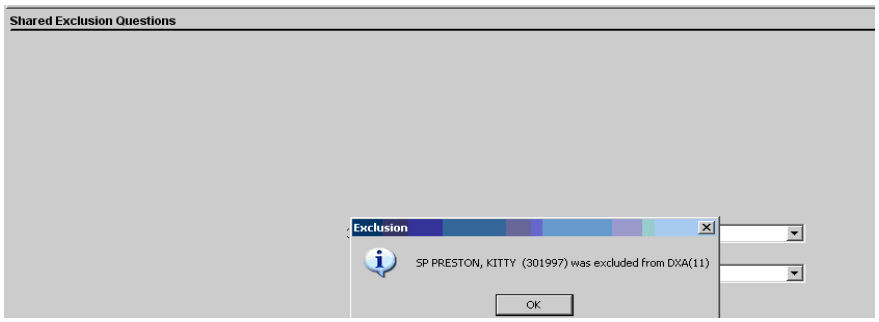


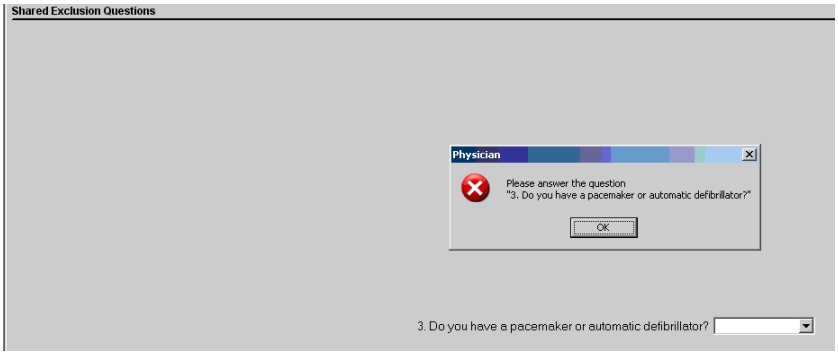
Exhibit 3-4 displays the shared exclusion question on pacemakers or automatic defibrillators.

Exhibit 3-4. Shared exclusion questions: Pacemaker/automatic defibrillator

- This is the only shared exclusion question for SPs who are male, and females who are not of childbearing age.

Exhibit 3-5 shows the data entry box for the pacemaker or automatic defibrillator question.

Exhibit 3-5. Shared exclusion questions: Required data entry

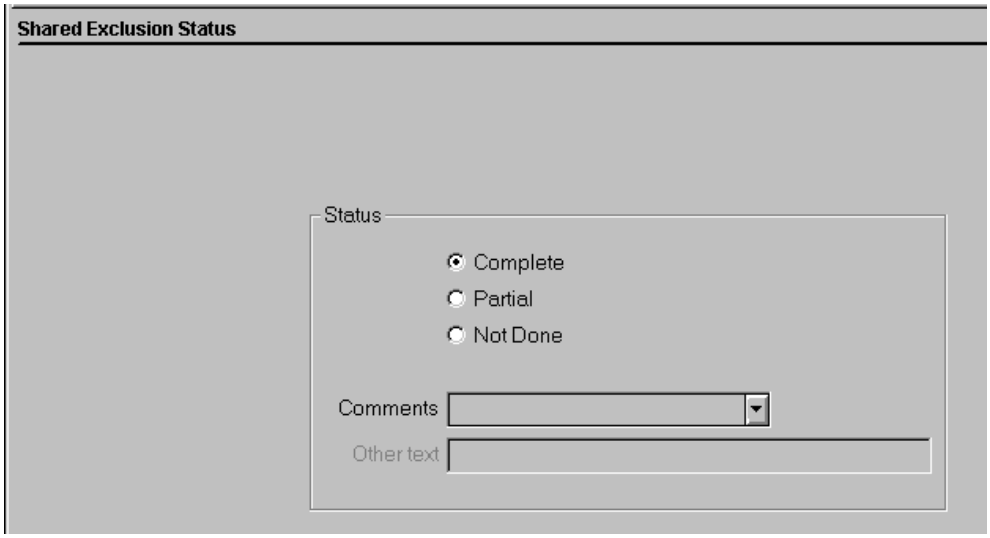


- If the Next button is pressed to go to the next screen, a message is displayed: "Please answer the question." The specific question that was not answered will also be part of this message.

- Click OK to this message and answer the question; then go to the next screen.

Exhibit 3-6 displays the component completion status radio buttons and comments box for the shared exclusion questions.

Exhibit 3-6. Component completion status for shared exclusions



- If all the shared exclusion questions are answered, the component status for shared exclusions defaults to Complete.
- If all questions were not answered, the status defaults to Partial. The examination is closed with the Close Examination button.
- If the SP was excluded by any of the shared exclusion questions, the system displays a series of messages to indicate the other components that are blocked for this SP.
- The SP is not excluded from DXA if the response to the question on the pacemaker or defibrillator is "Yes."
- The SP is excluded from DXA if the weight is greater than 450 pounds or the height is greater than 6'5", so the pacemaker/defibrillator question might be disabled if the SP is sent to body measures first.

3.3 STD and HIV Testing

During the clinician's examination, age-eligible participants are informed about the Sexually Transmitted Diseases (STDs) and Human Immunodeficiency Virus (HIV) tests conducted during the MEC examination. The clinician's role is to discuss these tests with SPs, educate participants about the STD and HIV testing, and explain the mechanism for getting their personal test results.

The confidential nature of the test result reports is explained. The specific tests are determined by age categories (Table 3-1).

Table 3-1. STD tests and age categories

Test	Age	Source
Trichomonas	14–59	Urine
Chlamydia	14–39	Urine
Genital Herpes	14–49	Blood
HIV	18–59	Blood

SPs consent to these tests during the household interview, but may change their mind prior to the examination. Some SPs agree during the home interview, but decide not to be tested when they arrive at the MEC. Other SPs do not agree to be tested during the home interview, but change their mind and want to be tested when they arrive for the examination. Whatever the outcome, the examiner is responsive to the decision of the SP, and the SP must give their informed consent for these tests.

3.3.1 Guidelines Affecting STD and HIV Test Result Reporting

Two guidelines affect the confidential reporting of STD and HIV test results to participants in NHANES. First, NHANES is not subject to state laws that require reporting STD results to state health departments. Second, adolescents in the United States can consent to the confidential diagnosis and treatment of STDs. Medical care for these conditions can be provided to adolescents without parental consent or knowledge. Therefore, there is no legal obligation to disclose findings to anyone other than the participant (Centers for Disease Control and Prevention, *1993 Sexually Transmitted Diseases Treatment Guideline*, MMWR 42 RR-14).

STD and HIV test results are confidential and are **not disclosed to anyone,** including the participant's doctor, insurer, family, or friends, except at the SP's specific request and **only** after the SP properly provides the password selected during the examination. Everyone working with the NHANES signs a legal document making them subject to the Privacy Act, the Public Health Service, and other laws.

Because of the medical, social, and emotional consequences of positive STD and HIV tests, disclosure of results is always handled in a sensitive, respectful, and confidential manner. SPs can only obtain their results when they call the toll-free telephone number provided to them during the

examination. STD and HIV test results are the only NHANES SP health examination results that are provided verbally. A written report can be sent on request after results are provided verbally. All other findings from the health examination are reported to persons in a written report that is mailed to them. The methods for reporting results of these tests differ slightly for adolescents and adults, as well as for non-English speaking Asians whose interviews were conducted in Chinese (Simplified and Traditional), Korean, and Vietnamese. These methods are described in the following sections.

3.3.1.1 Instructing SPs on How to Obtain Confidential Test Results

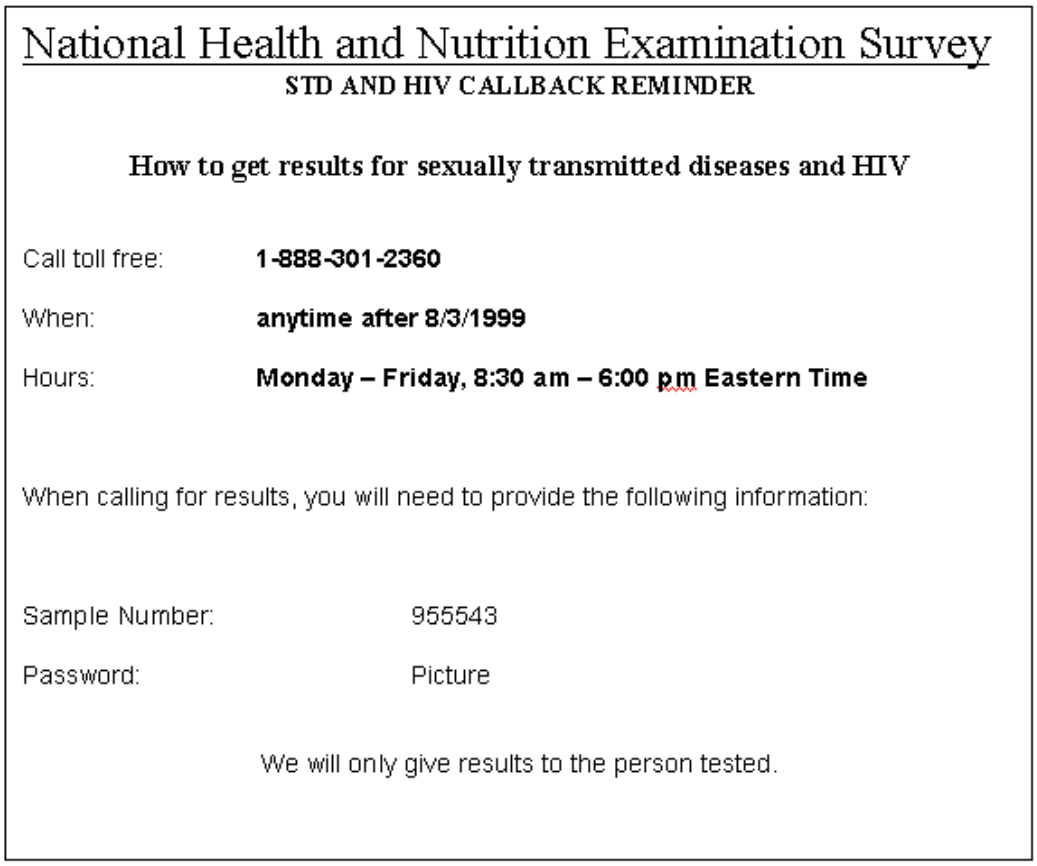
SPs are instructed to call the National Center for Health Statistics (NCHS) personnel for their password-protected confidential reports. Test results are not provided unless the caller correctly states the password. Under no circumstances are STD test results put in writing with a respondent's name, address, or any other personal identifiers unless requested by the SP when receiving results.

To ensure that these results are only provided to the SP for whom the results are specified, SPs are asked to provide their own password. SPs are more likely to remember a password that they have selected. Clinicians record the password in the clinician application and inform participants that they must call a toll-free number in order to get their individual results. SPs use their personally selected password to confirm their identity when they call for their results. The clinician encourages SPs to keep their password to themselves and not share the information with anyone.

All SPs receive a reminder notice (Exhibit 3-7, STD and HIV callback reminder) that includes the toll-free number, the date 30 days after the exam date when the results will be available, and their password. Adult participants (aged 18 years and older) receive their reminder notice from the coordinator as they leave the MEC. The reminder notice is in an envelope that is handed directly to the SP along with the Preliminary Report of Findings.

Minors (SPs 14-17 years of age) receive the same reminder notice, but instead of receiving it at checkout from the coordinator, the clinician personally places the form in a sealed envelope marked with a number that was previously placed on the SP's examination gown. (When SPs change into an examination gown at the beginning of the session, they are given a numbered basket in which to store clothing. The MEC staff marks the number of the basket on their gown for subsequent identification.) The clinician places the envelope in the SP's numbered basket. The clinician reminds the SP to retrieve the envelope from the basket when changing clothes to leave the MEC.

Exhibit 3-7. STD and HIV callback reminder



National Health and Nutrition Examination Survey

STD AND HIV CALLBACK REMINDER

How to get results for sexually transmitted diseases and HIV

Call toll free: **1-888-301-2360**

When: **anytime after 8/3/1999**

Hours: **Monday – Friday, 8:30 am – 6:00 pm Eastern Time**

When calling for results, you will need to provide the following information:

Sample Number: 955543

Password: Picture

We will only give results to the person tested.

Participants who do **not** call for their report are sent a letter reminding them to call the toll-free number to receive their special test results. For teens, if they do not call the survey, staff from NCHS will contact them by phone and tell them their results, whether positive or negative. For others, NCHS sends text messages to everyone who provides a mobile number. If a health problem is identified, the participant is informed and referred for treatment in their area.

Table 3-2 summarizes the STD/HIV testing protocol.

Table 3-2. Summary table of STD/HIV testing protocol

Age	Protocol
SPs age 14–17	• English and Spanish speakers select their password in any combination of letters/digits. • Clinician enters the password into the application. • Clinician prints the letter and places it into an envelope while SP is still in room. The clinician will not write any personally identifiable information on the letter or envelope except for the belongings basket number. • The letter is placed with SP's basket of belongings, and is retrieved directly by the SP when they change back into street clothing. The letter is not intended for any other individual.
Age 18–59	• English and Spanish speakers select their password in any combination of letters/digits. • Clinician enters the password into the application. • The reminder letter is printed with the Checkout Package at the coordinator station when the SP leaves the examination center.
Age 14–59 English and Spanish speakers	• English and Spanish speakers are instructed to call for results in 30 days on the reminder letter. • If the SP has not called for the results, a text message will be sent on days 38, 48, and 58. • The test message will read: "Reminder: Please call 888-301-2360 to get your password-protected test results from the health survey."
Age 14–59 Non-English speaking Asians	• Instruct SP that a representative from NCHS will contact them by telephone when results are ready after 30 days. • SP must provide this password when the representative calls them.

3.3.2 Testing for Trichomonas

With the SP's consent, testing for the presence of the STD trichomonas will be done for SPs aged 14–59 years from their urine sample. While the other STDs may be somewhat familiar to the SP, trichomonas will likely be less well-known, so the clinician needs to be prepared to provide some background and explanation of the disease and its treatment. Results of the testing will be reported to the SP in the same manner as the other STDs.

Here are some talking points the clinician can use to explain the cause, transmission, and effect of the trichomonas infection.

- Trichomoniasis (or "trich") is a very common sexually transmitted disease (STD) that is caused by infection with a protozoan parasite called Trichomonas vaginalis. Although symptoms of the disease vary, most women and men who have the parasite cannot tell they are infected.

- Trichomoniasis is considered the most common curable STD. In the United States, an estimated 3.7 million people have the infection, but only about 30 percent develop any symptoms of trichomoniasis. Infection is more common in women than in men, and older women are more likely than younger women to have been infected.

- The parasite is passed from an infected person to an uninfected person during sex. In women, the most commonly infected part of the body is the lower genital tract (vulva, vagina, or urethra), and in men, the most commonly infected body part is the inside of the penis (urethra). During sex, the parasite is usually transmitted from a penis to a vagina, or from a vagina to a penis, but it can also be passed from a vagina to another vagina. It is not common for the parasite to infect other body parts, like the hands, mouth, or anus. It is unclear why some people with the infection get symptoms while others do not, but it probably depends on factors like the person's age and overall health. Infected people without symptoms can still pass the infection on to others.

- About 70 percent of infected people do not have any signs or symptoms. When trichomoniasis does cause symptoms, they can range from mild irritation to severe inflammation. Some people with symptoms get them within 5 to 28 days after being infected, but others do not develop symptoms until much later. Symptoms can come and go.

- Men with trichomoniasis may feel itching or irritation inside the penis, burning after urination or ejaculation, or some discharge from the penis.

- Women with trichomoniasis may notice itching, burning, redness or soreness of the genitals, discomfort with urination, or a thin discharge with an unusual smell that can be clear, white, yellowish, or greenish.

- Having trichomoniasis can make it feel unpleasant to have sex. Without treatment, the infection can last for months or even years.

- Trichomoniasis can increase the risk of getting or spreading other sexually transmitted infections. For example, trichomoniasis can cause genital inflammation that makes it easier to get infected with the HIV virus, or to pass the HIV virus on to a sex partner.

- It is not possible to diagnose trichomoniasis based on symptoms alone. For both men and women, your primary care doctor or another trusted healthcare provider must do a check and a laboratory test to diagnose trichomoniasis.

- Trichomoniasis can be treated with a single dose of prescription antibiotic medication (either metronidazole or tinidazole), pills that can be taken by mouth. It is OK for pregnant women to take this medication. Some people who drink alcohol within 24 hours after taking this kind of antibiotic can have uncomfortable side effects.

- People who have been treated for trichomoniasis can get it again. About 1 in 5 people get infected again within 3 months after treatment. To avoid getting reinfected, make sure that all of your sex partners get treated too, and wait to have sex again until all of

your symptoms go away (about a week). Get checked again if your symptoms come back.

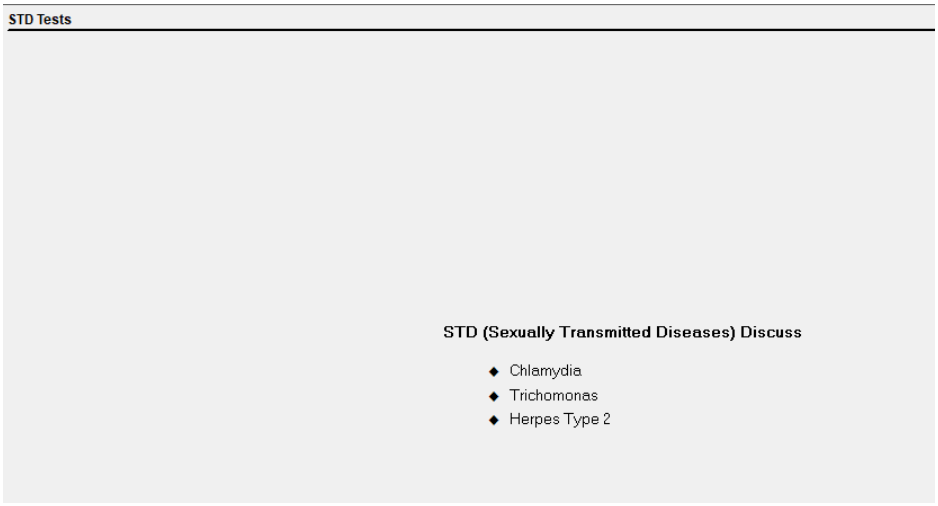
- Using latex condoms correctly every time you have sex will help reduce the risk of getting or spreading trichomoniasis. However, condoms don't cover everything, and it is possible to get or spread this infection even when using a condom.

- The only sure way to prevent sexually transmitted infections is to avoid having sex entirely. Another approach is to talk about these kinds of infections before you have sex with a new partner, so that you can make informed choices about the level of risk you are comfortable taking with your sex life.

3.3.3 STD and HIV Testing and Obtaining Results

Exhibit 3-8 lists the STD tests for 14- to 17-year-olds.

Exhibit 3-8. STD tests for SPs 14- to 17-years-old

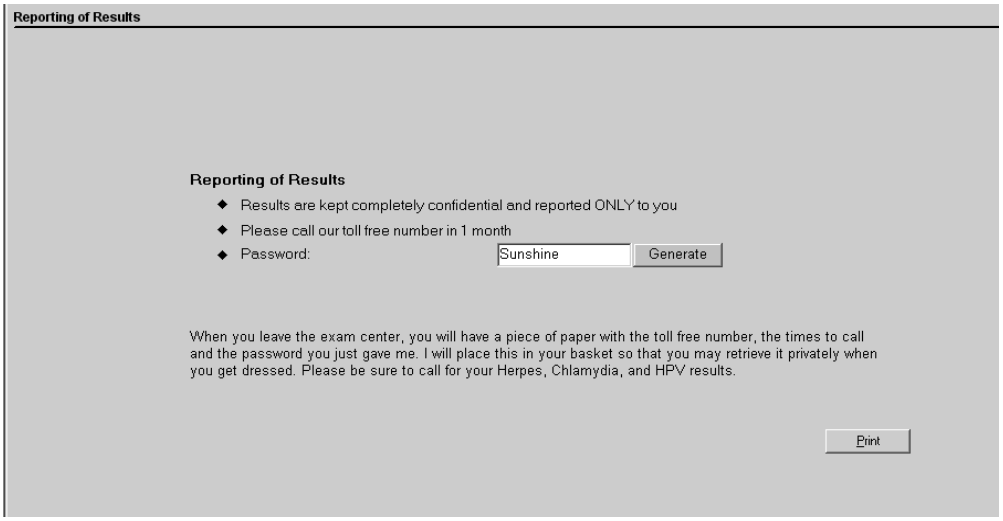


- If the SP is 14-17 years of age, the clinician discusses the method for the SP to receive STD results.

- The clinician asks the SP to give a password to use when calling to get their test results. If the SP cannot think of a password, the clinician will give the SP a password by clicking on "Generate." The system will generate a password and display it in the password field. Clinicians are discouraged from application-generated passwords, as the SP is more likely to forget that password, and may misplace or discard the instruction form. Be patient with the SP while they think of a password.

Exhibit 3-9 displays an automatically generated password for receiving STD information.

Exhibit 3-9. STD automatically generated password



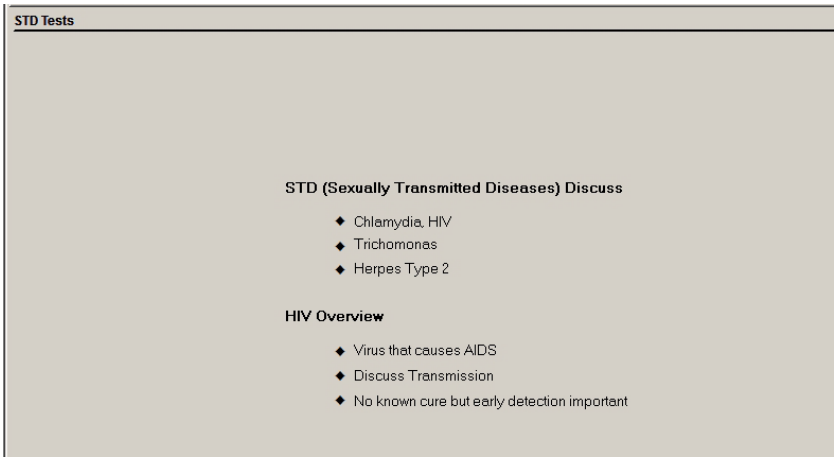
- Other SP information on minors is given to the parents at the time of checkout from the MEC. Due to the sensitive and confidential nature of STD results, the information reports for 14- to 17-year-olds are printed in the MPR 5 (Multiple Purpose Room 5).

- Click on the Print button to print the information form for the SP. After discussing the mechanism for obtaining test results, put the STD and HIV information form in a sealed envelope.

- On the envelope, write the number on the SP's examination gown (the number corresponding to the number on the basket containing the SP's clothes). Put the envelope in your mailbox or give it directly to the assistant coordinator, who will put the envelope in the basket corresponding to the number on the envelope.

Exhibit 3-10 presents the list of STD tests for 18- to 39-year-olds.

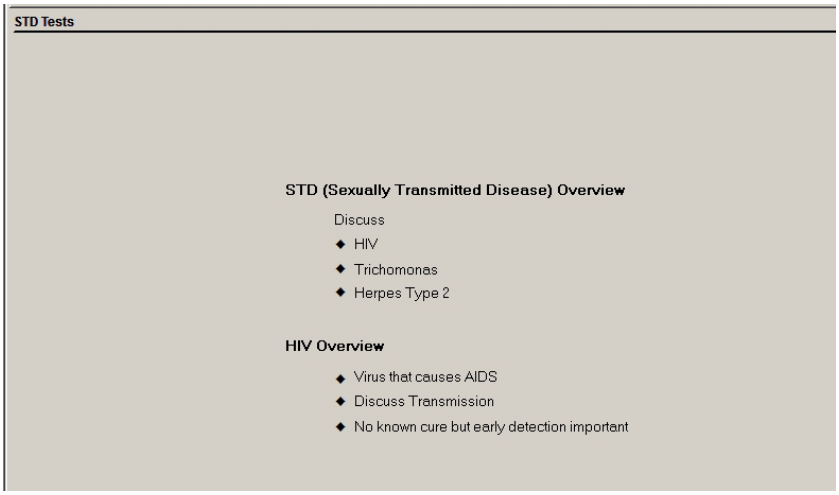
Exhibit 3-10. STD and HIV for SPs 18- to 39-years-old



- If the SP is 18-39 years of age, the clinician discusses the method for the SP to receive results for STD and HIV.
- The clinician asks the SP to give a password to use when calling to get the test results.
- If the SP cannot think of a password, the clinician will give the SP a password by clicking on "Generate."
- The system generates a password and displays it in the password field.
- The SP is given a printout during MEC checkout with the information needed to call for test results. The information printout form is printed at the coordinator station and placed with the SP's information packet.

Exhibit 3-11 presents the list of STD tests for 40- to 49-year-old SPs.

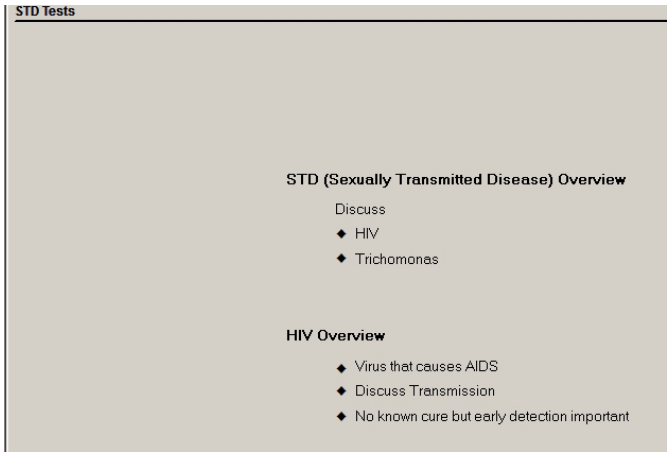
Exhibit 3-11. STD and HIV for SPs 40- to 49-years-old



- If the SP is 40-49 years of age, the clinician discusses the method for the SP to receive STD and HIV results.
- The clinician asks the SP to give a password to use when calling to get test results.
- If the SP cannot think of a password, the clinician will give the SP a password by clicking on "Generate."
- The system generates a password and displays it in the password field.
- The SP is given a printout at the time of MEC checkout with the information needed to call for test results. This information printout is printed at the coordinator station and placed with the SP's information packet.

Exhibit 3-12 presents the list of STD tests for 50- to 59-year-old SPs.

Exhibit 3-12. STD and HIV for SPs 50- to 59-years-old



- If the SP is 50-59 years of age, the clinician discusses the method for the SP to receive HIV results.
- The clinician asks the SP to give a password to use when calling to get test results.
- If the SP cannot think of a password, the clinician will give the SP a password by clicking on "Generate."
- The system generates a password and displays it in the password field.
- The SP is given a printout at the time of MEC checkout with the information needed to call for test results. This information printout is printed at the coordinator station and placed with the SP's information packet.

3.3.4 Informed Consent (IC) Designation in ISIS

SPs may refuse the STD and/or the HIV tests. They may do this at the household interview or in the phlebotomy room. The SP can also be excluded for STD and or/HIV tests during the clinician's examination, or at any time during their visit to the MEC. If the SP determines that they want to refuse any or all of these tests, the clinician accesses the Utilities menu from the toolbar and selects "IC Exclusions" (Exhibit 3-13).

Exhibit 3-13. Utilities menu for Informed Consent Exclusions

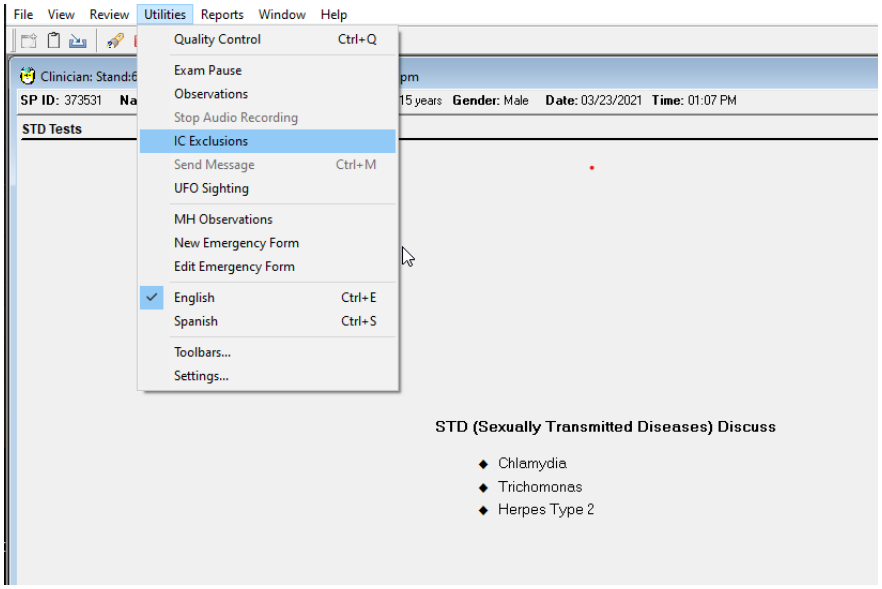
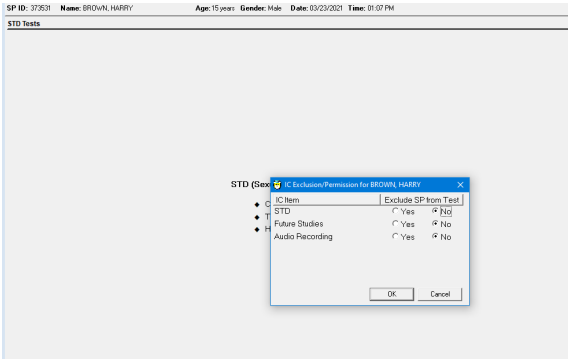
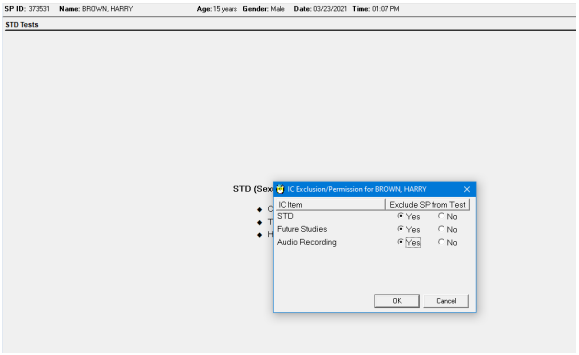


Exhibit 3-14 displays Informed Consent Exclusion Pop-up boxes, which are selected in the Utilities menu and feature Yes and No radio buttons.

Exhibit 3-14. STD and HIV—Informed Consent Exclusions



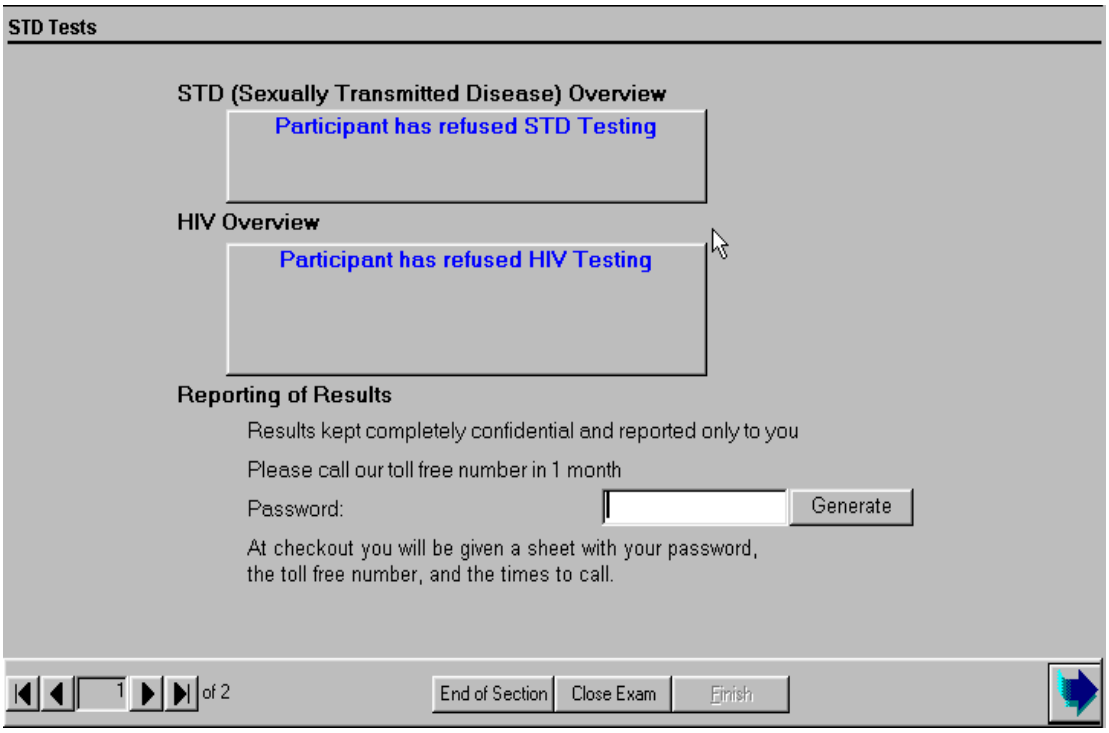


- If the SP had previously agreed to these tests and later decided to refuse these tests after discussion with the clinician, the specimens can be still be excluded. Select "Yes" to exclude the SP from HIV or STD tests. This sends a message to the phlebotomy and laboratory examination component to exclude the SP from these tests.

- The SP could refuse these tests initially and later change their mind after talking with the clinician or phlebotomist. In this situation, the Informed Consent Exclusion should be unchecked. This will remove the exclusion for these tests in the laboratory.

Exhibit 3-15 is a screen displaying boxes indicating SP's refusal for STD and HIV testing.

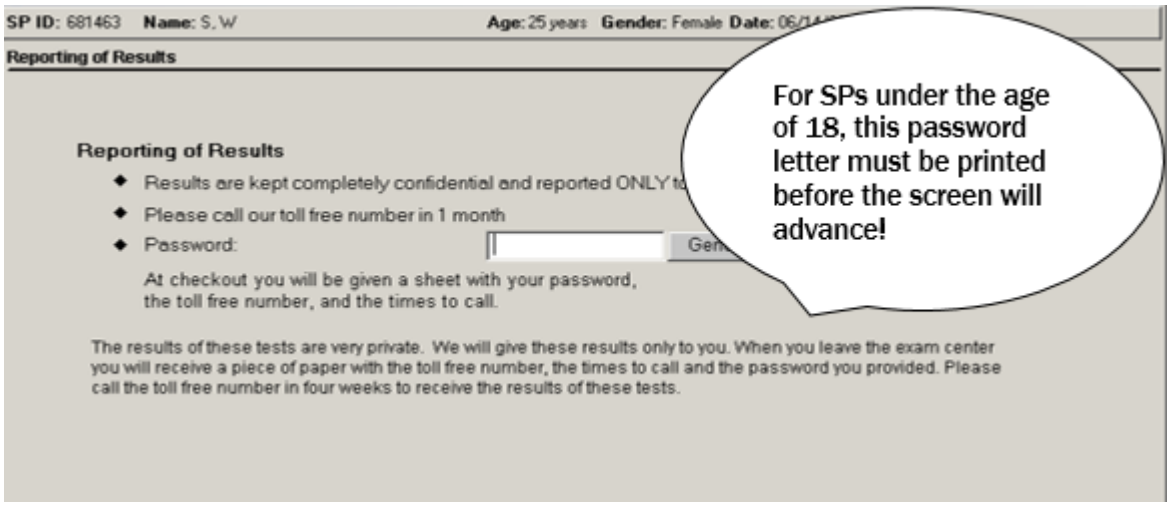
Exhibit 3-15. SP refusal for STD and HIV testing



- If the SP refused to have STD and HIV testing either during the consent process or in the phlebotomy room, the screen in the clinician's examination appears with a message over each section that was refused: "Participant has refused STD and HIV testing."
- If the SP refuses the testing, it is not necessary to discuss the mechanism for getting results.
- It is not necessary to have the SP select a password.
- Select the Next button to go to the component status.

Exhibit 3-16 displays the password entry process for the STD and HIV testing results.

Exhibit 3-16. Password entry requirement for STD and HIV results



- If a password is not entered, a message is displayed: "Please enter the password."
- Click "OK" to this message.
- Generate a password if one is needed.
- Select the Next button to go to the next screen.
- The STD and HIV test completion status defaults to "Complete."
- Select "Finish" to close the examination.

3.4 The Clinician's Role in the Liver Genetics Component

The Liver Genetics component is being instituted to test for targeted genetic variants hypothesized to be related to chronic liver disease and comorbid conditions with liver disease such as obesity, type 2 diabetes mellitus, chronic kidney disease, and cardiovascular disease and methylation sites. DNA methylation is one mediator that cells use to control gene expression and patterns have been associated with liver disease. Targeted genetic variants and methylation sites would be able to be combined with information from NHANES measures of liver steatosis/stiffness measures, current/past alcohol consumption, and comorbid conditions. The full Liver Genetics Protocol can be found in Appendix E.

3.4.1 Study Protocol

This component will be conducted on NHANES participants 18 years of age and older during NHANES 2021-2022. We will consent to eligible participants who attend their scheduled exam at the MEC. All eligible individuals will be asked to participate.

3.4.2 Exclusion Criteria

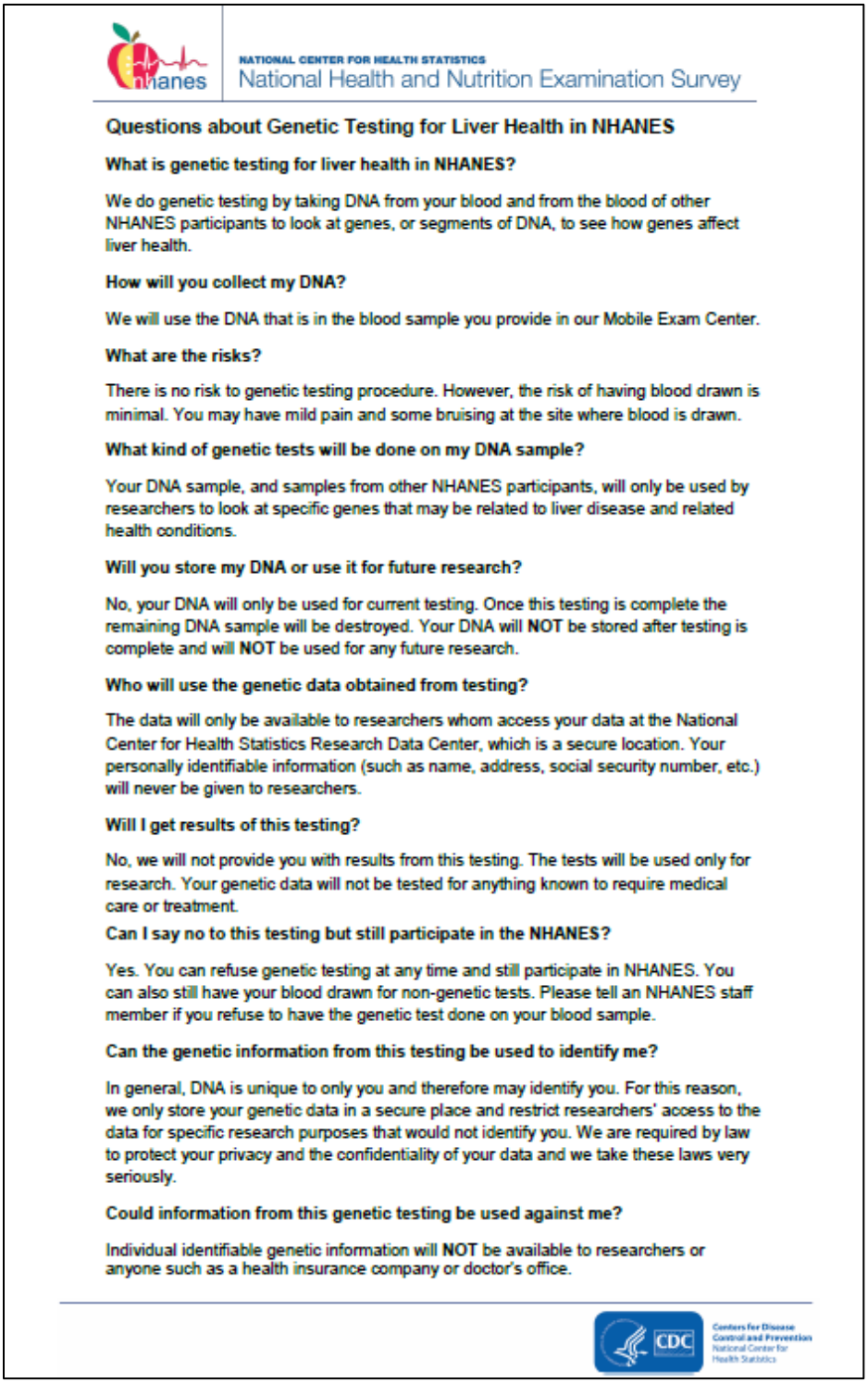
Participants aged 18 years or older are excluded if they do not consent to the MEC examination, if they are unwilling to give blood, or have an exclusion for a blood draw.

3.4.3 The Clinician's Role in the Liver Genetics Informed Consent

Information about genetic testing will be added to the NHANES 2021-2023 Health Measurements List to inform participants about this testing prior to consent. No additional consent for genetic testing will be obtained as samples will not be stored for future testing. Participants will not receive results of genetic testing.

Field interviewers will have on hand an informational handout about the genetic testing (in the form of questions and answers) (Exhibits 3-17 and 3-18). The interviewers will provide the handout to potential participants if they have questions. The home interviewers will receive training about the information in the handout, how to respond to further questions, and to explain that a clinician will be available at the MEC to answer further questions.

Exhibit 3-17. Genetic testing frequently asked questions (FAQ) handout (English)



NATIONAL CENTER FOR HEALTH STATISTICS
National Health and Nutrition Examination Survey

Questions about Genetic Testing for Liver Health in NHANES

What is genetic testing for liver health in NHANES?

We do genetic testing by taking DNA from your blood and from the blood of other NHANES participants to look at genes, or segments of DNA, to see how genes affect liver health.

How will you collect my DNA?

We will use the DNA that is in the blood sample you provide in our Mobile Exam Center.

What are the risks?

There is no risk to genetic testing procedure. However, the risk of having blood drawn is minimal. You may have mild pain and some bruising at the site where blood is drawn.

What kind of genetic tests will be done on my DNA sample?

Your DNA sample, and samples from other NHANES participants, will only be used by researchers to look at specific genes that may be related to liver disease and related health conditions.

Will you store my DNA or use it for future research?

No, your DNA will only be used for current testing. Once this testing is complete the remaining DNA sample will be destroyed. Your DNA will **NOT** be stored after testing is complete and will **NOT** be used for any future research.

Who will use the genetic data obtained from testing?

The data will only be available to researchers whom access your data at the National Center for Health Statistics Research Data Center, which is a secure location. Your personally identifiable information (such as name, address, social security number, etc.) will never be given to researchers.

Will I get results of this testing?

No, we will not provide you with results from this testing. The tests will be used only for research. Your genetic data will not be tested for anything known to require medical care or treatment.

Can I say no to this testing but still participate in the NHANES?

Yes. You can refuse genetic testing at any time and still participate in NHANES. You can also still have your blood drawn for non-genetic tests. Please tell an NHANES staff member if you refuse to have the genetic test done on your blood sample.

Can the genetic information from this testing be used to identify me?

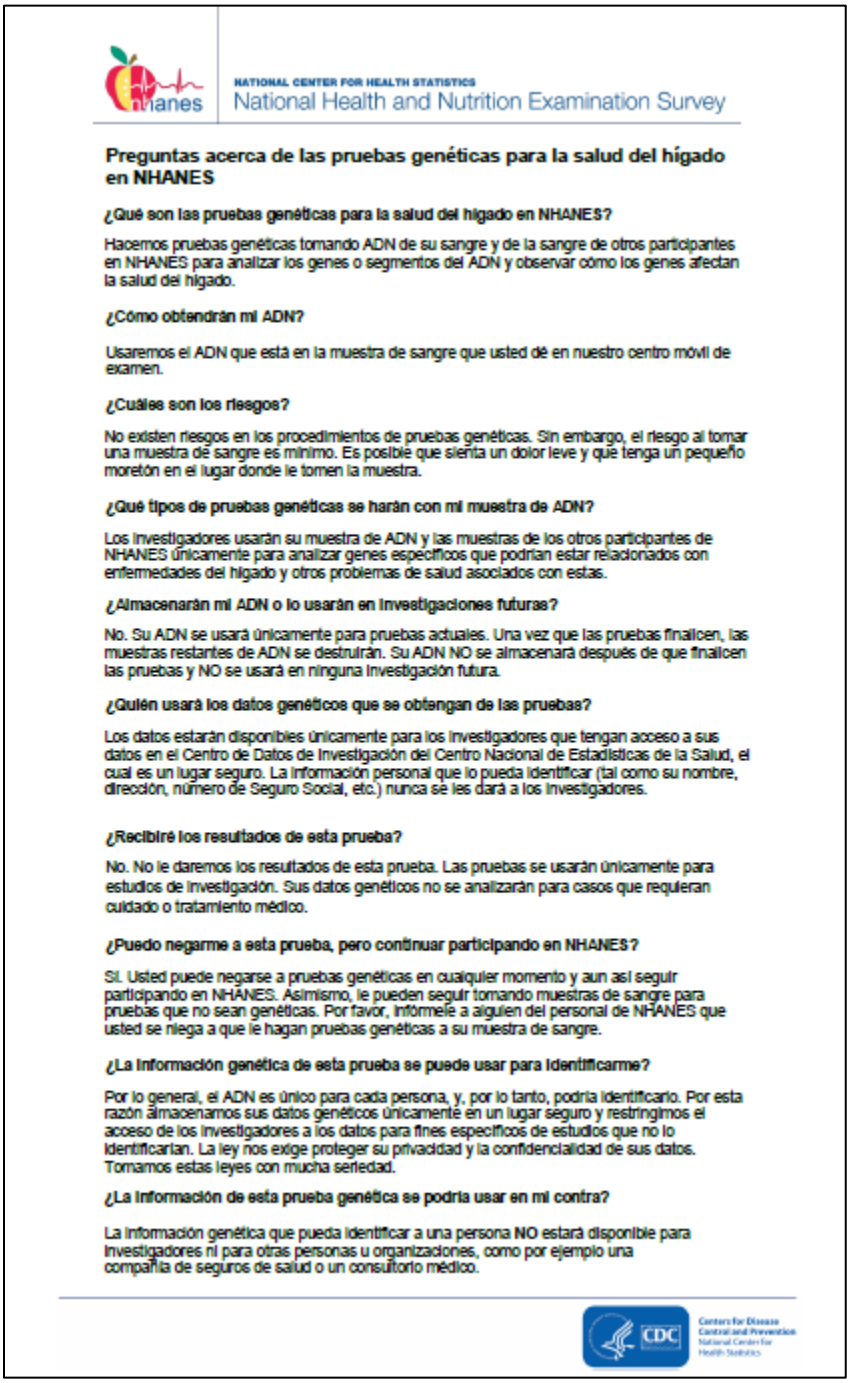
In general, DNA is unique to only you and therefore may identify you. For this reason, we only store your genetic data in a secure place and restrict researchers' access to the data for specific research purposes that would not identify you. We are required by law to protect your privacy and the confidentiality of your data and we take these laws very seriously.

Could information from this genetic testing be used against me?

Individual identifiable genetic information will **NOT** be available to researchers or anyone such as a health insurance company or doctor's office.

CDC Centers for Disease Control and Prevention National Center for Health Statistics

Exhibit 3-18. Genetic testing FAQ handout (Spanish)



NATIONAL CENTER FOR HEALTH STATISTICS
National Health and Nutrition Examination Survey

Preguntas acerca de las pruebas genéticas para la salud del hígado en NHANES

¿Qué son las pruebas genéticas para la salud del hígado en NHANES?

Haremos pruebas genéticas tomando ADN de su sangre y de la sangre de otros participantes en NHANES para analizar los genes o segmentos del ADN y observar cómo los genes afectan la salud del hígado.

¿Cómo obtendrán mi ADN?

Usaremos el ADN que está en la muestra de sangre que usted dé en nuestro centro móvil de examen.

¿Cuáles son los riesgos?

No existen riesgos en los procedimientos de pruebas genéticas. Sin embargo, el riesgo al tomar una muestra de sangre es mínimo. Es posible que sienta un dolor leve y que tenga un pequeño moretón en el lugar donde le tomen la muestra.

¿Qué tipos de pruebas genéticas se harán con mi muestra de ADN?

Los investigadores usarán su muestra de ADN y las muestras de los otros participantes de NHANES únicamente para analizar genes específicos que podrían estar relacionados con enfermedades del hígado y otros problemas de salud asociados con estas.

¿Almacenarán mi ADN o lo usarán en investigaciones futuras?

No. Su ADN se usará únicamente para pruebas actuales. Una vez que las pruebas finalicen, las muestras restantes de ADN se destruirán. Su ADN NO se almacenará después de que finalicen las pruebas y NO se usará en ninguna investigación futura.

¿Quién usará los datos genéticos que se obtengan de las pruebas?

Los datos estarán disponibles únicamente para los investigadores que tengan acceso a sus datos en el Centro de Datos de Investigación del Centro Nacional de Estadísticas de la Salud, el cual es un lugar seguro. La información personal que lo pueda identificar (tal como su nombre, dirección, número de Seguro Social, etc.) nunca se les dará a los investigadores.

¿Recibiré los resultados de esta prueba?

No. No le daremos los resultados de esta prueba. Las pruebas se usarán únicamente para estudios de investigación. Sus datos genéticos no se analizarán para casos que requieran cuidado o tratamiento médico.

¿Puedo negarme a esta prueba, pero continuar participando en NHANES?

Sí. Usted puede negarse a pruebas genéticas en cualquier momento y aun así seguir participando en NHANES. Asimismo, le pueden seguir tomando muestras de sangre para pruebas que no sean genéticas. Por favor, infórmele a alguien del personal de NHANES que usted se niega a que le hagan pruebas genéticas a su muestra de sangre.

¿La información genética de esta prueba se puede usar para identificarme?

Por lo general, el ADN es único para cada persona, y, por lo tanto, podría identificarlo. Por esta razón almacenamos sus datos genéticos únicamente en un lugar seguro y restringimos el acceso de los investigadores a los datos para fines específicos de estudios que no lo identificarían. La ley nos exige proteger su privacidad y la confidencialidad de sus datos. Tomamos estas leyes con mucha seriedad.

¿La información de esta prueba genética se podría usar en mi contra?

La información genética que pueda identificar a una persona NO estará disponible para investigadores ni para otras personas u organizaciones, como por ejemplo una compañía de seguros de salud o un consultorio médico.

CDC Centers for Disease Control and Prevention National Center for Health Statistics

When the MEC staff person is administering consent prior to the exam in the MEC, they will hand the SP a copy of the form to review. If the SP has questions, they will be referred to the clinician to answer any questions. There is an opt-out box for the genetic testing in the clinician's application screen. This process will follow the current STD model that is used by the clinicians. A copy of the handout will be placed in the SP's envelope when they check out of the MEC.

3.4.4 Report of Findings

All genetic variants and methylation sites will not be reported since they are not clinically actionable at this time. Resulting de-identified genetic data will be released to and only accessible through the NCHS Research Data Center (RDC).

3.5 The Clinician Examination Application and Utilities

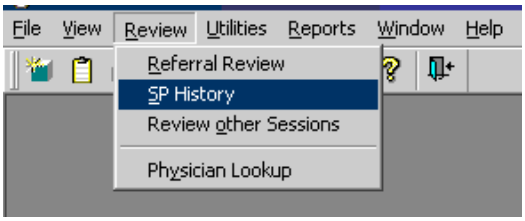
3.5.1 Review Menu Functions

The Review menu allows the user to access four functions: (1) Referral Review; (2) SP History; (3) Review Other Sessions; and (4) Clinician Lookup. The SP History review functionality of the clinician application will be described in this section; the Referral Review, Review Other Sessions, and Clinician Lookup functionalities are described fully in Chapter 4, as these options are specific to the referral review procedures.

3.5.2 SP History

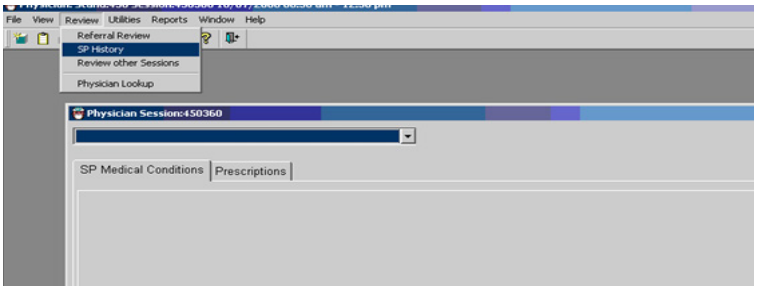
Medical conditions and medications reported during the home interview for all SPs in the session can be reviewed in the clinician's examination under "SP History" (Exhibit 3-19).

Exhibit 3-19. Review menu to select SP History



- To access "SP History," select "Review" from the toolbar and then choose "SP History."
- The "SP History" (Exhibit 3-20) box is displayed.

Exhibit 3-20. SP History screen



- A drop-down menu will appear to access individual SP information from the current session only.
- A tab appears on the screen—SP Medical Condition. Medical conditions include self-reported illnesses, as well as pregnancy status.
- Each SP's ID number, name, age, and gender is displayed.
- Highlight the name of the SP to view the medical conditions and self-reported pregnancy history.
- Switch between the tabs to review 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 3-21 shows no data available under SP Medical Conditions.

Exhibit 3-21. No data available under SP Medical Conditions tab

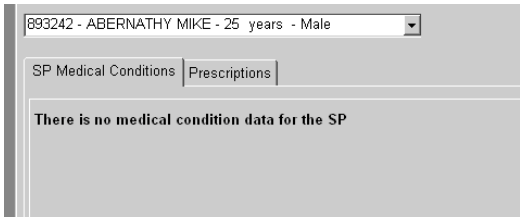
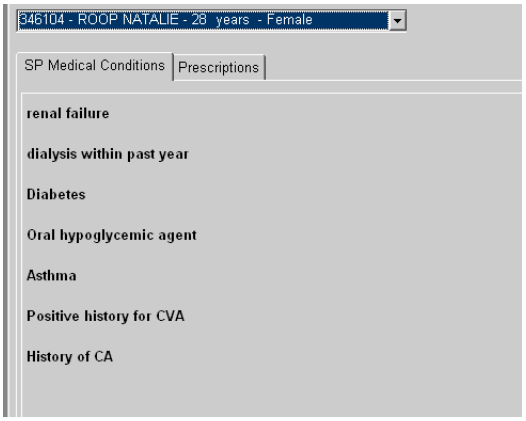


Exhibit 3-22 illustrates the appearance of numerous medical conditions.

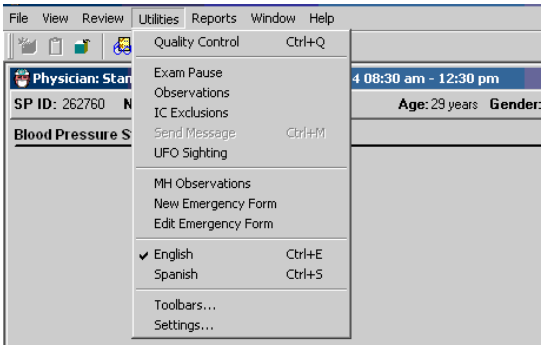
Exhibit 3-22. SP History medical data appearance



3.5.3 Utilities Menu

The Utilities drop-down menu is displayed in Exhibit 3-23.

Exhibit 3-23. Utilities drop-down menu



The Utilities menu consists of the following:

- Exam Pause (this function is also present on the icon toolbar below the menus);
- Observations;
- IC (Informed Consent) Exclusions;
- Send Message;
- UFO (Unusual Field Occurrence) Sighting;
- MH (Mental Health) Observations;

- New Emergency Form;
- Edit Emergency Form;
- English; and
- Spanish.

Quality Control

This option opens the quality control dialog box to initiate quality control procedures. See Chapter 7 for quality control procedures.

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 be used in case of an emergency in the MEC.

Observations

The observation field allows the user to document any additional information that could inform the data collection process. See Chapter 7.

IC (Informed Consent) Exclusions

The status of SP informed consent for HIV, STD, Genetic Testing, and Future Studies is displayed in the box for IC items. The clinician can change the status either way if the SP changes their mind regarding these lab tests at any time during the visit to the MEC. For specific guidance on the IC exclusion procedure, see Section 3.4 of this chapter.

Send Message

This function allows the clinician to send a message to the coordinator.

Unusual Field Occurrence (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.

Mental Health (MH) Observations

See Chapter 4 for specific guidance related to documenting mental health observations and referrals.

New Emergency Form

Select this utility when documenting a new Incident/Emergency report form. Refer to Chapter 5.

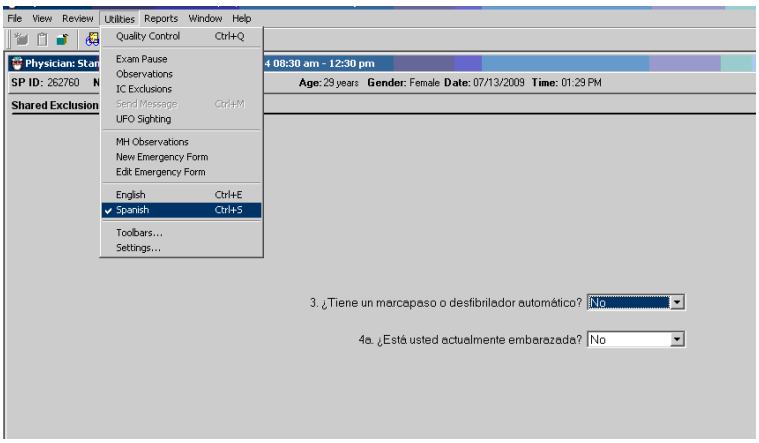
Edit Emergency Form

Additional or followup information may be added to an existing Incident/Emergency report 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 clinician, when using an interpreter for a Spanish-speaking SP, will switch the application to Spanish for the interpreter's benefit (Exhibit 3-24).

Exhibit 3-24. Spanish screen: Example of shared exclusion questions

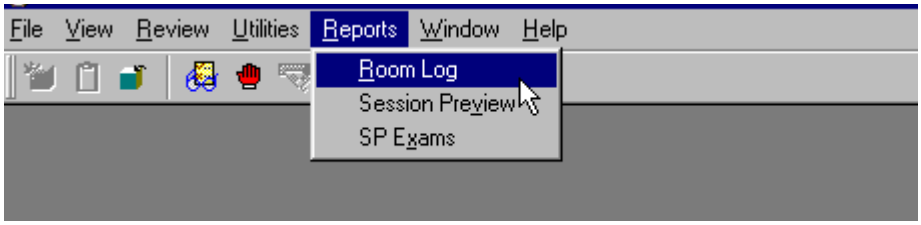


3.6 Report Utility

The Reports utility displays three different reports: (1) the Room Log, (2) Session Preview, and (3) SP Exams (Exhibits 3-25 through 3-27).

Room Log

Exhibit 3-25. Menu for selecting Room Log

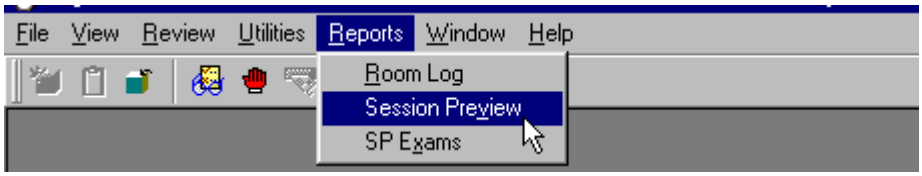


The clinician application tracks the status of the examinations and displays the information under the Clinician Room Log.

- The Room Log displays a list of the SPs who are eligible for this examination. All SPs are eligible for the clinician's examination. The SP examination status report displays all SPs in the session along with the status and status comment.
- Choose "Reports" from the toolbar and select "Room Log."

Session Preview

Exhibit 3-26. Session Preview

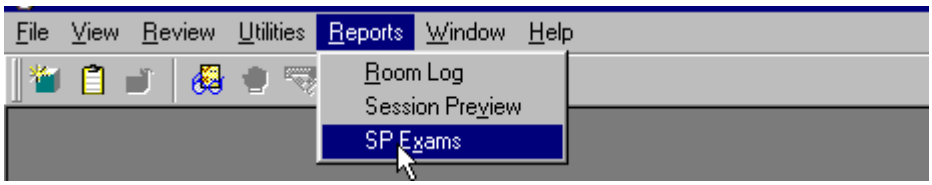


- To preview a list of SPs in the current session, select "Reports" from the toolbar.
- Select "Session Preview."
- The "Session Preview Report" displays a list of SPs in the current session.
- The ID, SP Type, SP Name, Age, Gender, Special Considerations, and Consent Comments are displayed.

- This report provides information about special needs or consideration for each SP, such as wheelchair used for mobility, disabilities, and consent issues.

3.6.1 SP Examinations

Exhibit 3-27. SP Exams

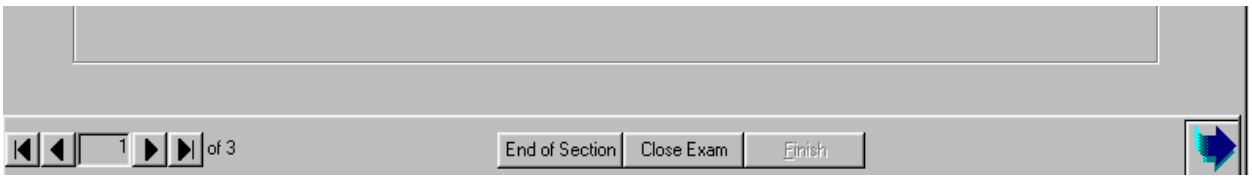


- To preview the status of the SP examinations in the current session, select "Reports" from the toolbar.
- Select "SP Exams" from the menu.
- The SP examination status report can be viewed for each SP in the session.
- The first column lists the components for which the SP is eligible.
- The second column displays the examination status: Complete, Partial, or Not Done.
- The status remains blank until the SP has been to that component.
- If applicable, the status comment and "Other" comment are also listed.
- Scroll up and down to view all SPs in the session. Page up and page down may also be used.

3.6.2 End of Section

Exhibit 3-28 displays the End of Section button.

Exhibit 3-28. End of Section



- The End of Section button is used to advance to the end of the current section without entering data in the required fields.

- The status defaults to Not Done, and a comment is required. Select the appropriate comment for the situation.
- One potential situation is when there is not enough time at the end of a session to complete the entire examination, but the SP needs the STD and HIV information sheet to be able to obtain test results. The clinician opens the examination, selects "End of Section" for the blood pressure and cardiovascular exclusion questions. The appropriate comment for both sections would be "No Time."
- The End of Section button can be selected from each section.
- This allows the screens to advance through each section until the STD and HIV results screen appears.

3.6.3 Close Examination Button

- The correct method of closing an examination is to select the Finish button after all the data have been entered.
- If there is a need to end the examination prematurely, the Close button can be selected at the bottom of the screen next to the End of Section button.
- When the Close button is selected, a pop-up box is displayed. The examination status defaults to Not Done or Partial depending on the stage of the examination when the Close button was pressed.
- Select the appropriate comment from the drop-down list.

3.6.4 Pausing an Examination

Exhibit 3-29 displays the button for pausing an exam.

Exhibit 3-29. Pause an examination

- There may be situations where the clinician is needed in another room in the MEC. If this occurs during an examination, select the icon with the red hand (the Pause icon).
- Clicking this icon pauses the examination in the clinician's room. The timer for the examination stops.

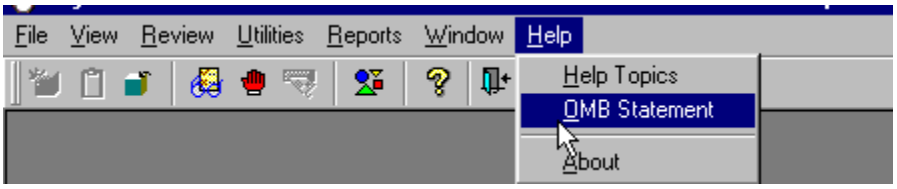
- The Pause icon acts as a toggle and the timer will not start again until the Pause icon is clicked again.

- Examination pause may also be accessed from selecting "Utilities" from the toolbar and then selecting "Examination Pause" from the menu.

OMB Statement

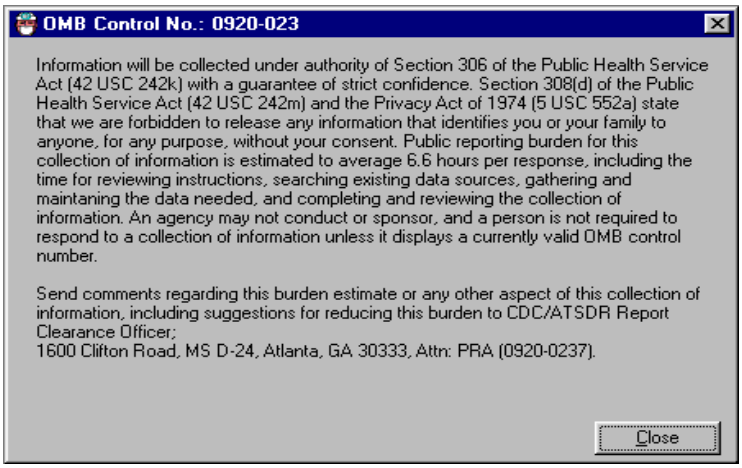
Exhibit 3-30 displays the menu to select the Office of Management and Budget (OMB) Statement on collection of information.

Exhibit 3-30. OMB Statement selection menu



The OMB Statement is found under the Help menu on the toolbar. Choose Help, and then select OMB Statement (Exhibit 3-31) from the menu.

Exhibit 3-31. OMB Statement



The OMB Statement is displayed. Click on Close to close this box.

4. Referrals

4.1 Clinical Referrals

Although the primary purpose of the MEC examination is data collection, not diagnosis or treatment, the examination may produce findings that warrant further attention. There is an obligation to inform SPs of any abnormal results from the examinations and to refer SPs to appropriate providers for treatment. MEC clinicians are responsible for referrals. Each examination component has a referral process built into the ISIS system. This automatic process alerts to findings that may require a referral. SPs and their providers may already be aware of some findings, but others may have been revealed for the first time during the MEC exam. MEC clinicians review the data provided and the categories set forth by the Physicians Advisory Group of the National Center for Health Statistics' Division of Health and Nutrition Examination Surveys to determine what type of referral, if any, is needed.

MEC clinicians can arrange for a referral to a care provider for SPs who do not have a local provider. These advance arrangements are made through an advance arrangement team that includes a physician from the National Center for Health Statistics.

Referrals may be based on data collected during MEC examination components (examination data-related referrals) or based on subjective or objective observations made by any MEC examiner (observation referrals). These two types of referrals are described in detail in this section.

Examination data-related referrals are based on predefined criterion levels from the examination data. These criterion levels were defined by the Physicians Advisory Group and are built into the ISIS system so that when the limits are exceeded, the system automatically flags this information to the clinician for the specific SP. The flag occurs when component data that are above or below the predefined limits are recorded. The examination components that send data-related referrals to the clinician system are the laboratory (pregnancy and complete blood count), mental health (from the MEC Interview health examination), and blood pressure from the health technician's measurements.

This chapter describes the referral procedures for exam-specific data results, as well as independent observations:

- Laboratory data: CBC and Pregnancy Tests;
- Blood Pressure;
- General Observations;
- Mental Health;
- Balance;
- Cognitive Functioning; and
- Automated Referral Procedures in the Clinician Application.

4.2 Referral Levels

The MEC clinician makes decisions about referring SPs for additional care based on a system rated by three levels (Table 4-1). This is important, because different MEC examinations generate various categories of urgent information that are often different, one from the other. Findings that are outside the normal limits should be reviewed to determine if additional follow-up care is needed. These three levels of referral apply across all MEC examinations. The Physician's Advisory Group defined the action required for each referral level. The edit limits or ranges for referrals in each component were defined by the component specialists and consultants and subsequently reviewed and approved by the Physicians Advisory Group. Based on the results of any component of the MEC examination, clinicians place SPs in one of three referral categories. The highest, most urgent referral is a Level 1 referral. Level 2 indicates medical findings that warrant attention within the next 2 weeks. Level 3 represents an examination finding that the clinician reviews, but does not refer the SP for further care. This method of referral ensures that clinicians from both exam teams review all findings that appear out of the standardized norm, and that there is a record made that the clinician reviewed the findings and made an informed decision, drawing upon his or her clinical background, about whether the SP should be referred.

Table 4-1. Table of referral levels

Referral level	Category	Action
1	4	Indicates major medical findings that warrant immediate attention by a health care provider.
2	3	Indicates major medical findings that warrant attention by a health care provider within the next 2 weeks. These findings are expected to cause adverse effects within this time period, and they have previously been undiagnosed, unattended, nonmanifested, or not communicated to the examinee by his or her personal health care provider.
3	1 & 2	Indicates no major negative medical findings, or minor medical findings that an examinee already knows about, and is under care for, or findings that do not require prompt attention by a medical provider.

4.2.1 Level 1 Referrals

These referrals are generated when there are major medical findings that warrant immediate attention by a health care provider, such as a dangerously high blood pressure and life-threatening emergencies. SPs determined to need a Level 1 referral usually terminate further MEC examinations. SPs are transferred out of the MEC and recommended for immediate medical care at a hospital or other care facility. SPs who refuse treatment from this level of referral are asked to sign a release stating that they are aware of the examination findings but are refusing treatment against the advice of the clinician. SPs must sign the release form before leaving the MEC. The release is available in both English and Spanish.

4.2.2 Level 2 Referrals

The clinician generates these referrals when there are major medical findings that require attention by a health care provider in the next 2 weeks because they are expected to cause adverse effects within this time. Level 2 referrals allow SPs to continue MEC examinations; however, they are advised to see their primary care provider within 2 weeks following the examination. A high but not dangerously high blood pressure is an example of a Level 2 referral.

4.2.3 Level 3 Referrals

Level 3 referrals consist of either no out-of-range medical findings or minor medical findings that an examinee already knows about, is under care for, or does not require prompt attention by a medical provider. Level 3 findings do not necessarily generate referrals. Examinees receive a report of the

findings from many of the examination components before leaving the MEC. In addition, a detailed Report of Findings is sent from NCHS approximately 2 to 4 months after completion of the examination. The latter report contains the results of some findings that are not available before SPs leave the MEC.

4.3 Laboratory Referrals

Urine and blood are collected for various laboratory tests on all SPs ages 1 year and older. A complete and detailed description of these tests can be found in the *NHANES Laboratory Procedures Manual*. Two laboratory findings—the complete blood count and the urine pregnancy test—are reviewed by the clinician and given to the participant in the preliminary Report of Findings prior to his or her leaving the mobile examination center. When these findings are outside the predetermined criterion levels for referral, clinicians decide whether a referral is needed. When a referral is indicated, the clinician provides the information to the SP. The laboratory findings and the parameters that generate referral advice to the clinician are shown in Tables 4-2 and 4-3.

4.3.1 Pregnancy Referral Requirements

Urine pregnancy tests are done on all SPs between the ages of 12 through 59 years, and on girls ages 8 through 11 years if they reported menarche during the household interview. The clinician is the **only** person who discusses the pregnancy results with the SP since some SPs may be unaware of their pregnancy at the time of the test. The clinician discloses results of positive pregnancy tests to the SP, unless the SP is 18 or over and had already reported the pregnancy during the interview. SPs under 18 years of age always see the clinician when a positive pregnancy test is reported. Negative pregnancy test results are provided to SPs only upon the SP's specific request. Clinicians discuss the importance of prenatal health care in situations where SPs have not seen a health care provider when they have a positive pregnancy test. Referrals are facilitated if appropriate. SPs with no source of prenatal care are referred to a local public health clinic or primary care provider.

Table 4-2. Complete blood count reference ranges—males

Age in years	1-5		6-18		19-65		66+	
White blood cell count (SI)	4.3	14.6	3.6	11.5	3.9	11.8	3.8	12.1
Red cell count (SI)	3.98	5.3	4.14	5.78	4.18	5.86	3.57	5.67
Hemoglobin (g/dL)	10.7	14.2	11.9	16.9	13.1	17.5	11.4	17.1
Hematocrit (%)	32.1	41.7	35.3	49.9	38.7	51.4	33.9	50.9
Mean cell volume (fL)	68.2	88.8	75.6	94.6	79.8	99.1	81.4	102.7
Mean cell hemoglobin (pg)	22.3	30.6	25	32.3	26.3	34	26.3	35
MCHC (g/dL)	32.3	35.6	32.3	35.3	32.3	35.3	32.1	35.1
Red cell distribution width (%)	11.4	15.8	11.4	14	11.4	14.5	11.8	16.2
Platelet count (%) SI	212	546	179	439	152	386	124	384
Mean platelet volume (fL)	6.1	8.9	6.6	10	6.8	10.1	6.6	10.2
Lymphocyte (%)	22.8	68.4	17.5	54.3	16.1	47.9	12.3	46.4
Monocyte (%)	4.6	15.2	4.8	13.7	4.4	13.5	4.6	14
Segmented neutrophils (%)	17.6	67.1	30.3	72.8	37.8	74.6	39.5	78.1
Eosinophils (%)	0.7	11.3	0.7	11.5	0.7	8.5	0.6	8.8
Basophils (%)	0.1	2.5	0.1	1.6	0.1	1.6	0.1	1.6

Table 4-3. Complete blood count reference ranges—females

Age in years	1-5		6-18		19-65		66+	
White blood cell count (SI)	4.3	14	3.9	12.2	4.1	12.9	4	11.6
Red cell count (SI)	3.96	5.28	3.84	5.24	3.64	5.2	3.51	5.34
Hemoglobin (g/dL)	11	14.2	11.2	15.1	10.6	15.6	10.9	15.9
Hematocrit (%)	32.5	41.9	33.5	44.6	32	45.9	32.8	47
Mean cell volume (fL)	70.2	89.1	74.7	94.9	74.6	98.2	80.3	100.6
Mean cell hemoglobin (pg)	23.3	30.8	24.5	32.6	24.3	33.8	26.4	34.5
MCHC (g/dL)	32.4	35.5	32.3	35.3	32.1	35.3	32.3	35.1
Red cell distribution width (%)	11.3	15.4	11.3	14.8	11.4	16.3	11.6	16.3
Platelet count (%) SI	215	547	190	446	168	441	155	428
Mean platelet volume (fL)	6.1	8.9	6.6	10	6.8	10.2	6.7	10.5
Lymphocyte (%)	21.6	68.8	17.2	54.7	14.1	47.6	13.7	46.9
Monocyte (%)	4.2	14.4	4.3	12.7	3.8	11.6	4.4	12.8
Segmented neutrophils (%)	19.4	69.5	31.9	74.3	39.8	78.1	40.9	78.1
Eosinophils (%)	0.6	9.9	0.6	9.9	0.6	7.3	0.6	7.5
Basophils (%)	0.1	2.5	0.1	1.6	0.1	1.7	0.1	1.7

4.3.2 Unmarried Minors Pregnancy Referrals

The finding of a positive pregnancy test in an unmarried minor (under age 18) requires clinicians to conduct a brief evaluation to determine the level of counseling and referral necessary. The clinician discloses a positive pregnancy test result directly to the minor.

Federal law requires clinicians to report child abuse. These pregnancy referral requirements are based on child abuse laws for SPs less than 18 years of age. When counseling the pregnant minor, clinicians take a brief history to determine whether the pregnancy may have resulted from sexual abuse. The index of suspicion for sexual abuse is based solely on what a minor discloses, rather than a full medical evaluation. Young women may refuse to provide information surrounding their pregnancy. If the information provided by a minor leads the clinician to be concerned about possible, probable, or definite sexual abuse, **the parent/guardian is informed** and a report is filed with Child Protective Services (CPS). If the clinician is unsure whether to report, the clinician discusses the case with a social worker at CPS. When presenting the case, MEC clinicians do not use the minor's name or any other identifier. If the social worker and clinician agree that the referral to CPS should be made, the clinician may provide the name and address of the minor. Clinicians may follow up the verbal reporting with a written documentation of findings relevant to the reporting. **These written reports are private and are not collected in the NHANES database.**

If the minor is under 14 years of age, clinicians discuss the circumstances of the pregnancy with the child, inform the parent, and report the case to CPS. Pregnancy in such a young age is probable child abuse. If the clinician is informed that the child is already receiving prenatal care, the clinician verifies this information directly with the provider. In cases where the child is already receiving prenatal care and has received a full medical evaluation, no report to CPS is indicated.

If the minor is 14 years and older, clinicians disclose results directly to the minor and assess (a) whether the minor is already receiving prenatal care or pregnancy counseling, (b) whether the minor's parent/guardian is aware of the pregnancy, and (c) whether the pregnancy is a result of child sexual abuse. If a minor who is 14 years or older is already receiving prenatal health care, clinicians confirm this with the local provider. No further referral or parental notification is necessary unless other examination findings meet the criteria for referral. If the minor is not receiving prenatal care, the clinician discusses with the SP the importance of a medical evaluation and pregnancy counseling

for the SP and facilitates a referral. SPs with no source of care are referred to a local public health clinic or primary care provider. Because a parent/guardian should be informed of a minor's pregnancy if she is not receiving prenatal care, the clinician will offer to help the minor tell her parent/guardian before leaving the MEC. **If the minor strongly opposes the disclosure of the pregnancy test results to a parent or guardian, the clinician respects the minor's confidentiality.**

4.3.3 Complete Blood Count

The MEC clinician reviews and interprets all CBC results. Abnormal results constituting action should be transmitted to the clinician immediately. The clinician determines if referral for the SP for treatment is necessary. The medical technologist sends an observation to the clinician whenever a critical or action limit is detected for any CBC parameter. This observation includes the date, time, responsible laboratory individual, person notified, and test results.

A new hematology analyzer (Coulter DXH 800) is replacing the existing analyzer in all mobile examination centers. Once installed and tested, the Complete Blood Count section of the NHANES Report of Findings will be based on the new Coulter DXH 800. This machine is more sophisticated and additional parameters will be reported.

This machine directly measures the red blood count (RBC), white blood count (WBC), hemoglobin (Hgb), and differential percentage. The mean corpuscular volume (MCV), red cell distribution (RDW), platelets (PLT), and mean platelet volume (MPV) are derived from histograms while other values are calculated. Reference ranges for normal values (Tables 4-2 and 4-3) were calculated from NHANES data, last updated in 2003. The following values are transmitted to the clinician for review:

1. **Red Blood Count.** Elevated RBC may reflect primary polycythemia (polycythemia rubra vera) or secondary causes of polycythemia (stress erythrocytosis, diseases associated with low oxygen, certain renal disorders, etc.). Decreased RBC count may indicate anemia.

2. **Hemoglobin.** Abnormal Hgb measurements usually reflect the same conditions as the RBC count and can define the type of anemia.

3. **Hematocrit.** Abnormal hematocrit values usually reflect the same conditions as the RBC and can help define the type of anemia.

4. **Lymphocytes.** Elevated counts (lymphocytosis) may be primary (leukemias, lymphomas, monoclonal B cell lymphocytosis) or secondary (viral infection, acute physical stress, pertussis, and chronic disorders such as autoimmune disease and cancer). Depressed counts (lymphopenia) can reflect a variety of uncommon inherited disorders or the more frequent acquired conditions such as viral and certain bacterial infections, the effects of immunosuppressive agents, and some chronic diseases.

5. **Monocytes.** These cells, derived from the bone marrow, are the precursors of tissue macrophages. Monocytosis is often seen in chronic infections (TB, brucellosis), acute protozoan and rickettsial diseases, and in neutropenia. Uncommon malignant disorders (monocytic leukemia, histiocytic lymphoma) and nonmalignant conditions (hemophagocytic syndromes) can also cause it.

6. **Neutrophils.** Elevated neutrophils (agranulocytosis) are seen in both primary (myelocytic leukemias, polycythemia rubra vera) and, more commonly, in secondary conditions (bacterial infections, chronic inflammation, corticosteroid use, cigarette smoking, etc.). Hereditary neutrophilia is rare. Decreased neutrophils (leukopenia) can also result from primary (myeloid malignancies, congenital disorders) and secondary (drug effect, viral infection, splenomegaly, autoimmune, and hereditary disorders) conditions.

7. **MCH.** The mean corpuscular hemoglobin, in picograms, is calculated from the ratio of Hgb to RBC. This measure of Hgb per RBC is used in conjunction with the MCV and the MCHC to further define anemias. For example, the MCH is elevated in macrocytic anemias and depressed in microcytic, hypochromic anemia.

8. **MCHC.** The mean corpuscular hemoglobin concentration is derived from the ratio of the Hgb to the volume of packed red cells (VPRC). It is also used to help define anemias, being elevated in macrocytic anemias and depressed in hypochromic anemias.

9. **RDW.** The red cell distribution width is a measure of the homogeneity of the RBC population. It is analogous to anisocytosis seen on microscopic examination. Most macrocytic and microcytic anemias, especially with reticulocytosis, will cause an increased RDW. There is no known pathological cause of a decreased RDW.

10. **Platelets.** A decreased platelet count (thrombocytopenia) can be caused by production abnormalities (radiation, drug-induced, cancer, folate or B12 deficiency, myelodysplasia syndromes, HIV, alcohol abuse, etc.), accelerated removal (ITP, SLE, rug antibodies, certain infections, etc.), and hypersplenism. Elevated counts (thrombocytosis) can be primary (myeloproliferative disorders such as CML and PRV, essential thrombocythemia) or secondary (acute trauma, chronic iron deficiency, inflammatory disease, cancer, splenectomy, etc.).

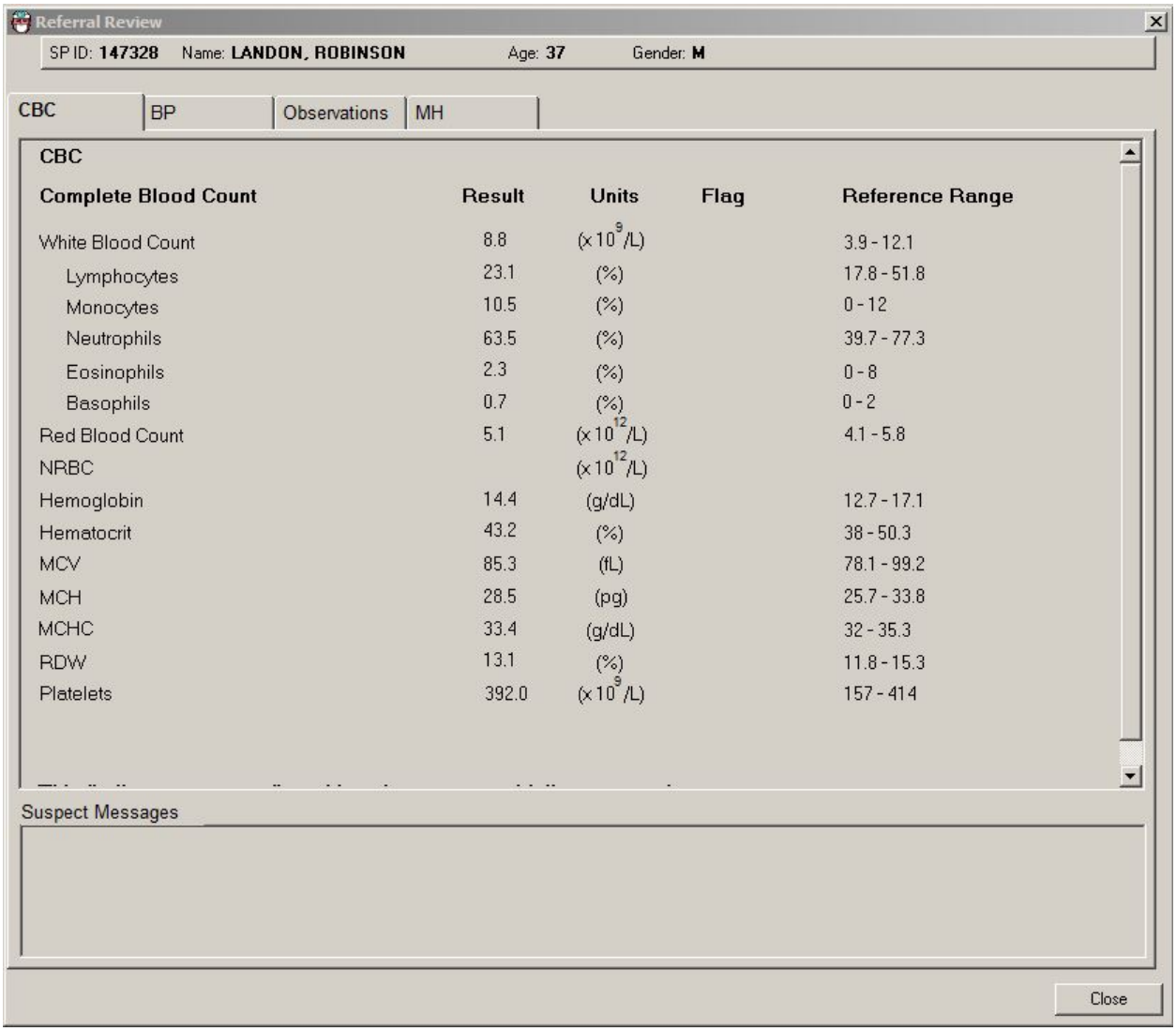
The machine might produce "suspect" messages—i.e., sickled cells, left shift, and giant platelets. If there is a suspect message (see Table 4-4), the message for the NHANES Report of Findings (see right column below) will be printed on the bottom of the Complete Blood Count report with the statement, "This finding was not confirmed by microscopy and follow-up may be necessary." The MEC clinician reviews all the Complete Blood Count results while the participant is still in the examining center. If a referral is necessary, the clinician will complete a referral form.

Table 4-4. Suspect messages

Suspect message	ID	Message for NHANES Report of Findings
Dimorphic Reds	1262	At least two populations of red blood cells may be present.
Giant Platelets	1263	Giant platelets may be present.
Imm Grans	1264	The following cells may be present: (a) metamyelocytes and myelocytes and/or promyelocytes, or (b) myelocytes and/or promyelocytes without metamyelocytes.
Left Shift	1265	A left shift may be present. The specimen may contain metamyelocytes without myelocytes, promyelocytes, or blasts.
LY Blast	1266	Lymphocyte blast cells may be present.
MO Blast	1267	Monocyte blast cells may be present.
NE Blast	1268	Neutrophil blast cells may be present.
RBC Frag/ Microcytes	1269	Red blood cell fragments and/or microcytic red blood cells may be present.
Red Cell Agglut	1270	Red blood cells clumps or rouleaux may be present.
Sickled Cells	1271	Sickled red blood cells may be present.
Variant LY	1272	Variant lymphocytes or immature or abnormal lymphocytes may be present.

The CBC review (Exhibit 4-1) tab under referral review will be split into an upper and lower section (as shown in the exhibit). The upper section will display the information currently sent to this section. The lower section of the page will display the information from the table above. Both sections should have a scrolling capability, should there be a large amount of information on either section of the page.

Exhibit 4-1. Referral review for complete blood count



Action Limits. Action Limits are a guide to inform the clinician that a CBC result(s) is/are abnormal. Since all specimens are run in duplicate, there is no reason to retest the sample in the vast majority of cases.

4.3.3.1 CBC Action Limits

The following limits constitute "Action Limits" where the referral application alerts the clinician when present:

- WBC male and female (all ages) < or = to 3 x 10^3 µL or > or = to 16.0 x 10^3 µL;
- Hgb male and female (<6 years) <6.5 g/dL or >14.5 g/dL;
- Hgb female (>6 years) <6.5 g/dL or >16.0 g/dL;
- Hgb male (>6 years) <6.5 g/dL or >18.0 g/dL; and
- PLT male and female (all ages) <50 x 10^3 µL or >800 x 10^3 µL.

4.3.3.2 Repeating a CBC

In rare circumstances a result from the complete blood count may be an extreme value that would be considered a "panic" value in clinical practice. An example is severe thrombocytopenia. The clinician may repeat the complete blood count if the participant reports no history of nosebleeds or prolonged bleeding and the clinician verifies that the site of the first venipuncture clotted normally. The second complete blood count will overwrite the first results in ISIS and will be used for reporting and referrals. Please follow the procedures below when it is determined that a repeat CBC must be drawn.

If the clinician feels a repeat blood count is needed, then he or she has the discretion to discuss this with the SP and have the phlebotomist draw a 3-ml EDTA tube for a repeat CBC if the SP agrees. Prior to a second phlebotomy, the clinician should visually inspect the site of the first venipuncture to rule out prolonged bleeding. If the puncture site looks normal, then a second phlebotomy can be requested. The SP always has the right to refuse the blood draw. The need for this action should be rare as evidenced by the four total low platelet counts in the last 2 years, according to the records.

After the clinician reviews the findings with the SP, and the SP agrees to a repeat CBC phlebotomy:

- The clinician should consult with the MEC manager to arrange to have the blood drawn at the next earliest opportunity.
- This additional blood draw will not be supported by the laboratory and phlebotomy applications.

- As long as the SP has not checked out of the MEC, or if the Report of Findings has **not** been printed, the lab application will allow the med techs to overwrite the existing CBC data with the new data and the new data will become the final result of record.
- The clinician will document this event under observations in the clinician application.

When the values from the Beckman Coulter® report are interpreted, various interfering substances and conditions may affect these parameters:

- Abnormal BUN, glucose, or sodium levels could affect the MCV.
- Abnormal WBCs could affect lymphocytes, monocytes, and granulocytes.
- Abnormally small WBCs could affect white count, lymphocytes, monocytes, and granulocytes.
- Clumped platelets could affect white count, lymphocytes, monocytes, granulocytes, RBC, MCV, RDW, platelet count, and MPV.
- Cryofibrinogen and cryoglobulin crystals could affect white count, lymphocytes, monocytes, granulocytes, RBC, hemoglobin, platelet count, and MPV.
- An elevated WBC could affect RBC, hemoglobin, MCV, RDW, platelet count, and MPV parameters.
- Fragile WBCs could affect white count, lymphocytes, monocytes, granulocytes, platelet count, and MPV.
- Giant platelets could affect white count, lymphocytes, monocytes, granulocytes, RBC, MCV, RDW, platelet count, and MPV.
- Hemolyzed specimens could affect RBC, hemoglobin, platelet count, and MPV.
- Lipemic specimens could affect MCV.
- Severely icteric plasma causes increased hemoglobin. Evaluate the CBC result carefully and report all parameters except the hemoglobin result.
- Nucleated RBCs could affect the white count, lymphocytes, monocytes, granulocytes, and hemoglobin values.

Possible causes of abnormal parameters:

- High RBC, Hgb, or HCT—dehydration, polycythemia, shock, chronic hypoxia;
- Low RBC, Hgb or HCT—anemia, thalassemia, and other hemoglobinopathies;
- Low MCV—microcytic anemia;

- High MCV—macrocytic anemia, liver disease;
- Low WBC—sepsis, marrow hypoplasia;
- High WBC—acute stress, infection, malignancies;
- Low platelets—risk of bleeding; and
- High platelets—risk of thrombosis.

4.4 Blood Pressure Referrals

Blood pressure will be measured by health technicians using oscillametic devices. SPs who have a BP measurement of "very high" and "severely high" will be referred to the MEC clinician for evaluation. The clinician may choose to measure the BP one more time. The clinician will determine the level of referral necessary using the established guidelines.

4.4.1 Blood Pressure Referrals—Adults

Tables 4-5 through 4-8 provide the matrix of combinations of systolic and diastolic blood pressure results and the referrals that are generated when these BPs are present for adults. The left column specifies the minimum and maximum systolic pressure (SBP) groupings. The first row specifies the minimum and maximum diastolic blood pressure (DBP) categories. The matrix cells specify the BP category severity (1 to 5) for the SBP and the DBP combination. The category severity defines the MEC referral level.

Table 4-5. Referral levels for blood pressure (adults)[1]

	Diastolic				
Systolic	**<80**	**80-89**	**90-99**	**100-109**	**>/=110**
<120	**1**	**3**	**4**	**4**	**5**
120-139	**2**	**3**	**4**	**4**	**5**
140-159	**4**	**4**	**4**	**4**	**5**
160-179	**4**	**4**	**4**	**4**	**5**
≥ 180	**5**	**5**	**5**	**5**	**5**

[1] Based on the ACC/AHA Hypertension Guidelines for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults, *American Journal of Hypertension,* 31(2), 2018, p.133-35.

Table 4-6. Blood pressure referral levels, category, and action guideline (adults)

BP category	Referral level	Clinician guideline referral action
5	1	Indicates major medical findings (BP) that warrant immediate attention by a health care provider.
3 and 4	2	Indicates major medical findings (BP) that warrant attention by a health care provider within the next 2 weeks. These findings are expected to cause adverse effects within this time period and they have previously been undiagnosed, unattended, nonmanifested, or not communicated to the examinee by his/her personal health care provider.
2	2	Indicates elevated blood pressure, minor medical findings that an examinee already knows about, and is under care for, or findings that do not require prompt attention by a medical provider prior to 3-6 months.
1	3	Indicates no abnormal BP findings.

Table 4-7. Adults blood pressure referral letter comments

BP category	BP referral level	Referral statement
5	1	The participant's blood pressure today is severely high. Based on national guidelines for the treatment of hypertension.
4	2	The participant's blood pressure today is very high. Based on the national guidelines for the treatment of hypertension.
3	2	The participant's blood pressure today is high. Based on the national guidelines for the treatment of hypertension.
2	2	The participant's blood pressure today is elevated. Based on the national guidelines for the treatment of hypertension.
1	3	The participant's blood pressure today is within the normal range.

Table 4-8. Table of blood pressure Report of Findings comments (adults)

Report of findings level BP category	Report of findings message – English	Report of findings message – Spanish
1	Your blood pressure today is within the normal range.*	Su presión sanguínea hoy de sangre hoy está dentro del rango normal. **
2	Your blood pressure today is elevated. Based on national guidelines for the treatment of hypertension,* you should take this report to a health care provider within the next 3-6 months to have your blood pressure rechecked.	Su presión sanguínea hoy está elevada. Basado en las guías nacionales para el tratamiento de la hipertensión**, usted debería llevar este informe a un proveedor de cuidado de salud en los próximos 3 a 6 meses para que le vuelvan a tomar la presión sanguínea.
3	Your blood pressure today is high. Based on national guidelines for the treatment of hypertension,* you should take this report to a health care provider within two weeks.	Su presión sanguínea hoy está alta. Basado en las guías nacionales para el tratamiento de la hipertensión**, usted debería llevar este informe a un proveedor de cuidado de salud antes de dos semanas.
4	Your blood pressure today is very high. Based on the national guidelines for the treatment of hypertension,* you should take this report to a health care provider within two weeks.	Su presión sanguínea hoy está muy alta. Basado en las guías nacionales para el tratamiento de la hipertensión**, usted debería llevar este informe a un proveedor de cuidado de salud antes de dos semanas.
5	Your blood pressure today is severely high. Based on national guidelines for the treatment of hypertension,* this level warrants immediate attention by a health care provider.	Su presión sanguínea hoy está extremadamente alta. Basado en las guías nacionales para el tratamiento de la hipertensión** y debido al nivel de su presión sanguínea, usted debe ver un proveedor de cuidado de salud inmediatamente.

*The New ACC/AHA Hypertension Guidelines for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults. *American Journal of Hypertension,* 31(2), 2018, p. 133-35.

**Basado en las Guías nacionales para la prevención, detección, evaluación y tratamiento de la hipertensión en adultos (Hypertension Guidelines for Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults) de la Asociación Estadounidense de Cardiología (ACC, por sus siglas en inglés) y la Asociación Estadounidense del Corazón (AHA, por sus siglas en inglés). *American Journal of Hypertension,* 2018; 31 (2):133-135.

4.4.2 Blood Pressure Referrals—Children

Children's normal blood pressures vary by age, weight, and height. Referral comments and Report of Findings comments are shown in Tables 4-9 and 4-10.

The table for children's blood pressures is found in the Blood Pressure Procedure Manual Appendix A, Child Blood Pressure Values.

Table 4-9. Referral comments for blood pressure (children)

BP category	Referral level	Referral statement*
4	1	The participant's blood pressure is **very high.***
3	2	The participant's blood pressure is **high.***
2	3	The participant's blood pressure is **elevated or in the elevated range.***
1	3	The participant's blood pressure is **normal.***

*Based on the American Academy of Pediatrics (AAP) Clinical Practice Guideline for Screening and Management of High Blood Pressure in Children and Adolescents. *Pediatrics* 2017; 140 (3):e20171904.

Table 4-10. Table of blood pressure Report of Findings comments (children)

Report of findings level BP category	Report of findings message
1	Your child's blood pressure today **is within the normal range.***
2	Your child's blood pressure today **is elevated or in the elevated range.***
3	Your child's blood pressure today is **high.***
4	Your child's blood pressure today is **very high.***

*Based on the American Academy of Pediatrics (AAP) Clinical Practice Guideline for Screening and Management of High Blood Pressure in Children and Adolescents. *Pediatrics* 2017; 140 (3):e20171904.

4.5 Observation Referrals

Observation referrals are not linked to specific examination data. An observation referral includes any observation by the technician or other examination staff about an SP's condition that may require attention by the clinician. An observation referral is sent through the ISIS process from any examination component examiner and may be initiated during the examination, but it is sent after the component examination is completed and the SP has left the component room. The examiner initiating the observation enters a message in the observation box and sends it electronically to the clinician. The observation sets a flag in the clinician component and coordinator applications and SPs are not checked out of the MEC until the clinician reviews and acts on this observation. Examples of observations include information from a dietary interviewer when children or adult SPs are thought to be malnourished, or mental health observations from a MEC interviewer. The clinician will discuss the issue with the SP and refer as deemed medically necessary.

4.6 Mental Health Observation Referrals

The confidential health and lifestyle interview conducted at the MEC will be conducted in the Audio Computer-Assisted Self Interview (ACASI) component and will be administered to SPs 12 years and older. The application is programmed to send a referral to the clinician to see any SP who meets the

criteria for a potential mental health problem. These conditions include depression, and suicidal/homicidal ideation.

4.6.1 ACASI Depression Screening

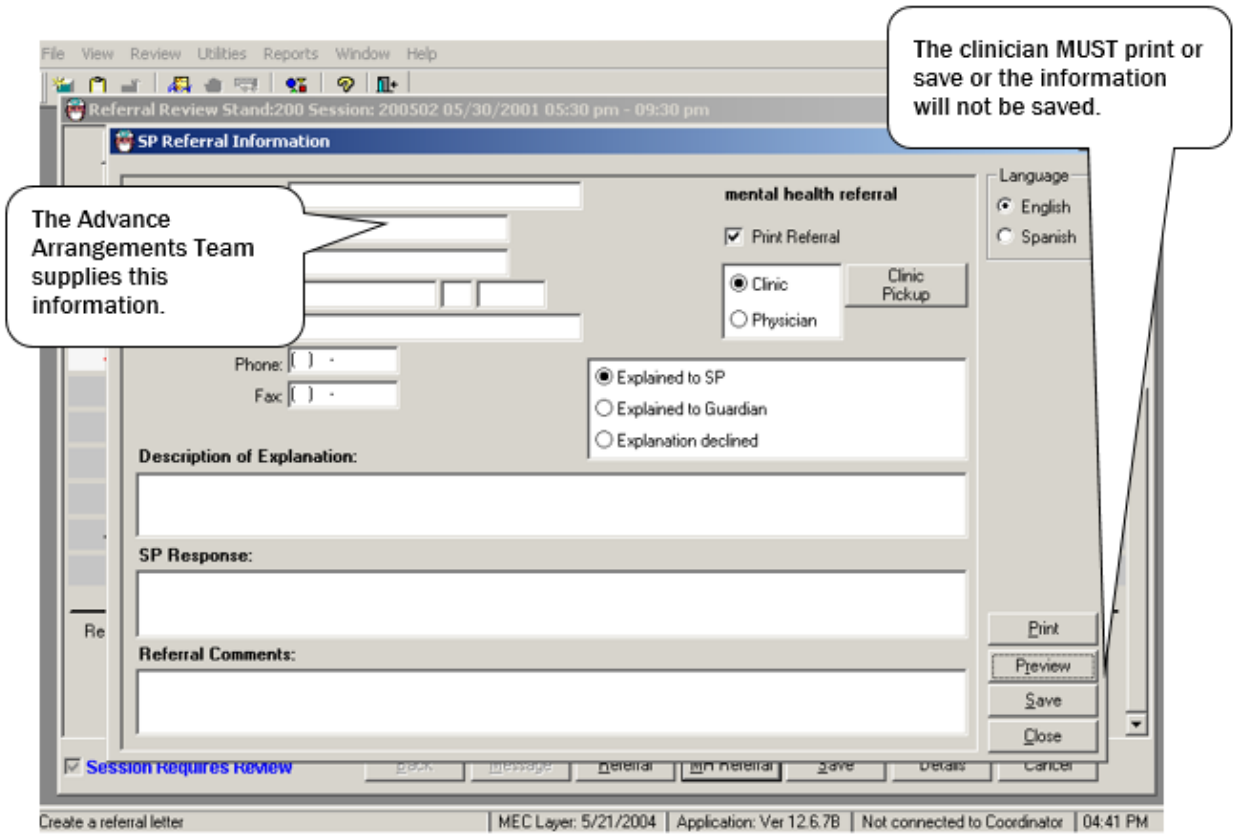
Certain information volunteered or reported during the mental health interview will initiate an automatic electronic mental health observation notification from the ACASI application to the MEC clinician application. The question asked in the ACASI application during the depression screener questionnaire that would prompt an observation to the clinician for mental health assessment is the following:

- DPQ090: Over the **last 2 weeks**, how often have you been bothered by the following problem: Thoughts that you would be better off dead or hurting yourself in some way? The response categories for this question are:
  - Not at all;
  - Several days;
  - More than half the days; and
  - Nearly every day.

Responses of several days, more than half the days, and nearly every day require a clinician referral for a mental health consultation. If the SP says he or she thought about it only one time in the last 2 weeks, the interviewer codes the response as "several days."

The clinician will code the observation as "action required," which will cause ISIS to alert the coordinator that the clinician needs to meet with the SP. The clinician is responsible for assessing the mental health problem and facilitating a referral, if needed. The Mental Health Referral is a separate referral screen, as shown in Exhibit 4-2, below.

Exhibit 4-2. Mental Health Referral screen



4.6.1.1 Suicidal Ideation

The MEC clinician is not responsible for making psychiatric diagnoses; nevertheless, thoughts and plans for suicide should be considered seriously. The MEC clinician should assess the need for a mental health referral for those who have either reported or voluntarily disclosed recent suicidal ideations or attempts.

Protocol for a MEC clinician receiving an observation from the mental health interview:

- Assess if the SP is currently suicidal. Ask the SP if she or he is depressed or thinking about suicide now. If so, then probe as to whether she or he has a plan and/or set a time for doing this. A person who is suicidal with a plan at a definite time is a **psychiatric emergency**, and a Level 1 referral.

Protocol for a participant who is in imminent danger:

- If the SP is currently under psychiatric care, ask the SP for permission to call the mental health care provider. The clinician should negotiate a follow-up consultation with the provider. If the participant does not have a provider, call the **referral center provided by the advance arrangements team.**

Protocol for a participant who is not in imminent danger:

- If the SP is under the care of a psychiatrist or other mental health care provider, there may be no need to refer unless the participant provides some indication that his or her symptoms are worsening.

- If the SP has not seen a health professional for suicidal thoughts, then refer him or her to the specific clinics or crisis hotline **provided by the advance arrangements team.**

For minors under 18 years of age, the initial assessment should be done with the youth in private. If a referral is necessary, the participant's parent/guardian must be notified.

4.6.1.2 Homicidal Ideations/Threats

Threats to kill a person or persons should be considered seriously. The MEC clinician should judge the mental stability of the participant. The clinician should ask about the specific plan for carrying out the threat and the timeframe. A homicidal threat with a lethal weapon and plan must be reported to the 911 system.

4.6.1.3 Reporting Child Abuse

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

4.7 Balance Referrals

Prior to participating in the Balance component if an SP provides an unsolicited comment that he/she is currently dizzy or lightheaded, the SP must be evaluated by the MEC clinician before proceeding. If an SP becomes dizzy during one of the balance tests, the test will be stopped and he/she will be instructed to sit on a chair until he/she is no longer dizzy or lightheaded. If the SP feels he/she needs to be seen by the MEC clinician, the MEC interviewer will have the SP immediately evaluated by the clinician.

Two pretest questions are asked before the standing balance portion of the Modified Romberg test (MRT).

1. Are you okay to begin this balance test?

   SPs responding "yes" continue to the MRT. SPs responding "no" receive a follow-up question.

   Are you having a problem that you would like to discuss with the doctor?

2. SPs responding "no" to the previous question are asked this follow up question. SPs who indicate that they need to speak to the clinician are exited from the exam to speak with the clinician. An automatic referral to the clinician with the message "SP reported a problem in the Balance Component that they wanted to discuss with the clinician" is also sent. The note to the clinician will appear as an observation as if the tech opened the observation box and typed a note. An example of when this may occur is if the SP has had a hip/knee replacement and he/she is unsure if the test is okay for them to participate in and they want to discuss it with the clinician first. SPs who do not want to speak to the clinician can continue with other parts of balance test but CANNOT do the MRT unless the participant changes his/her mind.

4.8 Clinician Application Referral Procedures

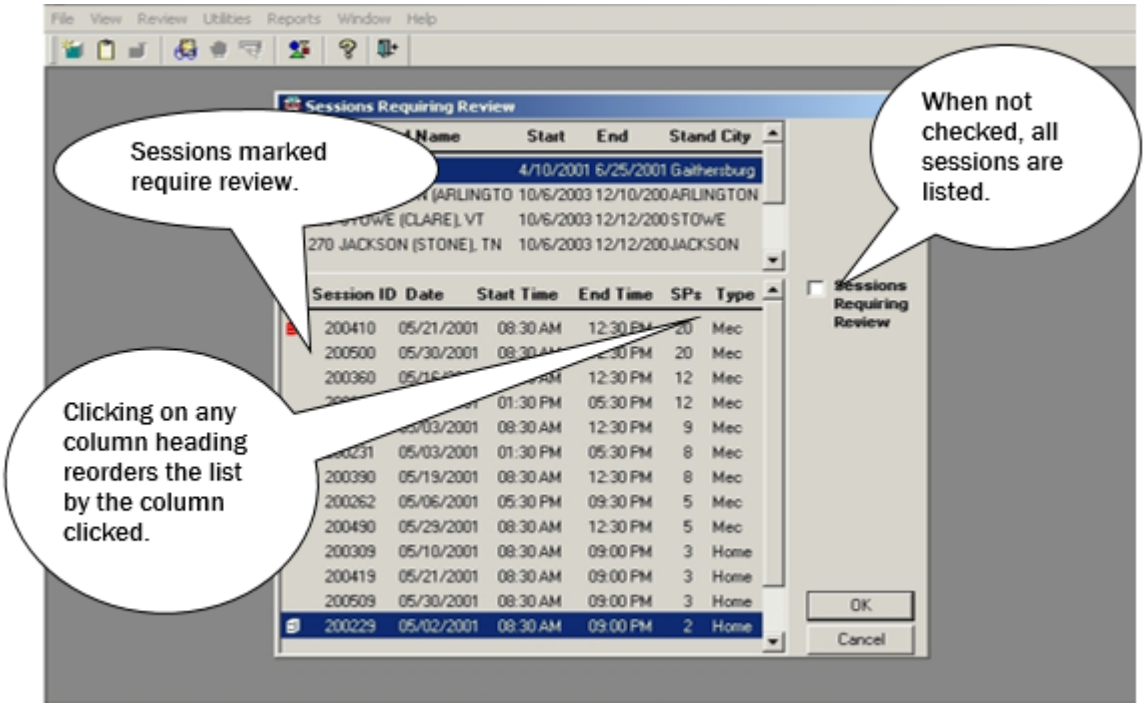
The clinician referral process is fully automated and supported by the clinician ISIS application and the coordinator application.

The "Sessions Requiring Review" box is displayed every time the clinician logs on to the application, and the clinician must review these sessions (Exhibit 4-3). When the ISIS application first opens for the clinician component, the "Sessions Requiring Review" screen opens by default. The purpose of

this screen is to prompt the clinician to complete reviews for SPs in all previous sessions. The clinician can select which sessions to review.

- When the clinician's application is opened, the "Sessions Requiring Review" pick list is displayed. If the clinician does not want to review referrals at this time, this screen may be closed by clicking on the "x" in the upper right corner or by clicking "Cancel" in the lower right corner.
- The top part of the screen displays the current stand.
- The lower part of the screen displays the Sessions Review.
- To view all sessions in the current stand, leave the box for "Sessions Requiring Review" unchecked. All sessions in the current stand will be displayed.

Exhibit 4-3. Review all MEC sessions in the current stand



- 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.
- Close the screen when completed.

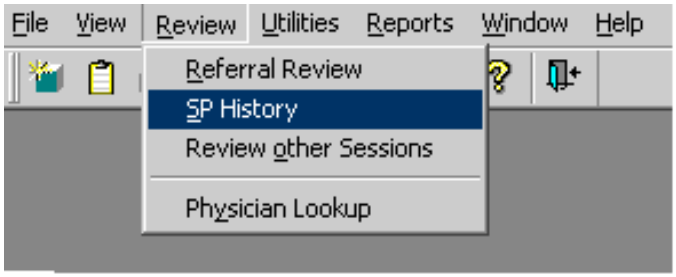
4.8.1 Data Entry Screens for Referrals

The following sections describe the ISIS screens and data entry process related to clinician referrals. There are three types of screens related to referral: "Sessions Requiring Review," "Review Box," and "Referral Review."

4.8.2 Review Menu

The review toolbar selection (Exhibit 4-4) has several review options:, Referral Review, SP History, Review Other Sessions, and Physician Lookup. Each of these options is described in the following sections.

Exhibit 4-4. Review menu for selecting referral review

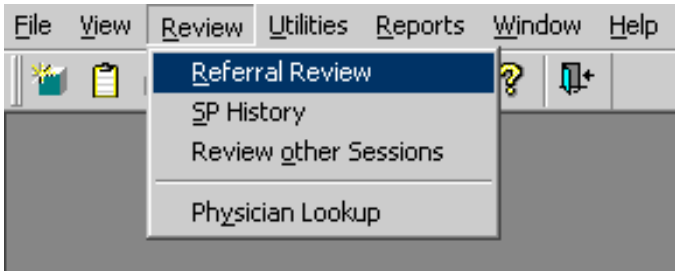


- Use this drop-down list to select the desired activity.
- Highlight the activity by pointing to it with the pointer.
- Click the activity to access the screens.

4.8.3 Review Box

- The Referral Review box option is the screen where all SPs who require an assessment of the need for a referral can be viewed.
- To access the Review box, first access the desired session (see Exhibit 4-3, shown earlier), then select "Review" (see Exhibit 4-4, shown earlier) from the toolbar, and last, select "Referral Review" from the drop-down list (Exhibit 4-5).
- This will access the referral review requirements for the current session.

Exhibit 4-5. Referral Review Selection screen

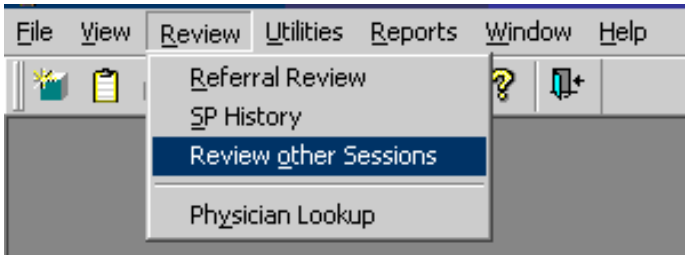


4.8.4 Review Other Sessions

The "Sessions Requiring Review" is accessed from the "Review Other Sessions" drop-down list under the "Review" selection on the toolbar. The "Sessions Requiring Review" screens inform clinicians which MEC sessions remain to be reviewed. The purpose of the review is to ensure that all referrals are completed. This is especially important since some referrals may not be able to be completed while SPs are still available on the MEC. Clinicians mark appropriate boxes about their referral decision for each SP.

Exhibit 4-6 shows the review selection and drop-down selection list for "Review Other Sessions" option that accesses the Sessions Requiring Review.

Exhibit 4-6. Review other sessions

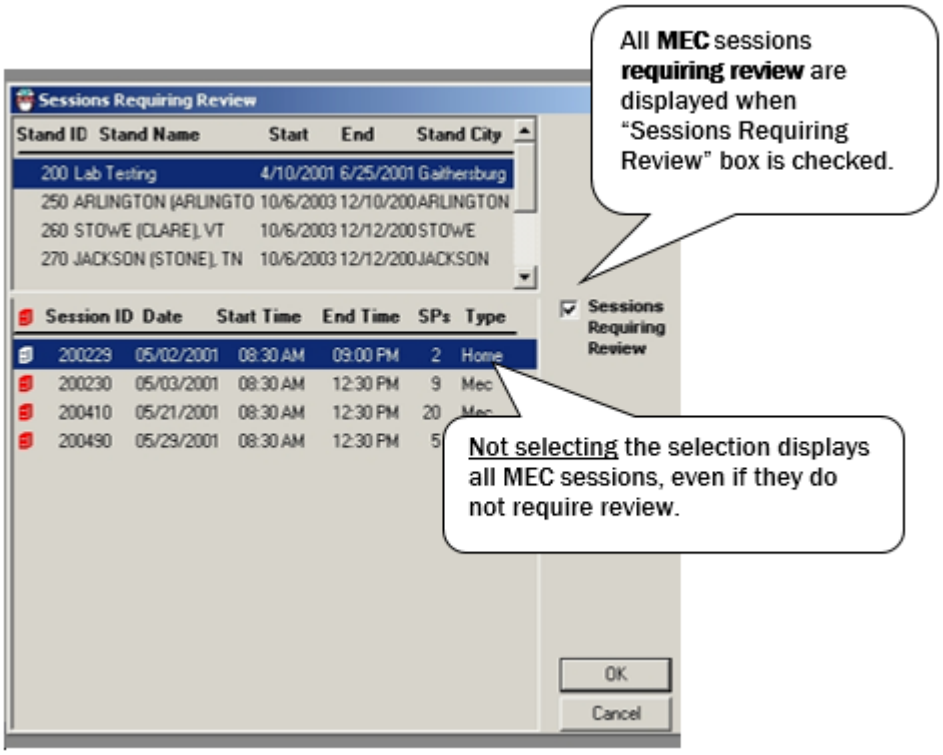


- When the "Review Other Sessions" option is clicked, the "Sessions Requiring Review" screen drop-down list is accessed. From this screen, clinicians make choices about which sessions need to be reviewed.

4.8.5 Sessions Requiring Review

The top part of the "Sessions Requiring Review" screen (Exhibit 4-7) 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 clinician.

Exhibit 4-7. MEC sessions requiring review

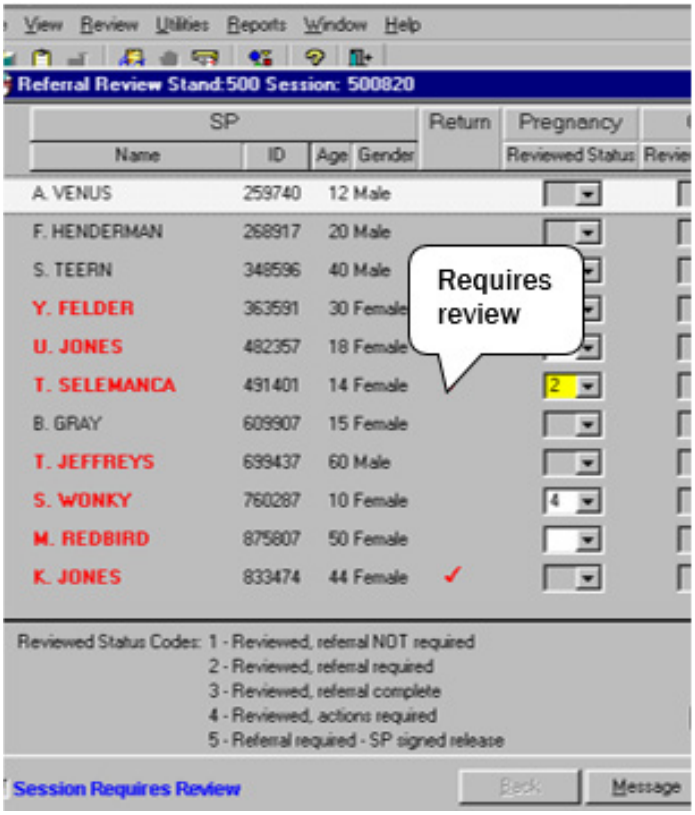


When the "Sessions Requiring Review" box is checked, all MEC sessions that require review are displayed. Referrals posted in the "Review Box" that the clinician has not reviewed cause the application screen to display a **red check mark beside the session indicating that the session requires review (Exhibit 4-8).** The **red mark remains** beside this session until the clinician reviews all referrals in the session. When all referrals are completed or reviewed, the system removes the red check mark.

4.8.6 Referral Review Box Screen

The "Referral Review" box (Exhibit 4-8) has the stand and session numbers on the top bar. Names of SPs requiring review are highlighted in red. The boxes for components requiring review are enabled. All other boxes are disabled or "grayed out." Note also that the SP's name is in red when a review is required.

Exhibit 4-8. SPs referred back to clinician for review for referral determination

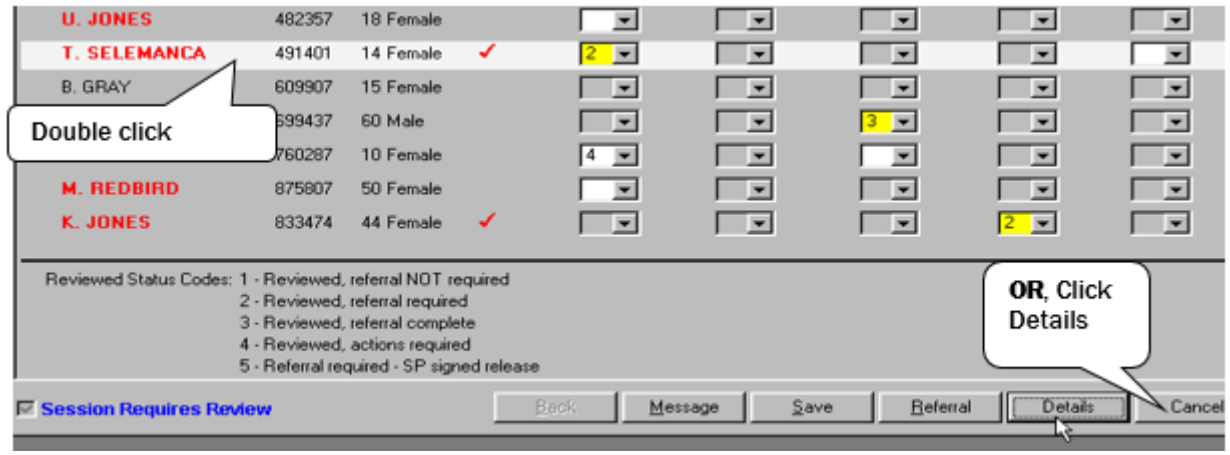


4.8.7 Selecting SP for Detailed Referral Review

To complete the referral, the clinician selects each SP in turn who has an indication that a review for referral determination is needed. The selection is made from the Referral Review screen (Exhibit 4-9).

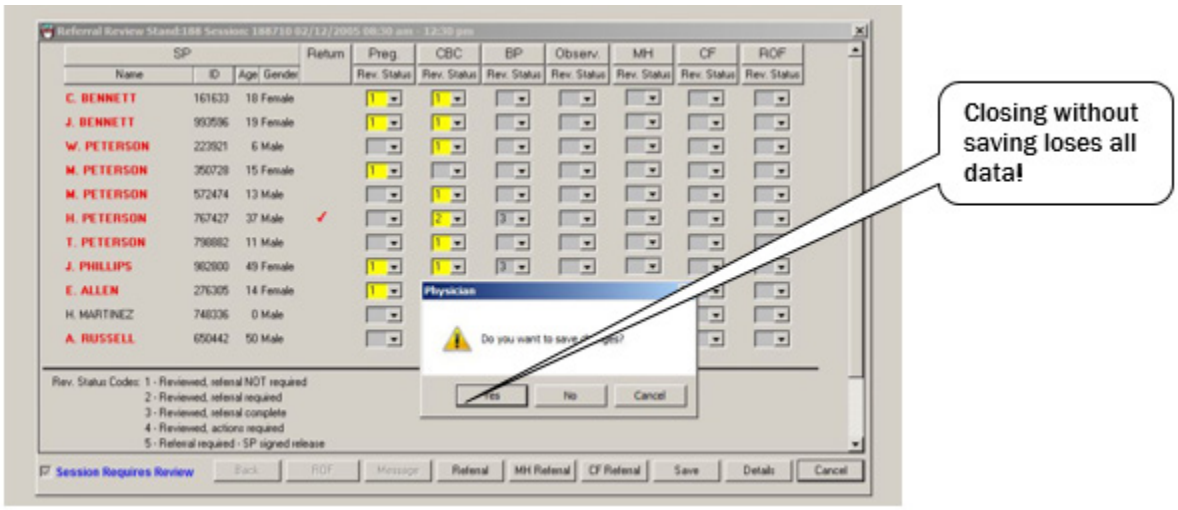
To select the SP for review, move the cursor over the desired name. Highlight the name of the SP to be reviewed. Double-click on the SP name, or click the "Details" radio button.

Exhibit 4-9. SP selection from Review box



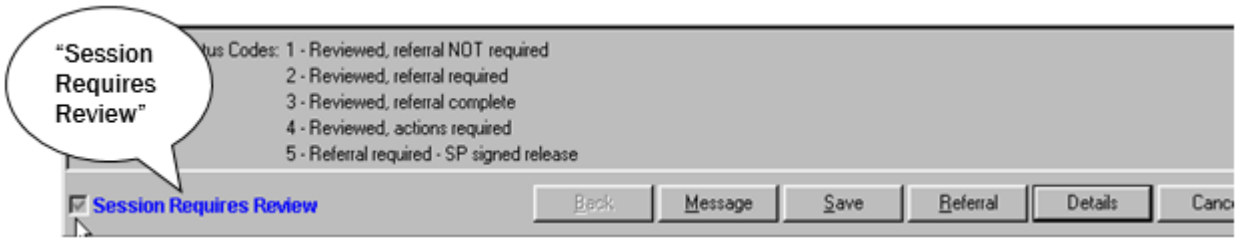
If you want to close a session before saving the results, a message will be displayed: "Do you want to save changes?" See Exhibit 4-10.

Exhibit 4-10. Warning to save changes



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 flag will be removed from the session requiring review list. See Exhibit 4-11.

Exhibit 4-11. Session requires review indicator



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. This box is especially useful if there is a long list of SPs. If the box is not checked, there is no need to scroll through the SP list.

The "Reviewed Status Codes" are listed at the bottom left of the screen (Exhibit 4-12).

Exhibit 4-12. Reviewed status codes legend

- **Code 1. "Reviewed, Referral Not Required."** If findings were reviewed, but the situation does not require a referral, select Code 1 from the drop-down menu.

- **Code 2. "Reviewed, Referral Required."** If a referral is required but there is not enough time to do it or if the SP is in another exam, check Code 2. This keeps the referral session active. A referral Code 2 turns the clinician's examination progress box on the coordinator's screen (for that SP) to green. This alerts the coordinator that the SP must return to see the clinician before checking out of the MEC. (If the SP has not completed the clinician's exam component, the box does not turn green. When the SP checks into the clinician's exam, the box turns green.) The box remains green as long as there are referrals for that SP with a referral Code 2. After the code is changed from 2 to another code, the box turns blue.

- **Code 3. "Reviewed, Referral Complete."** After the clinician reviews the referral, sees the SP, and completes the referral letter, Code 3 is checked. If no other referrals are needed, the session will be considered complete.

- **Code 4. "Reviewed, Action Required."** This is similar but not the same as Code 2. This code is marked when the SP has been reviewed and a referral generated; however, the clinician wants to take further action but has not been able to complete the action at this time. This situation could occur when the clinician needs to telephone a health care

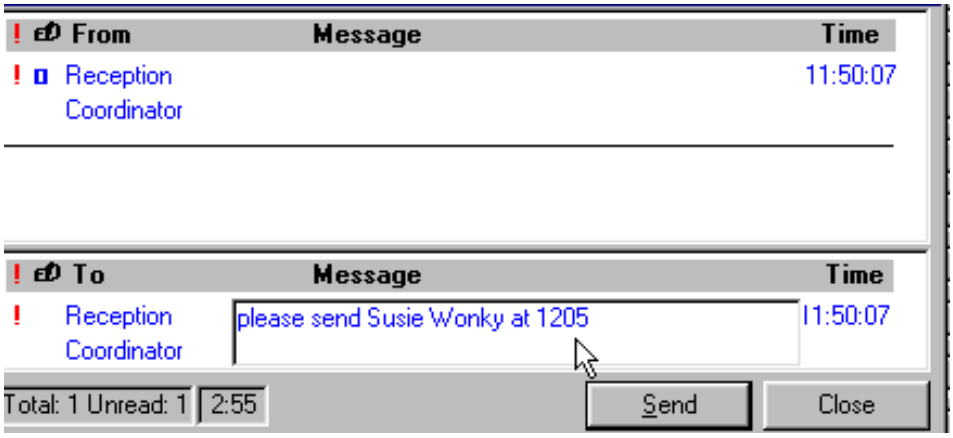
provider but has been unable to complete the process. This may be carried over to the next day or the next session. When Code 4 is checked, the SP may be checked out of the MEC but this session continues to be flagged, requiring review until this and other referrals are coded as 1 or 3.

- **Code 5. "Referral Required—SP Signed Release."** When SPs refuse to accept a required referral, they sign a release form. The clinician checks Code 5, which removes the red flag on the session if all other referrals are complete.

4.8.8 ISIS Message

To ensure that SPs see the clinician prior to leaving the MEC, the clinician can send a message to the coordinator to specify a time to send the SP to the clinician examination room to complete the referral (Exhibit 4-13).

Exhibit 4-13. Message to coordinator

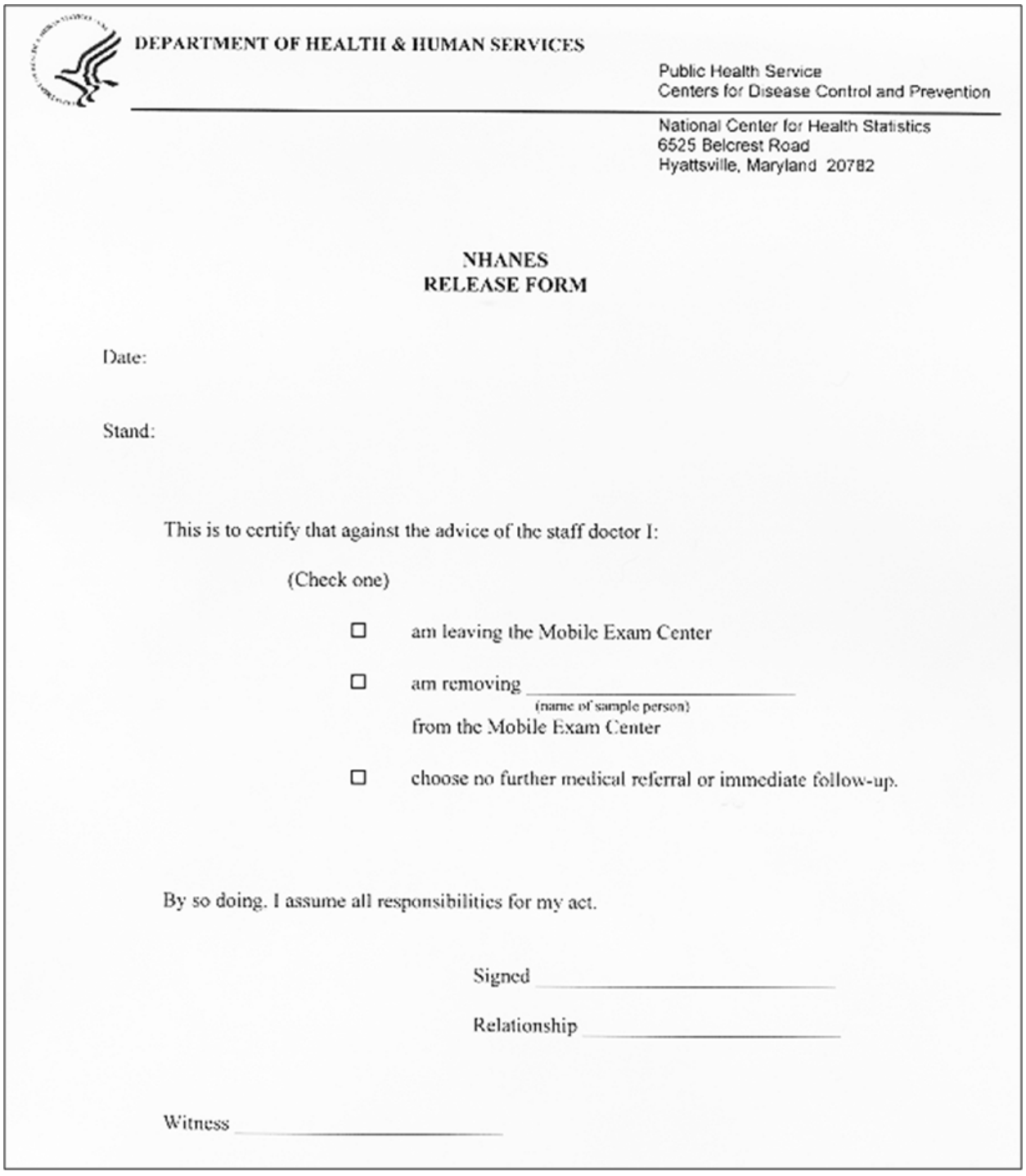


Notify the coordinator when it is a good time to complete this referral. Click "Message" from the tool bar utilities, type a message, and send to the coordinator.

4.8.9 NHANES Release Form for SPs Refusing Referrals

SPs who decline or refuse a medical referral are asked to sign the NHANES Release Form (Exhibit 4-14). The date and stand number must be completed. Note that the form is available in English and Spanish and is available for printing in the "Forms" directory.

Exhibit 4-14. 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 _____

Ask the SP to place a check mark next to the correct ending for the reference sentence:

"This is to certify that against the advice of the clinician, I:"

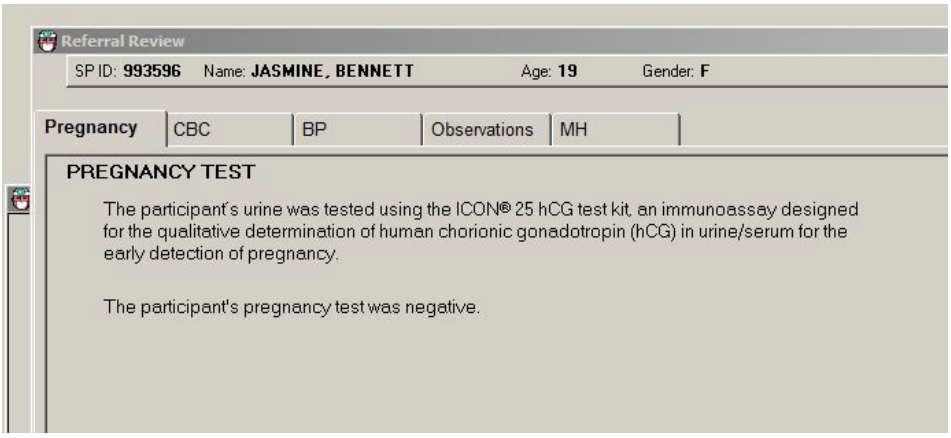
- ☐ am leaving the Mobile Exam Center
- ☐ am removing (name of sample person) from the Mobile Exam Center
- ☐ choose no further medical referral or immediate follow-up.

Ask the SP to sign this form and obtain a witness signature for the form.

4.8.10 Review Box for Pregnancy Details

The potential data for referral are selected from tabs for each SP that is referred: Pregnancy, CBC, BP, Observations, and Mental Health (MH). (Exhibit 4-15).

Exhibit 4-15. Details for pregnancy referral

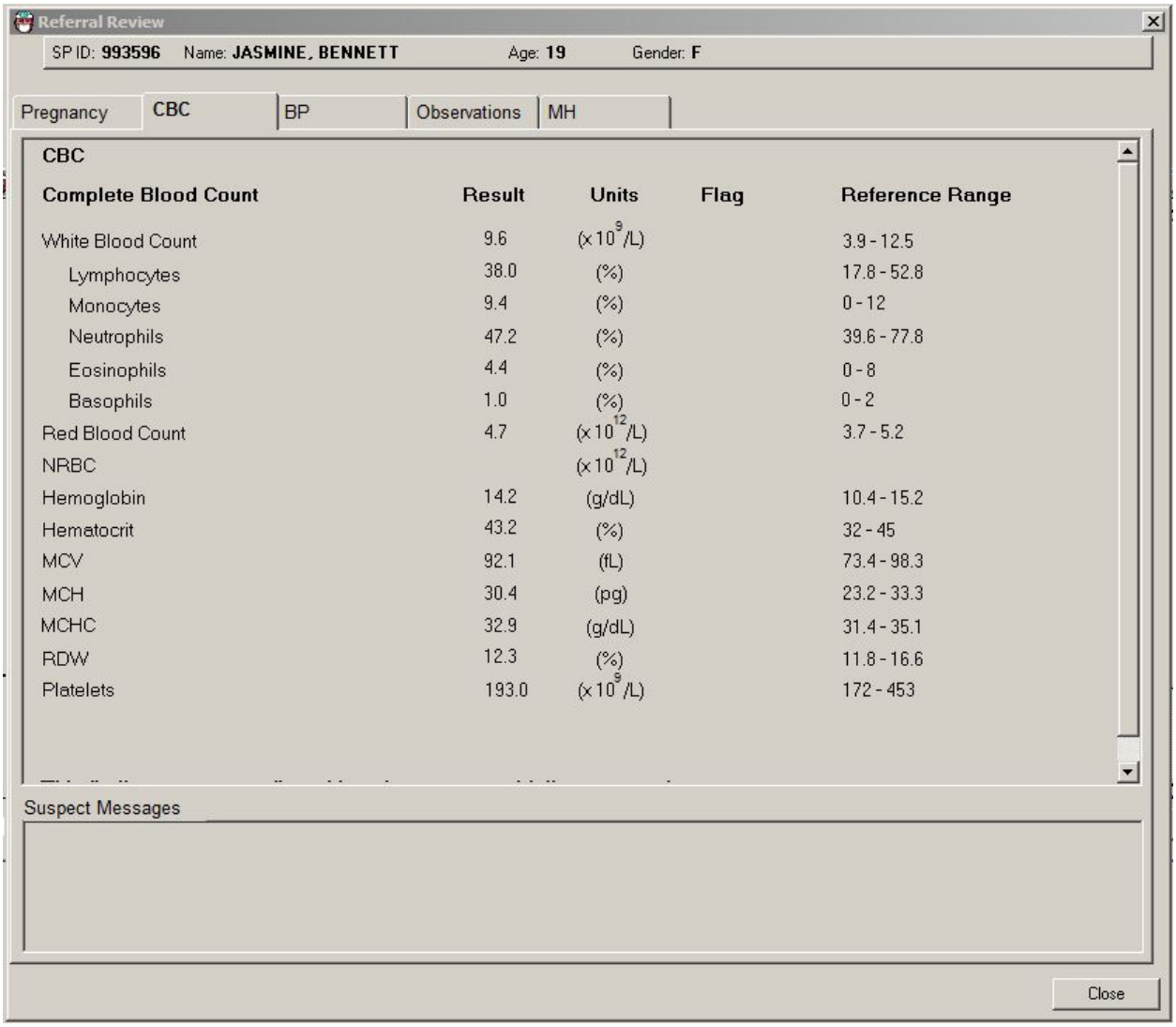


- If the "Pregnancy" tab is checked, the results of the pregnancy test in the lab are displayed. The results can only be one of the following for pregnancy:
  - The pregnancy test is negative;
  - The pregnancy test is positive; or
  - The pregnancy test is invalid.
- Complete the referral as appropriate.

4.8.11 Review Box for CBC Details

- Click on the CBC tab to review the results of the MEC laboratory CBC (Exhibit 4-16).
- The names of the tests are displayed in the left columns along with the units of measurement.
- The reference ranges are displayed in the far right column.
- The results and units of measurement are displayed in the next two columns.
- The flagged items are displayed as "low, high, and extremely high."
- Complete the referral as necessary.
- The CBC tab will be split into an upper and lower section. The upper section will display the information currently sent to this section. The lower section of the page will display the information below. Both sections should have a scrolling capability, which is helpful if there is a large amount of information in either section of the page.
- In order to make the clinician aware of the CBC results from the new Coulter, we are sending the suspect flags to both the clinician component and the Report of Findings. The clinician will access these results as they would any CDC results through the "referral review" details for an individual SP in the current session. However, the clinician's component **should display only the ROF suspect flag explanation**, not the suspect flag codes: machine-produced "suspect" messages—i.e., sickled cells, left shift, or giant platelets.
- The displayed suspect messages will appear so that the clinician can also see what the SP will receive. The bottom of the page, when any CBC suspect flag explanations are present, should also display the bolded statement **"This finding was not confirmed by microscopy and follow-up may be necessary."**

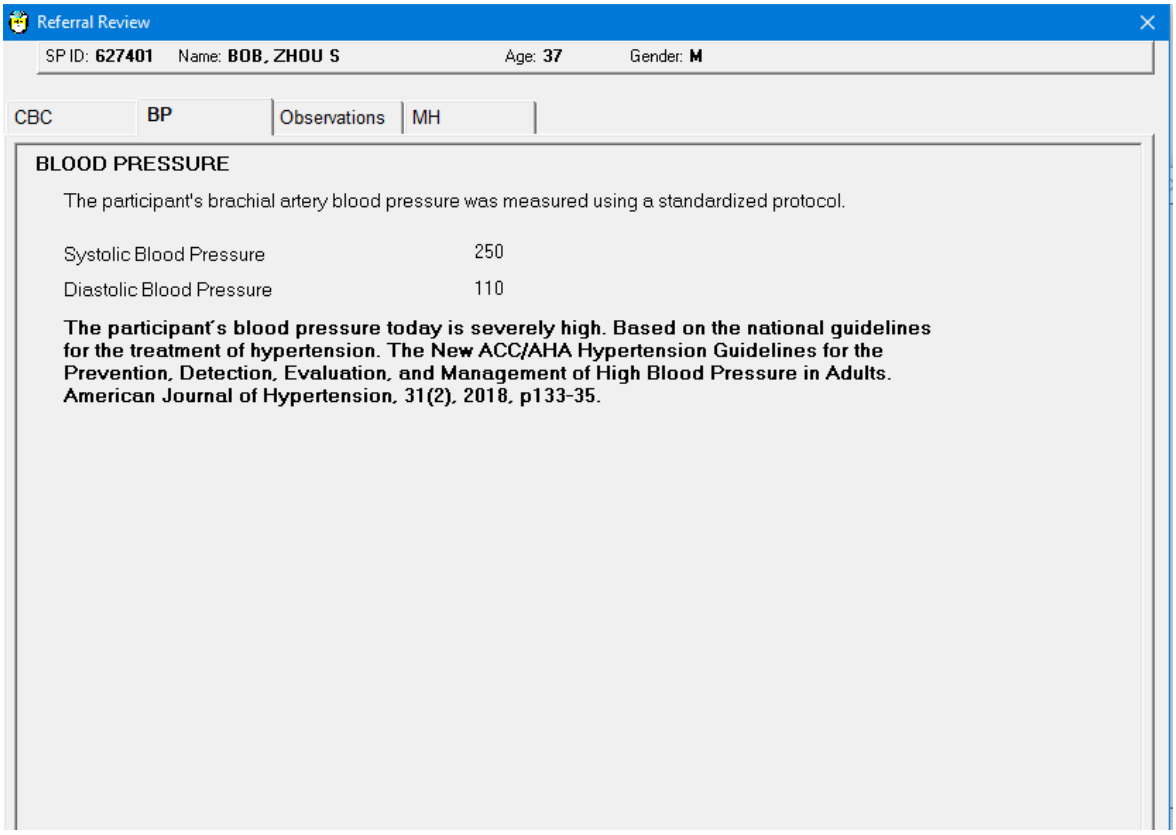
Exhibit 4-16. Details of complete blood count referral (1)



4.8.12 Review Box for Blood Pressure Details

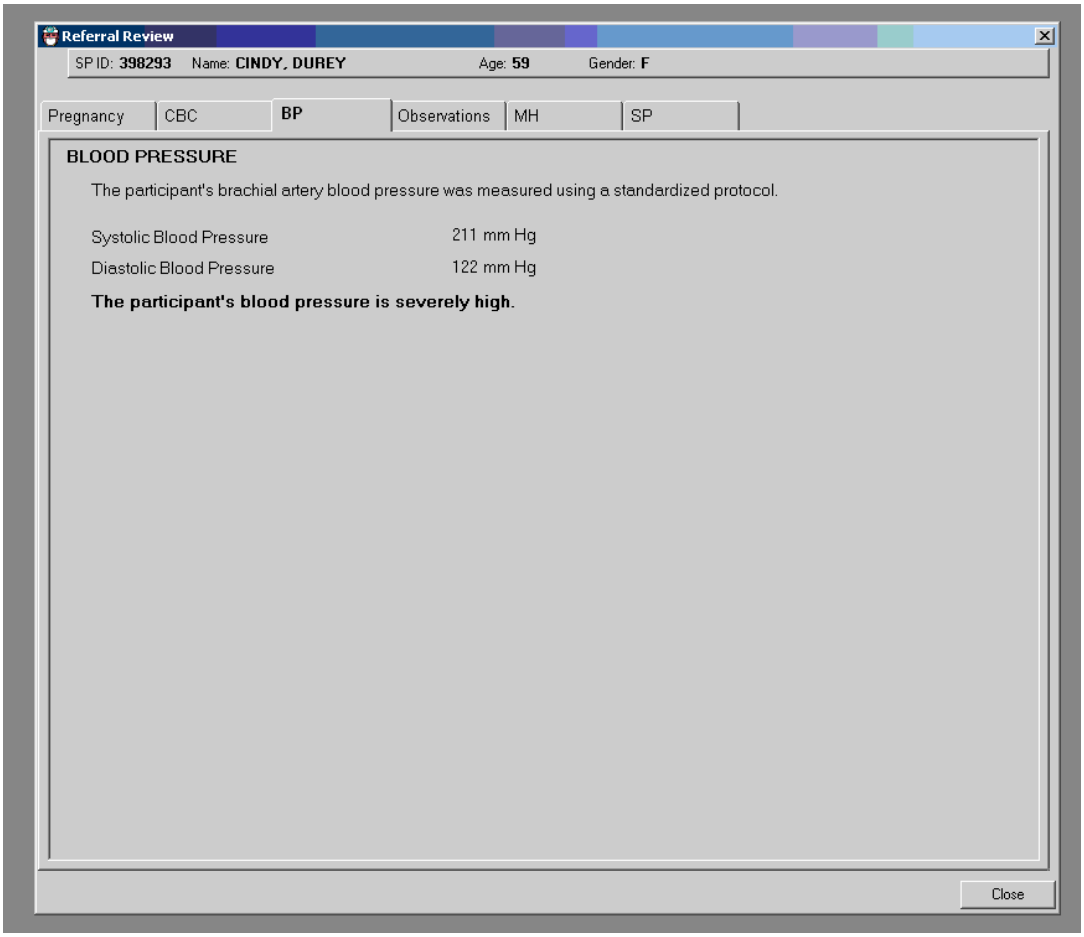
- Click on the blood pressure tab to view the blood pressure results (Exhibit 4-17).
- Complete the referral if necessary and enter the appropriate code.
- The blood pressure in the example shown in Exhibit 4-18 is very high for the age group and is a Level 2 referral. These results are discussed with the SP, and the clinician gives a Level 2 referral letter to the SP. The SP may take this letter to his or her health care provider.
- Click on the "Close" button to exit from this screen.

Exhibit 4-17. Details of very high blood pressure referral



- The blood pressure in Exhibit 4-18 is severely high. This is a Level 1 referral. The clinician should try to get an immediate referral to the SP's health care provider or to a local clinic.
- Complete the referral as necessary.
- Click on the "Close" button to exit this screen.

Exhibit 4-18. Details of severely high blood pressure referral

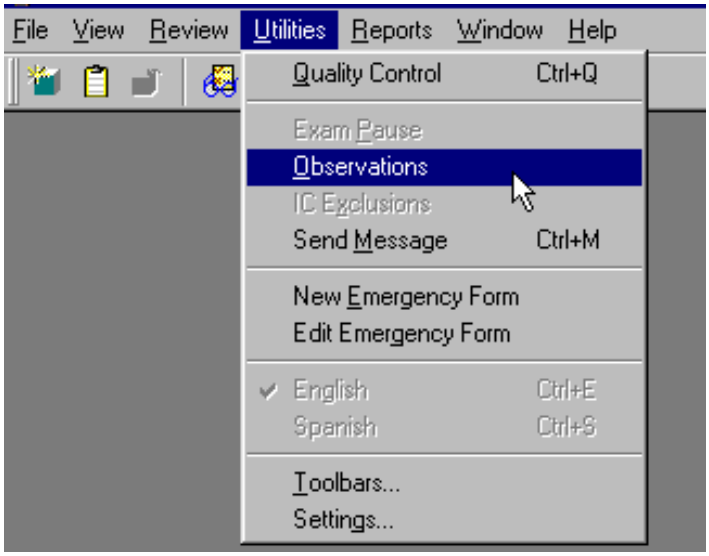


4.9 Observation Referrals

Observation referrals can be displayed by selecting "Observations" from the Utilities toolbar menu. This allows the clinician to select any SP from the list of SPs referred for observation. The clinician can also select the "Observations" tab from the Review in Box screen for the specific SP being reviewed.

- Select the "Utilities" menu from the toolbar to access the Observations Referral window and then select Observations from the menu (Exhibit 4-19).

Exhibit 4-19. Utilities menu for selecting observations referrals



The SP Observation picklist will appear with a list of all the names and ages of the SPs in the current session. Select the name of the SP for whom the observation referral is needed (Exhibit 4-20).

Exhibit 4-20. SP observation picklist

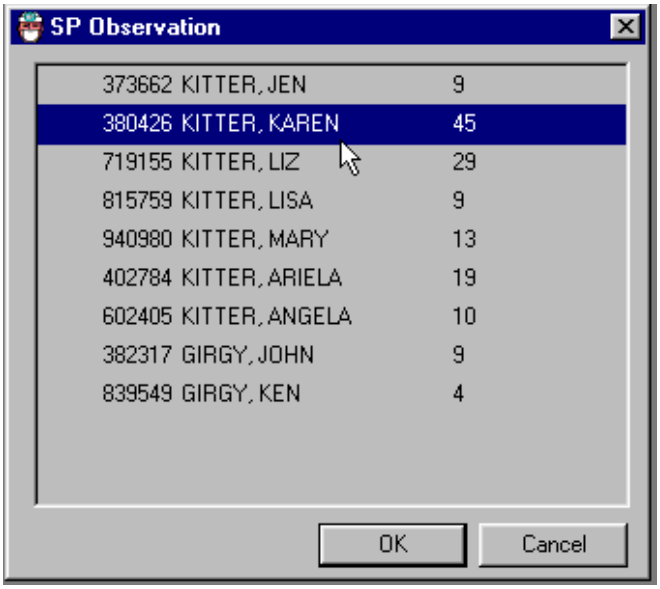
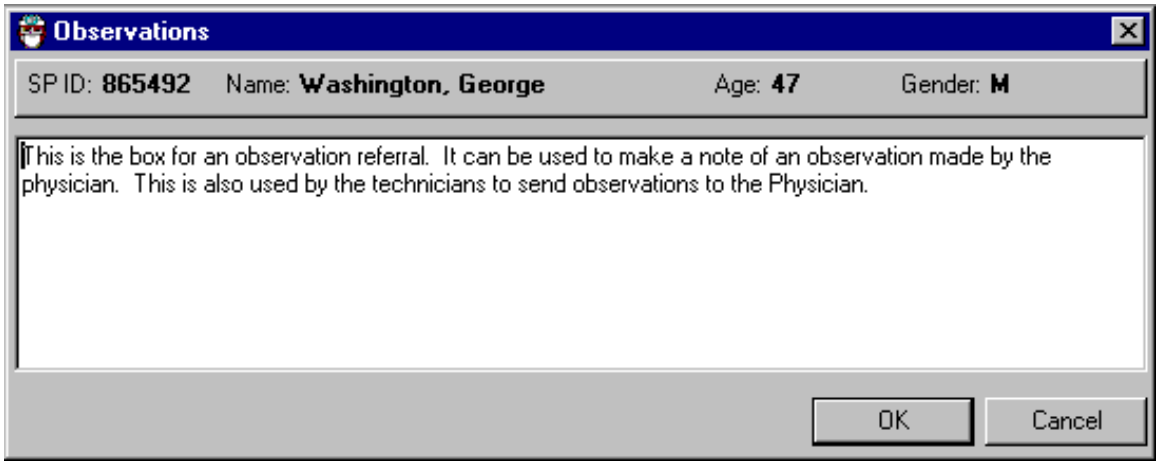


Exhibit 4-21 illustrates the Observations referral box that will be displayed in the other components. The technician will open this box, write the information in the referral information box, and send it to the clinician. This will be flagged in the clinicians exam system and the SP will not be able to leave the MEC until the clinician has reviewed this referral.

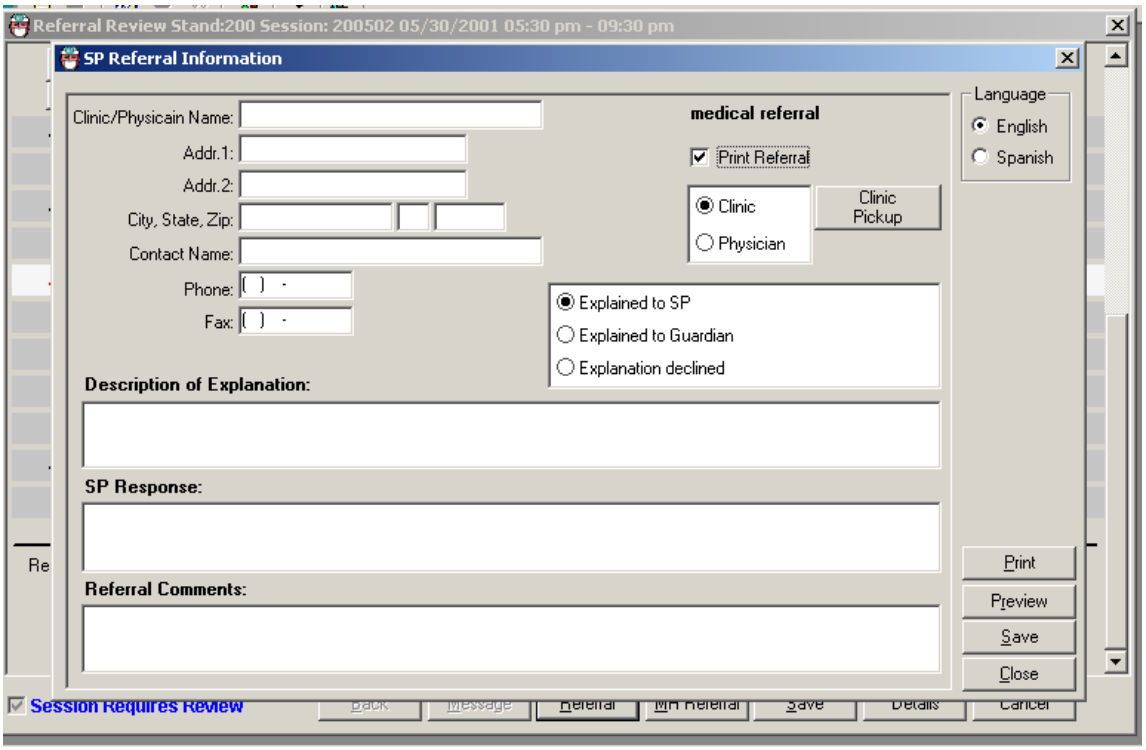
Exhibit 4-21. Observations Referral box



4.9.1 Referral Letter

When the "Medical Referral" button is clicked, Exhibit 4-22 is displayed. Enter a description of your explanation of the referral to the SP and how the SP responds. The box at the bottom of the screen (Referral Comments) is for entering clinician comments. These comments will appear on the second page of the referral letter.

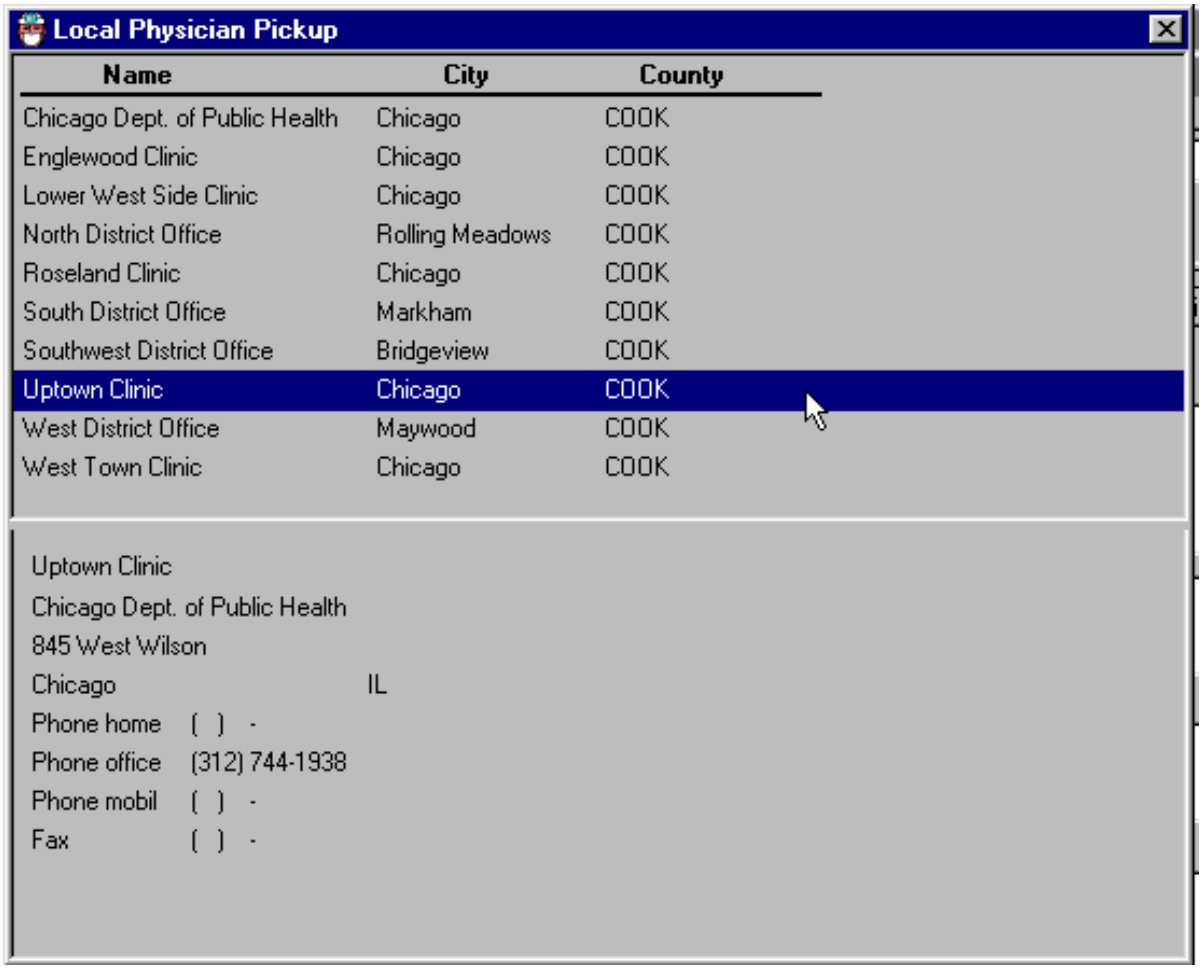
Exhibit 4-22. Clinic Pickup Medical Referral screen



4.9.2 Local Clinician Pickup

Select the name of the clinic or health care provider (Exhibit 4-23).

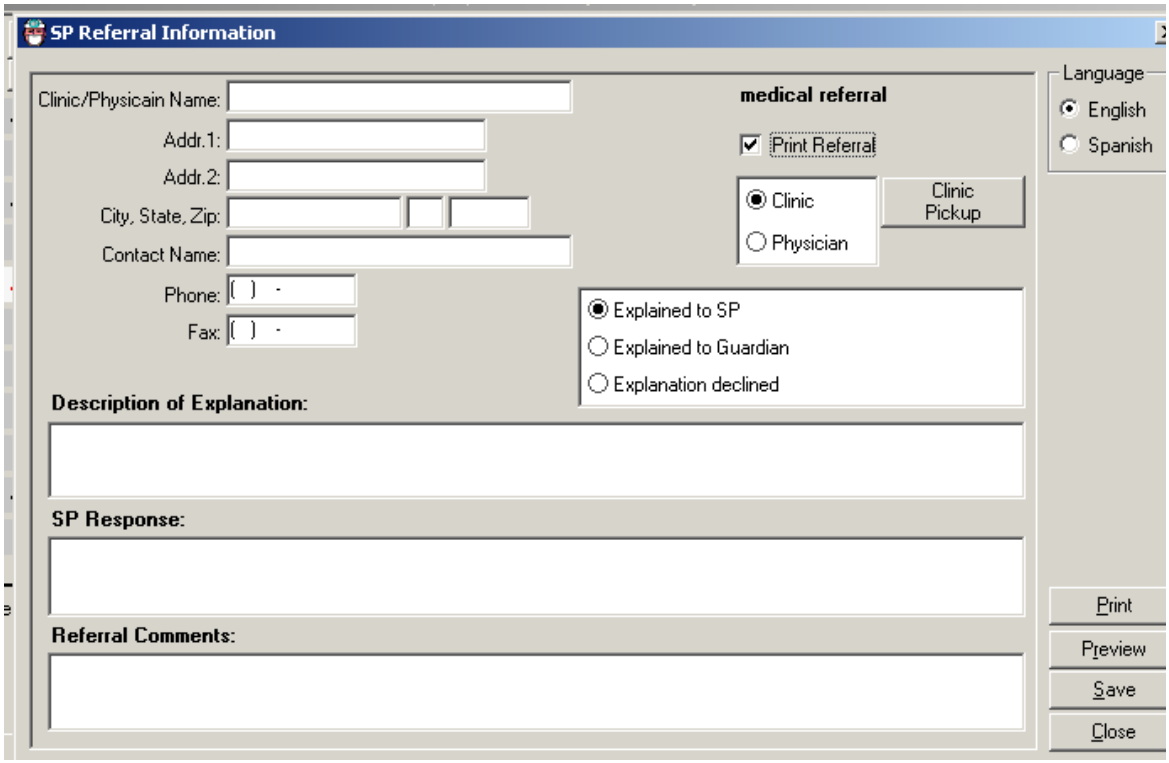
Exhibit 4-23. Local clinician and clinic pickup referral letter addresses



4.9.3 Referral Address Information

Describe the explanation given to the SP and the SP's response in the appropriate fields. These entries will not appear on the referral letter. The "Referral Comments" field may be used to enter comments to the referral physician (Exhibit 4-24).

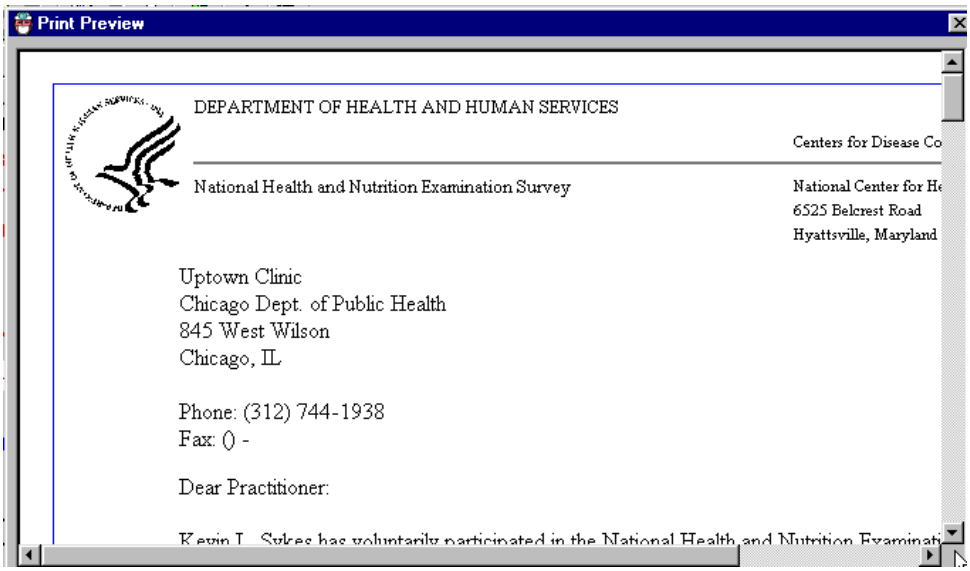
Exhibit 4-24. Local physician and clinic pickup data entered for referral letter information



4.9.4 Referral Letter Review

Select "Preview" from the Session Review in Box screen. A preview of the referral letter will be displayed (Exhibit 4-25). Use the scroll bar to view all areas of the letter.

Exhibit 4-25. Preview referral letter



4.9.5 Referral Letter Mock-Up

The data display for this referral letter (Exhibit 4-26) includes all areas for referral in a single letter.

Exhibit 4-26. Referral letter mock-up

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

<Insert Clinics Name> or <SPs Physician>
<Insert Clinic Address>
<Insert Clinic City, ST, Zip>
<Insert Point of Contact>
<Insert Phone Number>

Dear Doctor:

<SP Name> has voluntarily participated in the fourth National Health and Nutrition Examination Survey conducted at special facilities of the U.S. Public Health Service. The objectives of the survey are to obtain information on the health and nutrition status of the U.S. population. As a result of the testing that was done, it was noted that on **<Exam Date>**, a finding was revealed that was outside the survey's medically acceptable range. This finding is described on the attached Referral Comments page.

<Insert the following paragraph for SPs with Blood Pressure Level 1>
As indicated on the Referral Comments page the participant's blood pressure measurements were severely high. The measurements were taken three times; and the values indicated are the average of the last two measures. All survey participants with severely high blood pressure are instructed to see their doctor or clinic the same day, or go to a hospital emergency room to have their blood pressure rechecked.

This examination is intended to collect health measures for research. It is not a complete physical exam. No attempt has been made to diagnose or treat medical conditions of the participants. The findings disclosed to you are done so with the participant's permission.

Should you have any questions, you may contact me at the Mobile Exam Center. The phone number is ***<MEC Physician Phone>*** until **<MEC Stand End Date>**. After that date you may contact Dr. Kathryn Porter at the National Center for Health Statistics, Monday through Friday 9 AM to 6PM, EST. The toll free number is 1-800-452-6115.

Cordially,

<MEC Physician Name>, M.D.

5. Safety Issues and Emergency Procedures

5.1 Safety in the Mobile Examination Center (MEC)

The best approach to emergency situations in the MEC 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 MEC 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.

Promotion of safety and prevention of accidents and emergencies in the MEC is of particular concern in NHANES in view of the proportion of elderly SPs that will be participating in the survey. (Because we are taking all participants 0-19 years, all 60+years, but not all 20-59, there is **some** oversampling by age. The 60+ population is about 23 percent of the total population, and we expect about 26 percent of the exams to be for SPs 60+, so it's not a big oversample.)

5.1.1 Elderly Sample Persons

Care should be taken with all elderly SPs to minimize confusion and ensure the safe completion of the examination. Elderly SPs should be escorted when moving between exam procedures and should not be left alone for more than a few minutes, such as when changing clothes.

Instructions to elderly SPs should be provided in a clear, calm manner, and repeated as needed. It should not be assumed that the directions are understood until the SP offers an appropriate response. It may be necessary to guide SPs through each step required, such as providing a urine specimen or changing into a gown, to successfully complete a task. If the SP has difficulty understanding or performing tasks, try to offer one instruction or direction at a time and wait until the SP understands before proceeding.

Exam staff should be particularly alert to complaints or concerns from elderly SPs, as they may not clearly communicate the extent of their discomfort or concern. Staff members will need to further investigate SP complaints and refer all potential problems to the MEC clinician.

5.1.2 Sample Persons in Wheelchairs

Some SPs may arrive for the examination in wheelchairs, and the exam staff will have to facilitate the SPs' entry into the MEC and their progress through the examination. The Household Operations Support Staff use "Special Consideration" codes to inform the MEC if an SP will require assistance. See Section 5.2.3 for more details about these codes and associated reports.

SPs in wheelchairs will complete the COVID-19 screening and then enter the MEC through the handicap lift in trailer 1. Next, they will be taken to the coordinator for check-in. The MEC trailers are large enough to allow passage of most wheelchairs. In the event an SP's wheelchair cannot move easily through the MEC, the SP may be transferred to the MEC wheelchair located in the handicapped bathroom. If the SP can bear sufficient weight on at least one leg or can otherwise support themselves during the transfer, the clinician and another exam staff member should assist them into the MEC wheelchair to facilitate movement throughout the MEC.

SPs who cannot bear most of their weight on one leg and need assistance in transferring to the MEC chair **should not be lifted or moved out of their wheelchairs**. Lifting or moving SPs without their assistance could result in injury to an 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 clinician should make the decision to transfer or not transfer an SP based on the SPs ability to help themselves during the transfer.

5.1.3 Children in the MEC

Children in the MEC should be monitored at all times when not participating in an exam component. Young children should not be permitted to walk through the MEC unescorted, and should not interfere with the performance of any examinations. When waiting for an exam, young children should remain under the supervision of their parents, an older sibling, or relative. If the parents are willing and if an MEC staff member is available, the MEC staff may supervise the child if the parent is completing an exam that cannot be conducted with the child present.

5.2 Safety Precautions

A number of precautions have been taken to promote safety in the exam center.

5.2.1 Mobile Examination Center Preparation

- Fire extinguishers have been placed throughout the MEC to allow rapid response to fire. Exit doors are present in every trailer.

- A drug kit, an automated external defibrillator, two portable oxygen tanks, pocket cardiopulmonary resuscitation (CPR) masks, and portable blood pressure equipment are kept in one box in **Multipurpose Room 5 (MPR5) in trailer 2**. All staff must be able to recognize and locate this equipment without delay.

- The phone number "911" is to be used to activate EMS if applicable for the MEC location. The telephone number and address of the local fire and rescue squad will also be posted at the coordinator's station and in the staff room by the telephone.

- The address of the MEC will be posted in the coordinator's station, staff room, and lab so that the location can be reported correctly to EMS.

- The MEC 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, they should step outside the MEC.

5.2.2 Mobile Examination Staff Preparation

- All staff are required to be thoroughly familiar with the safety issues and emergency procedures;

- All examination staff members are certified in CPR and Basic Life Support (BLS) and recertified biannually;

- The clinician is certified in CPR/BLS and Advanced Cardiac Life Support (ACLS) and recertified biannually;

- The **MEC Manager is trained as the backup Safety Officer** on the MEC. In addition to CPR/BLS certification, the MEC Manager is certified in ACLS and recertified biannually; and

- Mock emergency drills will be held twice a year on each MEC to simulate a medical emergency and permit the practice of emergency procedures.

    – These emergency drills will be led by a physician consultant who has expertise in conducting these drills in the MEC environment. This consultant will work closely with the clinicians and MEC Managers to train them in the conduct of emergency procedures and the role of safety officer on the MEC.

5.2.3 On-Site Preparations at Each Stand

- The Household Operations Support Staff 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 MEC.

- As noted in Section 5.1.2, the Household Operations Support Staff will provide advance notice to the MEC coordinator of any SPs who will require assistance entering or moving through the exam center using Special Consideration codes. The codes are entered into the Special Consideration field on the MEC Appointment Schedule Report and the Session Preview Report. The coordinator and MEC Manager use the MEC Appointment report to plan and manage sessions. The Special Consideration codes used are outlined below in Exhibit 5-1:

Figure 5-1. Special consideration codes

BL	**Blind**
CN	**Cane needed**
CR	**Crutches**
DF	**Deaf**
HI	**Hearing impaired**
IN	**Inhaler**
LN	**Lift needed**
MI	**Mental impairment**
OB	**Obese**
OP	**Other physical impairment**
SA	**Substance abuse**
WL	**Walker**
WC	**Wheelchair**
Other (Specify)	

5.3 Reporting SP Problems to the MEC Clinician

SPs who report feeling ill or who appear to feel ill should be reported to the MEC clinician 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 clinician speak with an SP who has a particular complaint. If the SP is reluctant or refuses, and there is any question about the health or safety of the SP, staff members should consult the clinician for recommendations on how to proceed through the exam.

5.4 Medical Management and Referrals

5.4.1 Medical Referrals

Although the primary purpose of the MEC examination is data collection, not diagnosis or treatment, the exam may produce findings that warrant further medical attention. There is an obligation to inform the SP of any abnormal results from the exams and to refer the SP to the appropriate provider for treatment. The MEC clinician is responsible for the referral process. Each exam component has a referral process built into the ISIS system, which will alert the clinician to findings that may require a referral. Some of the exam findings may already be known to the SPs and their providers, but others may have been unknown until the day of the MEC exam. Based on the results of any component of the MEC examination, the clinician will place the SP in one of three categories:

- **Level I.** Major medical findings that warrant **immediate attention** by a health care provider, e.g., dangerously high blood pressure, emergencies.
- **Level II.** Major medical findings that warrant attention by a health care provider in the **next 2 weeks** because they are expected to cause adverse effects within this time period.
- **Level III.** Minor medical findings that an SP and their clinician already know about. Medical findings that do not require prompt attention by a medical provider.

A Level I referral usually results in termination of the MEC exam, with a transfer of the SP out of the MEC and into a hospital or other care facility. If an SP refuses treatment, they must sign a release stating that they are aware of the exam findings and are refusing treatment against the advice of the MEC clinician. The SP must sign the release form before leaving the MEC.

An SP with a Level II referral can continue the MEC examination and will be advised to see their primary care provider within the 2 weeks following the exam. If the SP does not have a health care provider, the MEC clinician can arrange for the SP to see a local provided by the health department.

5.4.2 Medical Management

The following section describes some medical scenarios that may occur during the MEC examination and actions to be taken by the MEC clinician. The section also provides guidance in determining the level of referral for an SP.

5.4.2.1 Allergic Reactions

SPs who experience allergic reactions will be treated according to the procedures adopted from the American Academy of Allergy Asthma and Immunology's (AAAAI) Anaphylaxis Emergency Action Plan. (Management of Anaphylaxis at COVID-19 Vaccination Sites | CDC.) Procedures that should be instituted immediately are outlined below. Any administration of epinephrine should also result in another MEC staff member calling 911. If anaphylaxis is suspected, take the following steps:

1. Rapidly assess airway, breathing, circulation, and mentation (mental activity). Laryngeal edema and angioedema of the tissue surrounding the airway is the most rapid cause of death.
2. An MEC staff member (not the clinician) should immediately call 911 for emergency medical services (EMS).
3. Place the patient in a supine position (face up) with feet elevated, unless upper airway obstruction is present or the patient is vomiting.
4. Epinephrine (1 mg/ml aqueous solution [1:1000 dilution]) is the first-line treatment for anaphylaxis and should be administered immediately.
    A. In SPs with a weight of 66lbs or more, administer a 0.3 mg intramuscular dose via autoinjector in the mid-outer thigh (through clothing if necessary). Children less than 66lbs should receive the pediatric autoinjector with a dose of 0.15mg.
    B. Epinephrine dose may be repeated approximately every 5-15 minutes if symptoms do not improve or if they return while waiting for EMS. The number and timing of epinephrine doses should be recorded and communicated to EMS.
    C. Because of the acute, life-threatening nature of anaphylaxis, there are no contraindications to epinephrine administration.
5. Nasal oxygen should be started.
6. Vital signs should be obtained and monitored every 5-10 minutes until EMS arrives.

After the procedures noted above have been done, a more extensive evaluation can be performed. The injection of epinephrine may be sufficient to prevent further symptoms. If, however, the SP

continues to have difficulty, other measures are instituted as deemed appropriate according to the patient's evaluation.

5.4.2.2 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 BLS courses.

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

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.

For further information on the treatment of choking victims, both conscious and unconscious, consult the current version of the BLS Provider Manual (BLS Provider Manual | AHA [heart.org]) (available in MPR5 in trailer 2).

5.4.2.3 Seizures

SPs who experience a seizure while in the MEC should receive immediate attention from the clinician. The following steps should be taken to secure the safety of the SP per the CDC's website for seizure first aid (Seizure First Aid | Epilepsy | CDC).

1. Ease the person to the floor.
2. Turn the person gently onto one side. This will help the person breathe.
3. Clear the area around the person of anything hard or sharp. This can prevent injury.
4. Put something soft and flat, like a folded jacket, under their head.
5. Remove eyeglasses.

6. Loosen ties or anything around the neck that may make it hard to breathe.

7. Time the seizure. Call 911 if the seizure lasts longer than 5 minutes.

Knowing what NOT to do is important for keeping a person safe during or after a seizure. Never do any of the following things:

- Do not hold the person down or try to stop their movements.
- Do not put anything in the person's mouth. This can injure teeth or the jaw. A person having a seizure cannot swallow their tongue.
- Do not try to give mouth-to-mouth breaths (like CPR). People usually start breathing again on their own after a seizure.
- Do not offer the person water or food until they are fully alert.

The clinician must use their clinical judgment based on the SP'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 clinician is also responsible for maintaining an airway, giving any indicated medications, and directing care of a seizing SP until an ambulance arrives or the seizure is over.

5.4.2.4 Hypoglycemia

Most SPs age 12+ assigned to a morning appointment block will arrive at the exam **after fasting for at least 8 hours**. It is expected that persons fasting for long time periods may feel faint during venipuncture and in subsequent procedures. If these individuals do not recover completely in a short time, their status should be reported to the MEC clinician. It is possible for some SPs to experience episodes of hypoglycemia, or low blood sugar, after fasting. Dizziness, slurred speech, confusion, and weakness are all symptoms of 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 SP, 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 clinician 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 SP 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 SP 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.

5.4.2.5 Use of Oxygen

When the oxygen tank is used in the MEC, 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.

5.5 Emergency Procedures

5.5.1 Medical Emergencies Overview

Before examinations begin at a stand, the Facilities and Equipment Specialist (FES) will have obtained information from the advance team about the types and availability of EMS in the area where the MEC is located. The FES will also invite the EMS to tour the MEC prior to the start day of SP examinations. EMS 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 MEC 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 MEC clinician. **The primary response of the clinician is to stabilize the SP's condition and to expedite a safe transfer to the nearest emergency medical treatment facility**.

The MEC examinations are designed to be safe for SPs. To ensure maximal safety, the clinician must be able to handle the initial management of an SP in distress. The response of the clinician is limited as **the MEC is not a diagnostic or treatment center**. The appropriate response of the clinician should be, as previously stated, to stabilize the SP in distress and facilitate a safe and expedited transfer to the nearest medical facility.

The clinician is responsible for directing the care of the SP in the event of an emergency. Staff members are responsible for the tasks assigned to them under the direction of the MEC Manager and the clinician.

The best overall approach to medical emergencies is prevention. The clinician may be called upon to decide if some procedures should not be administered to certain SPs to avoid potential medical problems if the SP does not fit easily into the preexisting medical exclusion categories for that procedure. The examining clinician can, at their discretion, exclude the SP from a component if they

believe the test may endanger an SP's health. The specific reasons for excluding the SP 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 MEC clinician 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 an SP to an emergency room when circumstances warrant.

The clinician is to be notified immediately of any situation involving an SP whose safety is of concern. Any questionable situation should be considered an emergency and evaluated by the clinician. In addition to the equipment and supplies that are transported to the site at the time of the emergency, a list of the medications (prescription and nonprescription) that the SP is currently taking will be available. The medication list may provide pertinent medical history information to the clinician so that a more accurate assessment of the SP 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 Clinician's Exam ISIS application.

When ambulance personnel trained in emergency medical care arrive to transport an SP in distress (Level I referral), the clinician should ensure communication of all medical measures that were taken prior to EMS arrival. The Household Operations Support Staff will contact the SP's family as soon as possible to inform them of the incident and the medical facility to which the SP was taken.

5.5.1.1 Emergency Supplies and Equipment

A limited number of emergency supplies are located in MPR5 described below.

Emergency cardiac and respiratory care supplies located in the clinician room:

1. Oxygen tanks (2)
   - Primary: Secured to wall beside window
   - Backup: Secured to wall under desk

2. Oxygen masks and tubing (kept in oxygen tank carrying case)
   - Nasal cannula: 1 adult, 1 pediatric
   - Oxygen mask: 1 mask
   - Extension tubing
3. Automatic External Defibrillator (AED)
4. Emergency Kit medications
   - Ammonia ampules
   - Aspirin, 325 mg tablets
   - Diphenhydramine liquid 12.5 mg/5 ml
   - Diphenhydramine tablets 25 mg
   - EpiPen®—adult
   - EpiPen—junior
   - Glucose tube
5. Emergency Kit – supplies
   - AED Battery (spare)
   - Oral airways: infant, small, medium, large
   - Pen light
   - Pocket CPR masks (2)
   - Pocket BP cuffs—child, adult, and large adult
   - Protective eyewear
   - Scissors
   - Stethoscope (2) —child and adult
   - Sterile gloves—two pairs
   - Surgilube packets
   - ½" Transpore tape
   - Tongue depressor

The drugs in the emergency kit are described in more detail in Table 5-1.

Table 5-1. Drugs in emergency kit

Medication	Form supplied	Dose	Route administered
Ammonia	Ammonia Aspirol	0.3 ml	Inhaled
Aspirin	Unit dose package	325 mg	Oral
Diphenhydramine	Liquid	12.5 mg/5ml	Oral
Diphenhydramine	Tablets	25 mg	Oral
Epinephrine-adult	EpiPen	0.3 mg 1:1000	IM injection
Epinephrine-peds	EpiPen Jr.	0.15 mg 1:2000	IM injection
Glucose tube	Insta-Glucose 31 gm	1-2 tbsp	Oral
Nitroglycerin (25 tabs)	Nitrostat	0.4 mg 1/150 gr	Sublingual

Please note that the drug kit does not contain antiarrhythmic medications or narcotics. Only the clinician should administer emergency procedures and use the contents of the emergency supplies other than the stethoscope and blood pressure cuff.

Oxygen Cylinders and Supplies

There are two size D aluminum oxygen cylinders on the mobile examination center. The cylinders are 15.27" long by 4.38" diameter with an oxygen capacity of 415 liters. The ***PRIMARY*** oxygen cylinder is attached to the wall beside the window in **MPR5**. 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 are stored in the external pockets of the bag. The clinician is responsible for conducting an inventory of all oxygen administration supplies at stand setup and teardown and ordering replacements through the inventory management system.

The ***BACKUP*** oxygen cylinder is secured to the wall under the desk in **MPR5.** This cylinder and regulator are also encased inside a soft carry bag. When the primary cylinder is off the MEC, the backup cylinder should be moved to the primary cylinder location until the primary cylinder is returned. The oxygen administration supplies should remain in the MEC at all times.

Oxygen Administration

The primary oxygen cylinder should be used first in all emergencies. If oxygen is depleted from this cylinder, then the backup cylinder should be used. 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.

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

The backup oxygen cylinder should be used for all instructional and training purposes. The primary cylinder should never be used for this purpose.

Oxygen Cylinder Monitoring

The MEC Manager and the clinician are responsible for monitoring the supply of oxygen for both the primary and the backup cylinders. The 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 during the next session worked. Both the MEC Manager and the clinician are responsible for signing the form when the oxygen level is checked. The completed forms are sent to the home office at the end of the stand with all other end of stand mailings.

Oxygen Tank Refilling/Replacement

When either cylinder is less than one-half full, the facility and equipment specialist is responsible for refilling the cylinder. During SP sessions, one cylinder must be present on the MEC, even if only half full. Never remove both cylinders for refilling at the same time during the stand when SPs will be present. 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. Oxygen suppliers almost always require a prescription for oxygen; however, this depends on the laws of individual states. At this time, we do not switch out the cylinder, as is the practice with most oxygen replenishment practices—the

cylinders on the MECs are refilled so that we can provide standardization of the regulators and tanks as the MEC travels across the country.

Automated External Defibrillator

The AED requires one battery to function during use. The expiration date for each battery is set by the manufacturer and is recorded on the battery, as well as on the Clinician Examination start of stand and end of stand inventory forms. The importance of ensuring the availability of these critical inventory items cannot be overemphasized. This is a start of stand, weekly, mid stand, and end of stand QC check requirement.

Reference Materials in the Clinician Exam Room

Reference materials available to the clinician include:

1. *The Merck Manual of Diagnosis and Therapy*, 20th Edition. Robert S. Porter. April 2018. Wiley Publishers.
2. *Clinician's Desk Reference 2012*; Thompson Healthcare.
3. *Emergency Medicine Manual*, 8th Edition. Rita K. Cydulka, David M. Cline, et al, 2017.

5.5.1.2 MEC Standard Medical Emergency Protocol

Due to the limited space in the MEC trailers, congregations of more than three or four people in one room are almost impossible. Subsequently, staff response to an emergency has been designed to limit the number of people needed to be together at one time. For example, a true cardiac or respiratory arrest requires only three people to be close to the patient for an extended period of time: two staff members to perform CPR and one clinician. Two staff members will act as a runner and a recorder but will be required to do so without hindering the performance of CPR or the clinician's access to the patient. The wheelchair lift should be lowered in anticipation of EMS needing to use it. Once an ambulance arrives, the path to the victim must be clear to allow transfer to EMS staff. If possible, the closest emergency exit door should be opened for EMS personnel to transfer the patient to an ambulance. Other types of emergencies, such as a fall or a seizure, will require the presence of the clinician and only one or two staff as requested by the clinician and the MEC Manager. There should be no spectators in the vicinity that may inhibit care of a patient.

5.5.1.3 Staff Roles in an Emergency

First Responder

The first responder is the person who either discovers the victim or is with the victim at the time of the event. Do not leave the victim alone at any time. Call for another staff member to alert the coordinator and the clinician of the situation immediately and initiate CPR if needed. The first person who responds to your call will be the runner for the event. If another staff member is immediately available, call for that person to assist you with CPR. If no one is available, continue one-person CPR until someone arrives to assist you. Once the clinician arrives, explain briefly what happened and they will direct care of the patient while you and your partner continue CPR. The clinician will also ensure that there is a designated recorder for the event.

If the clinician is the first person on the scene, they should call for help to alert the coordinator and MEC Manager immediately and then initiate CPR if needed. The clinician should continue one-person CPR until two other staff members arrive to take over CPR while the clinician directs care of the patient. The MEC Manager will confirm that all roles in the emergency response have been filled and that all unneeded staff are clear of the area. If the coordinator has taken on a role in the emergency, the MEC Manager will assign another staff member to take over for the coordinator. The coordinator will then return to the reception area to manage the SPs in the MEC. If the MEC Manager is not in the MEC at the time of the event, the chief health technologist should be notified to follow the MEC Manager's emergency protocol responsibilities.

Laboratory Staff

Activate the EMS system by calling 911 or other emergency numbers posted at the coordinator station. Request an ambulance for a medical emergency and give the location of the MEC.

Coordinator

The coordinator's responsibilities in the event of an emergency are as follows:

- Notify the MEC Manager of the emergency and provide any information you have regarding the need for staff assignments. If the MEC Manager is not in the MEC at the time of the event, notify the chief health technologist who will then follow the MEC Manager's emergency protocol responsibilities.

- Retrieve any SPs left unattended in exam rooms while staff members are assisting with the emergency. Staff should remain in the exam rooms with the SPs if they are not called upon to assist in the emergency. All other SPs should remain in the reception area with the coordinator. If the event occurs in the reception area, SPs in the reception area should be escorted to other exam rooms.

- Remain in the reception area with the SPs or designate another staff member to do so. Maintain calm and assure SPs the situation is under control.

MEC Manager

The MEC Manager's responsibilities in the event of an emergency are as follows:

- Check that the following response team is on the scene: 1 runner, 1 recorder, 2 people performing CPR (if necessary), and the clinician.

- Check that all other staff members are clear of the area.

- Post the assistant coordinator or other available staff member outside the MEC to direct EMS to the site of the emergency.

- Locate the emergency exit closest to the site of the emergency to facilitate transfer of the patient to EMS. The cargo lift on trailer 2 is **NOT** approved for transporting SPs from the MEC.

- Contact the field office immediately after the SP has left the MEC to inform the field office manager of the emergency. The field office will notify the SP's family of the event if the SP came alone to the MEC.

If the MEC Manager is not available at the time of the emergency, the chief health technologist will follow the protocol for the MEC Manager's responsibilities.

MEC Clinician

The MEC clinician is responsible for directing care of the SP until EMS arrives. Once the emergency equipment is on the scene, the clinician should ensure that a staff member is recording events on the MEC Incident/Emergency Report form. The clinician should not perform tasks such as CPR unless they are the first person on the scene. If the clinician is the first responder, they should begin CPR until two other staff members arrive. The clinician is also responsible for the operation of the AED and the administration of medications. The clinician will follow the ACLS algorithm and emergency protocols as outlined in the clinician manual. If possible, the clinician

should obtain consent from the SP or the SP's family to contact the SP's designated primary health care provider as soon as possible to report the occurrence and give the name of the medical facility to which the SP was taken.

If the clinician is not on the MEC, the MEC Manager is trained as the back-up Safety Manager.

Recorder

Any staff member could be called upon to act as recorder for the event. The recorder will be responsible for documenting the time of the emergency and the sequence of events that follow the initiation of emergency care on the MEC Incident/Emergency Report form (Exhibit 5-3).* The order of the events and time sequence are the critical elements in documentation. MEC Incident/Emergency Report forms will be kept in the clinician's emergency kit and are available on ISIS by clicking on the ambulance icon in the Toolbox. Instructions for completing this form are found in Exhibit 5-4 of this manual.

Runner

Generally, the first person to respond to the call for help will be the runner for the event. The runner's first responsibility is to notify the clinician, the coordinator, and the MEC Manager of the event. Once the appropriate people have been notified, the runner is responsible for retrieving supplies and equipment and making phone calls as directed by staff at the scene.

Other staff members should remain clear of the site and assist in keeping order in the MEC unless asked to help. No SPs should be left alone in the MEC. If a staff member has a role in the emergency and is in the process of examining an SP, the SP will be returned to the reception area while the staff member is in the emergency. All other staff will remain in the exam rooms with SPs until the crisis has passed. The coordinator is responsible for managing SPs in the reception area. The MEC Manager is responsible for managing the MEC staff. In the absence of the MEC Manager, the chief technologist will manage the MEC staff response during the emergency.

* All exhibits are located at the end of this chapter.

5.5.1.4 The Clinician's Role and AED Operation

As explained previously, the MEC is not a diagnostic or treatment center, and the liability insurance obtained for Westat clinicians does not cover any type of treatment procedure (except emergency stabilization). The primary response of the MEC clinician should be to stabilize the SP's condition and to expedite a safe transfer to the nearest emergency medical treatment facility. MEC clinicians are required to be BLS certified. The clinician and the MEC Manager are the only staff responsible for the operation of the AED, but only the clinician can direct the use of oxygen and medications. The AED can be placed on a patient for the purpose of monitoring a heart rhythm, but only one lead will be displayed. The clinician is not expected to make a diagnosis based on the AED monitor. The AED should be used only for monitoring a heart rate, or when ventricular tachycardia or ventricular fibrillation is suspected or imminent. Any patient who is unconscious is a candidate for application of the AED. The AED will advise a shock only in the event of ventricular tachycardia or fibrillation. The AED does not have cardioversion capability, nor will the clinician be able to deliver a shock if the AED does not advise a shock. As there are no antiarrhythmic medications in the emergency drug kit, the response to a cardiac emergency is basic life support with defibrillation if indicated.

5.5.1.5 Documentation

After the SP has left the MEC, the clinician should make sure that the incident and outcome are documented in the automated system in the clinician's ISIS application. The clinician will also complete a full report on a separate form, the MEC Incident/Emergency Report form, described below. The recorder will also use this form to record events on the scene. The recorder's notes of the event will be especially important in the completion of the clinician's report and should be kept with the clinician's documentation of the incident. The MEC Manager should review the final report prepared by the clinician and add any information not included in the clinician's report. The MEC Manager's addendum should include only information about the event that is not in the clinician's report. Any discrepancies in reports should be brought to the attention of the Director/Deputy Director of MEC Operations before being made final. Notification and documentation of the emergency incident should be directed to the Director/Deputy Director of MEC Operations as soon as possible.

5.5.1.6 MEC Incident/Emergency Report Form

A hard-copy form titled "MEC Incident/Emergency Report" will be used for recording the sequence of events or actions that are taken during the emergency response. An example of the form is shown in Exhibit 5-2. Guidelines for completion of the form are in Exhibit 5-3. During the emergency, the recorder will use the form to record vitals, treatments, and some patient outcomes. The clinician will then use the recorder's notes to complete a final official MEC Incident/Emergency Report form. The MEC Manager will then review the final form with the clinician and make any necessary additions.

The NHANES Emergency Management Protocol checklist (Exhibit 5-1) and the MEC Incident/Emergency Report documentation guidelines (Exhibit 5-2) are located in the emergency kit in MPR5 in trailer 2. The NHANES Emergency Management Protocol checklist is also located in the major hallways of the MEC.

5.6 Psychiatric/Behavioral Problem Procedures

There are situations that may arise regarding SP behavior that will require special handling. They include:

- **Previous Psychological Injuries, Deterioration, and/or Deprivation.** Due to changes in mental status, the SP may seem confused or may actually have dementia.
- **Inebriation Due to Intoxication with Alcohol and/or Drugs.** The SP will be less able to grasp ideas, reason, problem-solve, calculate, and attend to the tasks at hand. Therefore, the potential for injury, trauma, and violence is present.
- **Belligerence.** This will include SPs with noncompliant or abusive behavior.
- **Suicidal/Homicidal Ideation.** If an SP expresses intent to harm either themselves or someone else, the SP should be referred to the clinician. The clinician will evaluate the SP and determine the need for a referral to a psychiatric facility.

If the SP is so demented, confused, intoxicated, or belligerent that it is impossible to continue the examination, the MEC Manager should calmly terminate the MEC examination and have the SP leave the center without delay. For those SPs who require assistance going home, have a family member escort them home or call a cab.

Suicidal and homicidal ideation are considered psychiatric emergencies and are generally handled by referral.

For any psychiatric emergency, an incident form should be completed and the incident reported by telephone to the Director/Deputy Director of MEC Operations as soon as possible.

5.7 Natural Disaster Procedures

In the event of an unforeseeable occurrence (i.e., hurricane, tornado, fire, etc.), certain procedures should be followed, depending on whether the event happens before or during an examination session.

5.7.1 Disaster Prior to an Examination Session (Predicted Event)

- The stand coordinator should contact the home office for instructions regarding whether to cancel the session. If the session is canceled, the Household Operations Support Staff will then notify the MEC Manager who in turn will notify the MEC staff.
- If residents of mobile homes and trailers have been notified to evacuate, the Household Operations stand manager should make the decision to cancel the session. She or he should then call the home office to report the occurrence and cancellation of the session and notify the MEC Manager. The MEC Manager should notify the MEC staff.
- The Household Operations stand manager and MEC Manager may place the staff on standby procedures, with instructions to be ready to work but accessible by phone at home awaiting orders from the MEC Manager regarding status of operations.

5.7.2 Disaster During an Examination Session

If an examination session is underway and SPs are in the MEC when the MEC Manager or coordinator is notified by the Household Operations support staff of a pending natural event, the following procedures should be followed:

- The MEC Manager and the clinician should make a joint decision regarding closing the MEC and/or canceling the session. The first priority should be the safety of the SPs and staff.
- The MEC staff and SPs should evacuate the MEC as soon as possible and go directly to a safe haven, such as a building close by or the staff hotel. The staff and SPs should remain at this site until the impending event is over and it is safe to proceed outside.

- After the event, the MEC Manager and the clinician should decide whether or not to continue the exam session if the SPs are willing to stay for the rest of the session.
- If either the decision is made to cancel the session or the SPs decline to remain, the appointments for those SPs will need to be rescheduled by the field office.
- It is essential for the MEC Manager to notify the Household Operations stand manager of the outcome of events. The stand manager should then notify the home office immediately.
- Examiners who were conducting an exam or interview when evacuation of the MEC was ordered should interrupt the exam in the ISIS system. The reason for interruption of the exam must be accurately documented in ISIS and in room logs as soon as possible after the MEC is reopened.
- The MEC coordinator should document the reason for exam components omitted because of the closure of the MEC.
- Staff not requested to be involved in the emergency must stay away from the scene, remain in the exam rooms with SPs, and assist in maintaining order in the MEC.

Exhibit 5-1. NHANES Emergency Management Protocol checklist

Mobile Examination Center Emergency Management Protocol	
First Responder	✓ Call for help and assess victim for A-B-C, and initiate CPR ✓ Send closest staff to notify clinician, MEC Manager, and coordinator of the emergency; this person assumes the role of runner
Clinician (and or MEC Manager in the absence of the clinician):	✓ Direct the care of victim until EMS arrives ✓ Operate automated external defibrillatorAED ✓ Give medications ✓ Instruct recorder what to document
Lab Staff	✓ Activate EMS by calling 911 when advised
Coordinator:	✓ Retrieve unattended SPs and return them to the reception area ✓ Remain with SPs in reception area and provide reassurance ✓ Confer with MEC Manager regarding the continuation of exams
MEC Manager: *In the absence of the MEC manager, the coordinator will assume this role.*	✓ Ensure appropriate number of staff for emergency response; assign as necessary ✓ Traffic controlD ✓ Ensure clear access to the emergency exit door closest to the scene ✓ Post assistant coordinator or other staff member outside the MEC to greet ambulance personnel ✓ Notify the field office of the event as soon as possible
Runner:	✓ Obtain equipment and supplies as directed
Recorder:	✓ Record events on the MEC Emergency/Incident Report Form as directed by clinician
Assistant coordinator:	✓ Posted at the door to direct ambulance personnel to emergency site

Exhibit 5-2. MEC Incident/Emergency Report

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Rd
Hyattsville, Maryland 20782

MEC INCIDENT/EMERGENCY REPORT

Incident/Emergency	Person Type
○ Incident ○ Emergency	○ SP ○ Tech ○ Other

General Information

Clinician Name:	Recorder Name:
Emergency Date:	Runner Name(s):
Start Time: End Time:	Who Called 911:
Location:	Who Found:
Description:	

Personal Information

Person ID:	Age:	Gender:
Last Name:	First Name:	Middle Name:

Exhibit 5-2. MEC Incident/Emergency Report (continued)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention
National Center for Health Statistics
3311 Toledo Rd
Hyattsville, Maryland 20782

Vitals

Time	Heart Rate	Systolic BP	Diastolic BP	Respiratory Rate	Comments

Treatment

Time	Medication/Equipment	Comment

Exhibit 5-2. MEC Incident/Emergency Report (continued)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Rd
Hyattsville, Maryland 20782

Symptoms

Observation

Assessment

Plan

Page 3 of 5

Exhibit 5-2. MEC Incident/Emergency Report (continued)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Rd
Hyattsville, Maryland 20782

Urgent Care

☐ Transported to Hospital	Hospital Name:
Ambulance Arrival Time:	Ambulance Departure Time:
Emergency Service Name:	
☐ Clinician Accompanied SP to Hospital	

Notification

☐ Family Member Notified	Name:	Date/time:
	Relation:	
☐ Family Clinician Notified	Family Phys Named:	Date/time:

Signature:_____ Date:_____

Exhibit 5-2. MEC Incident/Emergency Report (continued)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention

National Center for Health Statistics
3311 Toledo Rd
Hyattsville, Maryland 20782

Vitals

Time	Heart Rate	Systolic BP	Diastolic BP	Respiratory Rate	Comments

Exhibit 5-3. MEC Incident/Emergency Report documentation guidelines

The Vitals and Treatment sections on page 2 should be completed first during the emergency. If the spaces on page 2 are insufficient, the last page should be used for recording vital signs. The "comments" section of the last page can be used to record treatments. The remaining sections should be completed as soon as the emergency is over. The recorder should collect most of the information requested on page 1 before turning the notes over to the clinician for compilation of the final report. The following information is to be documented:

Page 1:

- Check either Incident or Emergency, depending on the event. The difference is to be determined by the clinician and the MEC Manager;
- Check whether the person was an SP, a tech, or other (such as a guest or someone who has accompanied an SP to the exam);
- Names of the clinician, runner, recorder, person who called 911, and person who found the victim;
- Date of the emergency response;
- Time that the emergency response started, beginning from the time the victim was found;
- Time that the emergency response ended, i.e., time the ambulance arrived or time the victim left the MEC;
- Location of the emergency in the MEC;
- Description of the victim upon discovery; and
- If the victim is an SP, escort, or guest, the sample number, age, gender, and first and last names should be recorded. If the victim is a staff member, the first and last names are sufficient.

Page 2:

- Vitals and Treatment sections to be recorded at the time of the event by the recorder.

Page 3:

- The sections Symptoms, Observation, Assessment, and Plan are to be completed by the clinician after the event.

Page 4:

- The section Urgent Care is to be completed by the clinician if the SP is transported to a hospital;
- The section Notification will be completed by the MEC Manager after notifying the field office of the emergency; and
- If the clinician has obtained consent from the SP or the SP's family to contact the SP's care provider, the clinician must record the name of the health care provider and the date and time the health care provider was notified of the SP's status.

6. MEC Injury Blood Exposure Procedures

6.1 Introduction

The manual describes the procedures to be taken when a staff member is injured in the mobile examination center (MEC) or sustains an exposure to bloodborne pathogens.

6.2 MEC-Related Injuries and Blood Exposure Checklists by Position

6.2.1 All Injuries, Including Needlestick Incidents

6.2.1.1 MEC Employee

Immediately report any injury to the MEC clinician. If the MEC clinician is not available, report immediately to the MEC manager. The MEC manager must be informed as soon as possible after the injury. Any serious injury or potential bloodborne pathogen exposure of MEC staff will require a conference call with National Center for Health Statistics (NCHS) staff within 24 hours after the incident has been reported.

6.2.1.2 MEC Clinician with MEC Employee

Evaluate the injury and determine whether treatment from a medical facility is indicated. If the employee is not able to do so, provide the evaluating/emergency room physician with a description of the employee's duties as they relate to the injury on the MEC Incident/Emergency Report. If treatment is required, the MEC clinician may accompany the employee to the appropriate facility if necessary. The MEC manager may also consider going in place of the clinician if the employee injury is serious or if additional assistance is needed. If the clinician accompanies the employee to the treatment facility, the MEC session may continue if the remote physician is available. The Study Manager and Director of MEC Operations must be notified as soon as possible if the session must be closed.

Complete a Westat Workplace Accident/Emergency Report and a MEC.

Incident/Emergency Report for every injury that employees report. The Westat Workplace Accident/Emergency Report and MEC Incident/Emergency Report is available on the MEC computers under Utility folder/Application Manuals. The MEC Incident/Emergency Report is also integrated into the clinician's application. The Westat Workplace Accident/Emergency Report should be sent as soon as possible, but no later than 24 hours following the injury, to the Director of NHANES MEC Operations and Westat's Accidents and Injuries mailbox (Accidents&Injuries@Westat.com). The Director of MEC Operations will forward notifications of significant injuries or bloodborne pathogen exposures to NCHS.

6.2.1.3 MEC Manager Responsibilities

- As soon as possible, notify the Director of MEC Operations of the injury, although notification of minor injuries may be delayed until evaluation and treatment are complete.
- Check with the MEC clinician to ensure that the MEC Incident/Emergency Report has been completed.
- Complete the Westat Workplace Accident/Injury Report and notify Westat's Accident and Injuries team within 24 hours by sending an email with the attached report to Accidents&Injuries@Westat.com. Copy the Director of MEC Operations on the email.
- Westat's Human Resource Services (301-251-4380/1-800-937-8281, x4380) and Security Services departments (301-279-4500/1-866-937-7327) will coordinate all internal and external administrative activities, including notification to the appropriate Westat insurance provider.
- Employees or supervisors who receive additional or supplemental reports related to an injury (including a police report) must forward such reports to Westat's Accident and Injuries team in a timely manner.

6.2.2 All Blood Exposure Incidents

6.2.2.1 MEC Clinician with MEC Employee

Evaluate the injury and determine whether treatment from a medical facility is indicated. In addition, the employee should be evaluated at an emergency room for post-exposure testing and post-exposure prophylaxis counseling and initiation. The MEC manager may accompany the staff

member to the appropriate facility. The employee should be prepared to provide the following information to the evaluating/emergency room physician:

- Documentation of the route of exposure and circumstances on the MEC Incident/ Emergency Report; and
- Description of employee's duties as they relate to exposure on the MEC Incident/ Emergency Report.
- Inform the emergency room that it is a workman's compensation claim so that appropriate billing can be initiated.
- Save all paperwork provided at the visit and provide copies to Accidents&Injuries@Westat.com and the Director of MEC Operations.

Westat project managers and/or Westat Workman's Compensation team members will assist the employee in obtaining additional outside or expert medical consultation as needed.

6.2.2.2 MEC Clinician with Sample Person

- The MEC clinician should meet with the participant who was the source of the exposure. Use the National Health and Nutrition Examination Survey Consent to Obtain Hepatitis B/Hepatitis C/HIV Testing and Consent to Release Results form (Attachment C) to guide the conversation with the source.
- Discuss the rationale for testing and attempt to get informed consent from the SP for the testing and release of the results (to the exposed employee's physician) for Hepatitis B, Hepatitis C, and HIV tests.
- Ask the SP to sign the NHANES Consent to Obtain Hepatitis B/Hepatitis C/HIV Testing and Consent to Release Results form.
- The SP's physician will obtain the blood sample and will receive and report the results to the exposed employee's physician and the SP. The SP may choose to talk to their personal physician or an infectious disease physician from the community or local health department before a blood sample is obtained and sent for testing. At the direction of the NCHS project officers, Westat will pay for this visit and test.
- Provide a copy of the signed consent to the SP (yellow copy) and the employee (pink copy). Give the original (white copy) to the MEC manager.
- If the SP refuses to be tested, document the refusal in writing on the MEC Incident/ Emergency Report form.

6.2.2.3 Director of MEC Operations Responsibilities

- Notify the appropriate home office staff and the NCHS Medical Director, and distribute copies of the MEC Incident/Emergency Report form as necessary. In conjunction with the Westat Human Resource Services and Workman's Compensation team, make available—at no cost to the exposed employee—a confidential medical evaluation and follow-up. The exposure report of the employee's injury must include the following:
  - Date and time of exposure;
  - Documentation of route of exposure and the circumstances under which the exposure occurred;
  - Identification and documentation of the source individual, unless prohibited by state or local law;
  - Documentation of blood collection and testing from the exposed employee for determination of HBV, HCV, and HIV status, and any additional serologic testing obtained;
  - Postexposure prophylaxis when medically indicated as recommended by the U.S. Public Health Service;
  - Counseling; and
  - Evaluation of reported illnesses.
- Within 15 days after the evaluation of the exposure incident, obtain the following from the evaluating/emergency room physician:
  - Written opinion as to whether Hepatitis B vaccination is indicated;
  - Statement that the employee was informed of the results of the medical evaluation and was told about any conditions resulting from the exposure that require further evaluation and treatment; and
  - Specific findings or diagnosis that relate to the employee's ability to receive the Hepatitis B vaccine.
- Establish a confidential medical record for each exposed employee and maintain documentation of the original injury and exposure for the duration of employment plus 30 years. Medical records must include the following:
  - Employee's name and Social Security number;
  - Employee's Hepatitis B vaccination status, including vaccination dates and any medical records relating to the employee's ability to receive vaccinations;

- Results of examinations, medical testing, and postexposure evaluation and follow-up procedures;
- Health care professional's written opinion; and
- A copy of the information provided to the health care professional.

- Be available to discuss the incident with NCHS staff within 24 hours of reporting the incident to the appropriate home office staff; and
- Establish and maintain a Sharps Injury Log for recording percutaneous injuries from contaminated sharps. This log will be kept with the Study Manager for the Laboratory and Phlebotomy components.

6.3 Checklist for Employee Requiring Treatment for Blood Exposure Incident

Provide the following information to the evaluating/emergency room physician:

- Documentation of the route of exposure and circumstances on the MEC Incident/Emergency Report;
- Description of the employee's duties as they relate to exposure on the MEC Incident/Emergency Report; and
- All medical records, including vaccination status, if available (check with employee).

6.4 Sample Person Checklist for Blood Exposure Incidents

- Provide pretest counseling first.
- Ask the SP to sign the NHANES Consent to Obtain Hepatitis B/Hepatitis C/HIV Testing and Consent to Release Results form.
- Provide a copy of the signed consent to the SP (yellow copy) and the employee (pink copy). Give the original (white copy) to the Director of MEC Operations via the MEC manager.
- If the SP refuses to be tested, document the refusal in writing on the MEC Incident/Emergency Report form.

7. Quality Control

7.1 Elements of the Quality Control Program

To ensure complete and accurate data collection, the quality control program for this study will take place in mobile examination centers (MECs) and will consist of the following major elements:

- Monitoring equipment and equipment repair; and
- Site visit observations by NCHS and Westat.

7.2 Monitoring Equipment and Equipment Repair

The equipment and room supplies need to be checked on a regular basis. Some checks are completed daily and others need only be completed weekly or at the beginning and end of each stand. These checks include maintenance inspection of equipment and supplies and preparation of the room and equipment for the session exams. The specific timeframes for equipment QC are as follows: start of stand, weekly, and end of stand.

All of the quality control (QC) processes are recorded in the computer application, which reminds the clinician to perform the time-sensitive QC procedures. If the QC procedures have not been completed for that period, a reminder message will be displayed each time you log on until the QC procedures have been completed for that time period. The home office component staff monitors the equipment QC completion rates and provides feedback and/or retraining as warranted.

Each time you log on to the application, the system will remind you to do QC checks if the checks have not been completed for that time period. The specified QC checks performed at the beginning of stand, daily, weekly, and end of stand are selected by the clinician. If you do not have time to do the checks when you log on, you can bypass this message and complete the checks at a later time. However, a reminder message will be displayed each time you log on until you have completed the checks for that period. After you have completed the checks and marked them as done (see Exhibit 7-5), the message box with the reminder will not be displayed again until the appropriate time has passed.

7.2.1 Maintenance of Equipment

Clinicians maintain all equipment used in their component. The following sections specifically state the requirements that clinicians follow to check and maintain equipment used for the pulse measurement. The following items are checked on a routine basis.

Littmann Pediatric Stethoscopes

1. Check that the stethoscope has no cracks in the tubing.
2. Earpieces are securely attached.
3. Head of stethoscope is securely attached to tubing.
4. Diaphragm is secure, no cracks.

7.3 Frequency of QC Procedures

The designated intervals for the QC procedures are start of stand, daily, weekly, and end of stand checks.

7.3.1 Daily QC Checks

1. No daily checks.

7.3.2 Weekly QC Checks

1. Check functioning of all emergency equipment.
2. Complete inventory of emergency medications.
3. Check the stethoscope tubing for cracks or tears.
4. Check stethoscope diaphragm for cracks.
5. Check that the head of the stethoscope is securely attached to the tubing.

7.3.3 Start of Stand Checks

1. Complete weekly checks.

7.3.4 End of Stand Checks

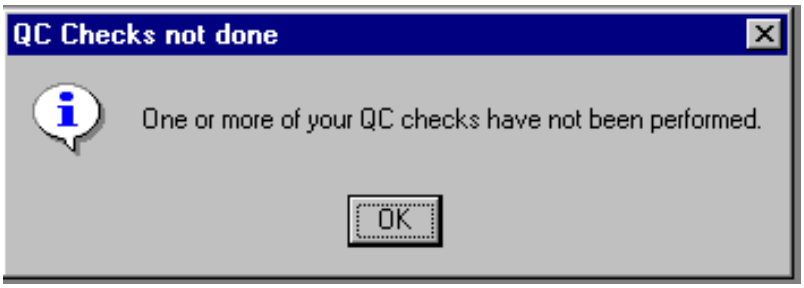
1. Complete teardown procedures.

7.4 ISIS Data Entry Screens for QC on Equipment

7.4.1 Data Entry Screens for QC on Equipment

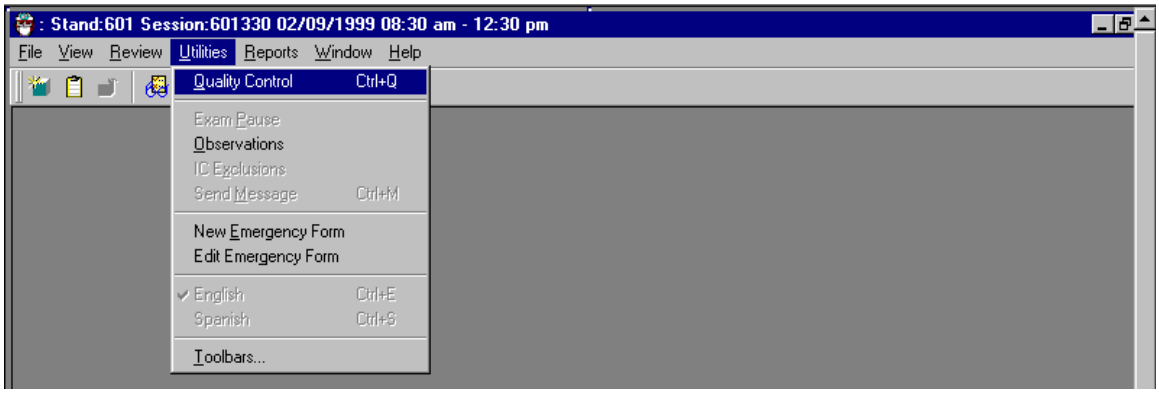
When you log on to the application before the quality control checks are performed, the system (Exhibit 7-1) displays a message: "One or more of your QC checks have not been performed."

Exhibit 7-1. Quality control logon with reminder message



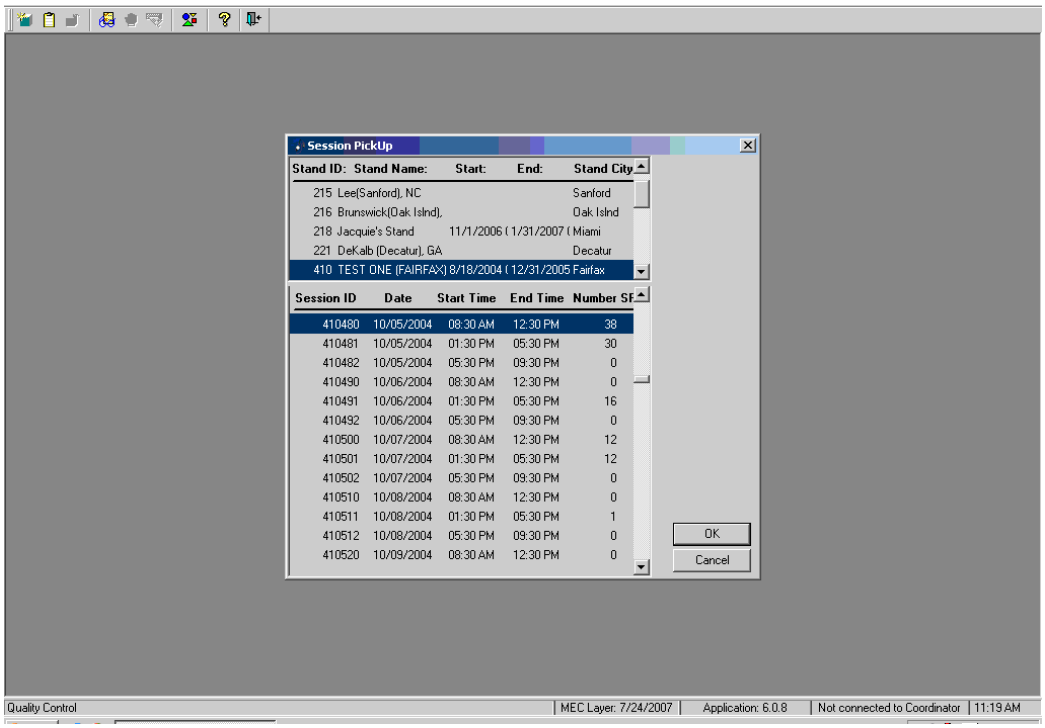
Click OK to this message. When you want to complete the QC checks, select Utilities, and then select Quality Control from the menu (Exhibit 7-2). Clicking on the QC icon from the Toolbar is another way to access the QC screens.

Exhibit 7-2. Utilities menu to select quality control



When QC is selected from the Utilities menu, the Session Pickup box will be displayed. Select the current session (Exhibit 7-3).

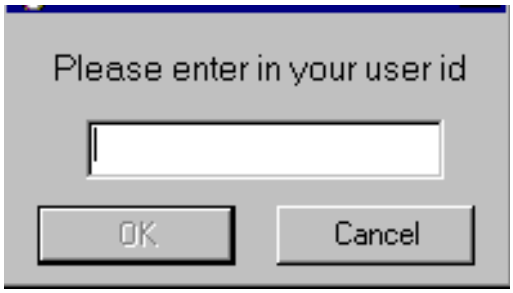
Exhibit 7-3. Session pick-up box



When QC is selected from the Utilities menu, the User ID entry box (Exhibit 7-4) will be displayed.

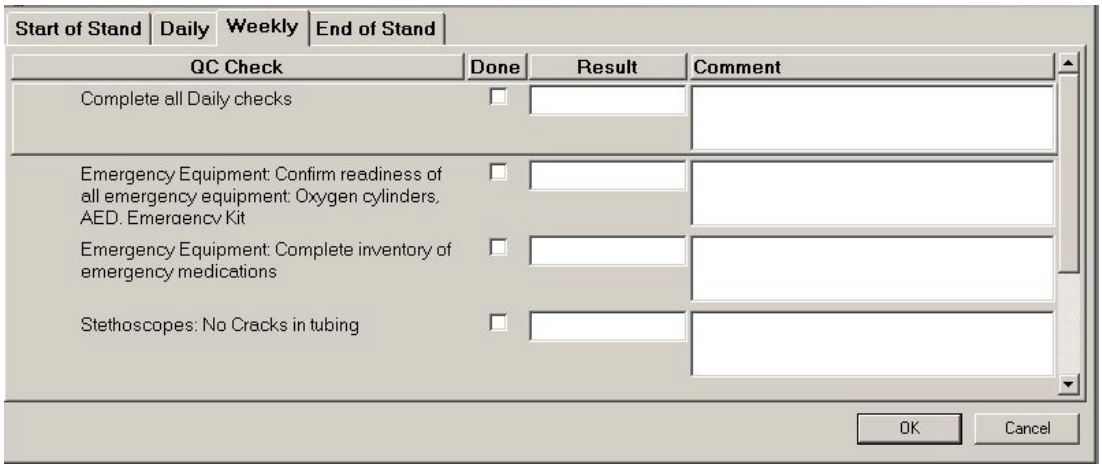
Each clinician will have a personal ID. This ID will be used to identify the person who completed the QC checks for this time period. Enter your User ID and click "OK." If you do not want to do the QC checks at this time, click "Cancel." You will still be able to conduct the exam.

Exhibit 7-4. Quality control logon



On the QC screens, check "Done" for the listed items when that item has been completed (Exhibit 7-5).

Exhibit 7-5. Example of a Quality Control screen



You are not required to enter anything in the "Result" or "Comment" fields unless there is a problem with the equipment. The Result field is used to enter values for selected QC items if required. The Comment field is used to enter information about problems encountered with the QC item check.

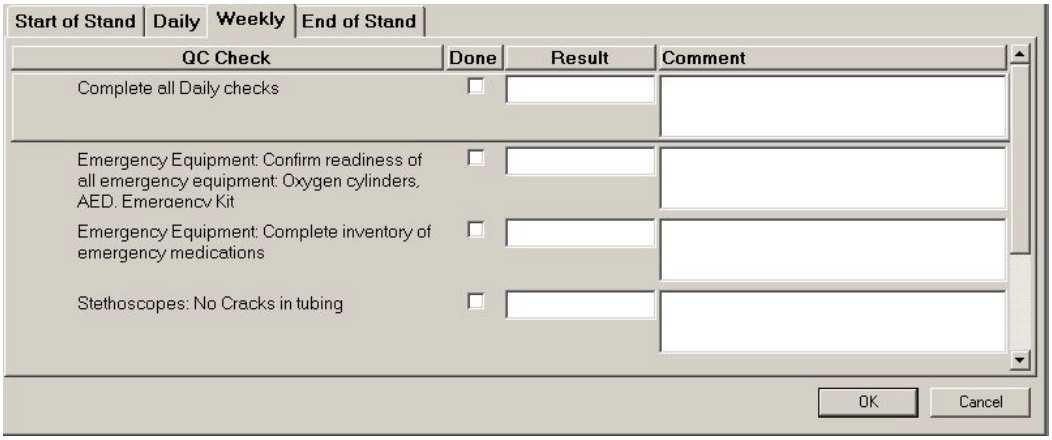
7.4.2 Daily Checks

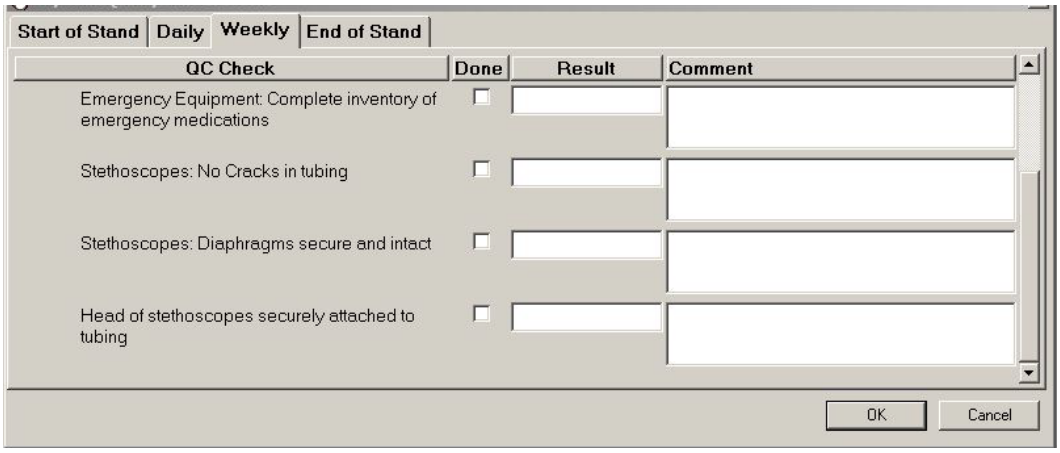
There are no daily checks.

7.4.3 Weekly Checks

Use the scroll bar to move to the remaining items. When you are finished with the weekly item checks, click OK to close the QC box (Exhibit 7-6).

Exhibit 7-6. Quality control weekly checks

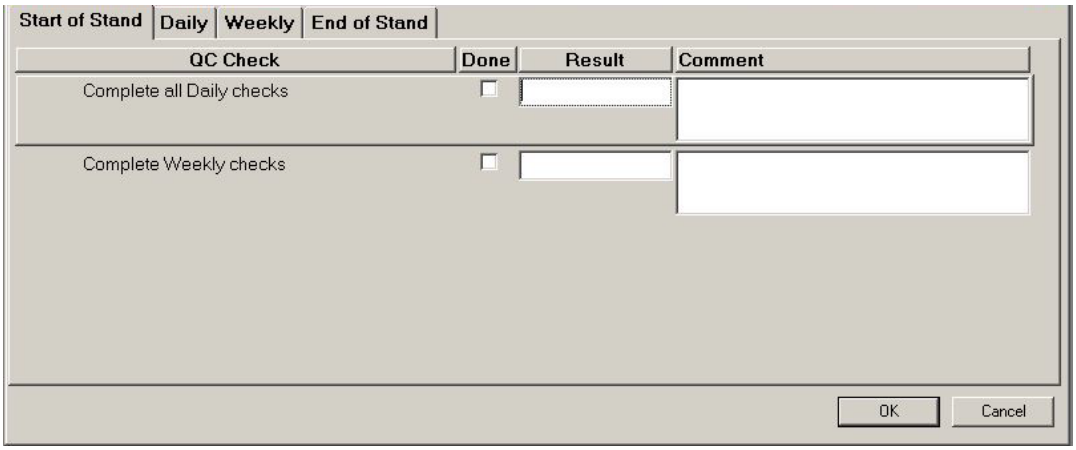




7.4.4 Start of Stand Checks

The start of stand checks are shown in Exhibit 7-7.

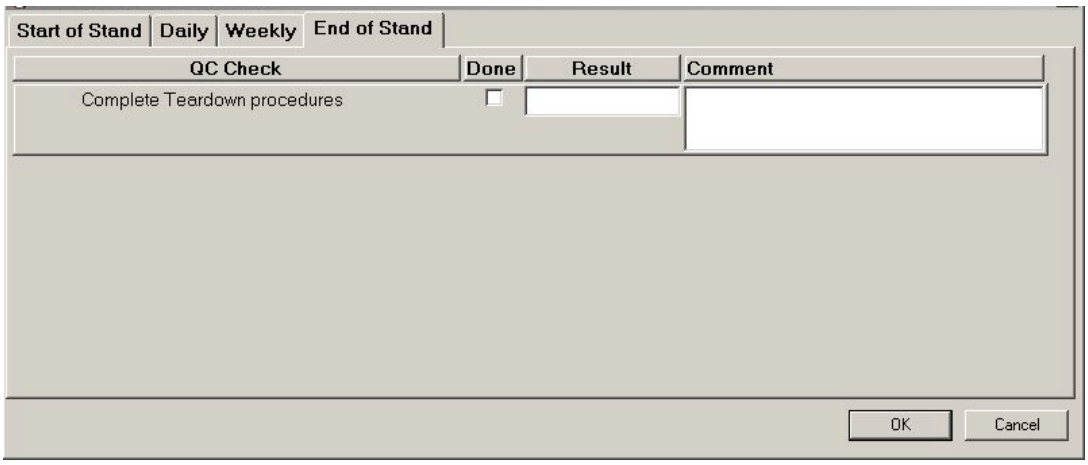
Exhibit 7-7. Quality control start of stand checks



7.4.5 End of Stand Checks

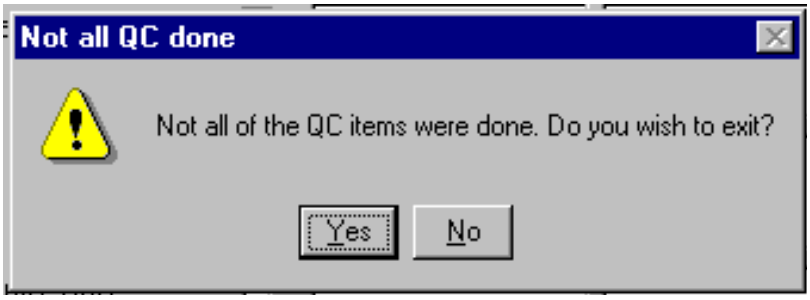
The end of stand checks are introduced in the screen in Exhibit 7-8.

Exhibit 7-8. Quality control end of stand checks



When you have completed all checks, click OK to close the QC box. If you do not check that all items are complete, the system will display this message: "Not all the QC items were done. Do you wish to exit?" (See Exhibit 7-9.)

Exhibit 7-9. Quality control incomplete entry



If you want to complete the items before exiting, click No to this message and complete the items. If you do not wish to complete all QC checks, click Yes to this message. If all QC items were not complete, the system will remind you each time you log on that the QC checks are not complete.

Below is a summary of the clinician QC procedures.

Weekly checks

1. Check functioning of emergency equipment: oxygen cylinders, AED.
2. Complete inventory of emergency medications.
3. Check Littmann Cardiology III Stethoscopes:
   - Check that the stethoscope has no cracks in the tubing.
   - Earpieces are securely attached.
   - Head of stethoscope is securely attached to tubing.
   - Diaphragm is secure, no cracks.

Appendix A

STD Information Sheets and Role Plays

Appendix A
STD Information Sheets and Role Plays

MEC Information Sheets
Infections with Herpes Simplex Virus Type 2 (HSV-2)

Mode of infection

- Almost always sexual

Laboratory assay used in NHANES

- Type-specific immunodot assay using sera, which measures antibodies specific for HSV-2. This test result is an indicator of past infection.

Frequency

- Approximately 1 in 10 adolescents
- Increases with age among white adults to over 1 in 4 adults
- Increases with age among black adults to over 1 in 2 adults

Location of the initial infection and of symptoms

- Women
  - Skin around the vagina, urethra, and rectum
  - Skin of inner thighs and on the buttocks
  - In the vagina and on the cervix
- Men
  - Skin on and around the penis
  - Skin of inner thighs
  - Rectum and skin around the rectum and on the buttocks

Latent infection

- Most of the time, the virus remains dormant in nerve cells connected to the lower spinal cord.
- Symptoms occur when the virus begins to replicate in skin cells around the nerve endings.

Symptoms of uncomplicated infection

- Most infected individuals report no symptoms.
- Blisters that break to form multiple small tender sores that heal spontaneously within a week.
- Episodes recur with highly variable frequency, symptom-free intervals ranging from days to months.

Complications

- Occasionally, the sores are sufficiently painful to interfere with urination.
- Rarely, infection of the brain occurs.
- Rarely, babies born to infected women contract serious infections.

Diagnosis

- Blood tests to detect antibody.
  - In NHANES, a special blood test is used that is not yet available to most physicians. The blood test detects antibody and is usually correct, but no test is 100 percent accurate.
  - Physicians can order blood tests, but they do not reliably distinguish between the type 2 herpes simplex virus infection and type 1 infection that is the infection that most commonly causes fever blisters of the mouth and is not usually sexually transmitted.
- Cultures and other tests detect the virus in blisters and sores, except during the later stage of healing.
- Frequently, the blisters, sores, and history of recurrences are characteristic, and the physician requires no laboratory test to make the diagnosis.

Note: Except by using the NHANES type of blood test, the infection cannot be detected unless blisters or ulcers are present.

Treatment

- No treatment is curative.
- Antiviral drugs suppress symptoms, which usually recur after the drug is stopped.
- Treatment of each recurrence, separately, is not usually worthwhile, because healing occurs before the drug can act.

Preventing infection of others

- Transmission-related factors
  - Intimate, usually sexual, contact is required.
  - Infected individuals are most infectious when they have sores, but they most often infect others when they are asymptomatic.
  - Infected individuals, who never have symptoms, often shed herpes virus, but how many are infectious is unknown.
- Prevention measures should be taken, but they are not entirely effective.
  - Visit a physician, who can help the infected person determine when a herpes outbreak is occurring.
  - Avoid intercourse during outbreaks.
  - Use condoms.
  - Make sex partners aware of need for preventive measures and residual risks.

MEC Information Sheets
Infections with Human Immunodeficiency Virus (HIV)

Mode of infection

- Sexual transmission and percutaneous blood exposure (IV drug use, needle sticks in health care workers, etc.).

Laboratory assay used in NHANES

- Serum is screened for HIV-1 antibody using an FDA-licensed enzyme immuno assay kit. Repeatedly reactive specimens are then tested by an FDA-licensed Western blot assay.

Frequency

- Approximately 3 in 1,000 adults
- Approximately 2 in 1,000 white adults
- Approximately 11 in 1,000 black adults
- Approximately 4 in 1,000 Mexican American adults

Diagnosis

- Blood tests to detect antibody.

Incubation (infection to AIDS diagnosis)

- Median 8-10 years in untreated individual, but varies by age.
- Treatment with HAART (highly active antiretroviral therapy) is altering the median incubation time.

Treatment

- HAART, if given early, can slow or stop disease progression.
- Treatment of opportunistic infections as they occur.

Preventing infection of others

- Condom use has been demonstrated to be effective against transmission.
- Only abstinence or monogamous relationship (between two HIV-negative partners) is totally effective in preventing exposure.

Table A-1. Reproductive Health/Sexually Transmitted Diseases

STD	Symptoms	Treatment	Things to know
HIV/AIDS (virus)	None or mild flu-like symptoms early in infection. With onset of AIDS many years after infection, persistent cough, unexplained weight loss, diarrhea, fever, etc.	Treatment is available to slow or stop disease progression. Many serious AIDS-related infections can be prevented by medications.	Early treatment can delay serious complications. Treatment of pregnant HIV-positive women can reduce transmission to the baby.
Gonorrhea (clap, drip, GC) (bacterium)	Most women and many men have no symptoms. **Women:** Abnormal vaginal discharge, burning on urination, or lower abdominal pain. **Men:** Discharge of pus from penis, burning on urination.	Can be cured with antibiotics. Sex partners need to be treated.	If not treated, can lead to more serious problems. Gonorrhea can lead to infertility in women. A mother can pass the infection on to her baby.
Chlamydia (bacterium)	Most women and many men have no symptoms. **Women:** Mild or no symptoms, vaginal discharge, burning on urination, or lower abdominal pain. **Men:** Discharge from penis, burning or pain on urination.	Can be cured with antibiotics. Sex partners need to be treated.	If not treated, can lead to more serious problems. Reproductive organs can be damaged (Pelvic Inflammatory Disease). A mother can pass the infection on to her baby.
Genital Herpes (virus)	Most women and many men have no symptoms. Painful blisters. Painful urination. Swollen glands in groin area and fever.	Herpes cannot be cured but medication can reduce symptoms.	Symptoms disappear and may recur at any time. Infected persons are most likely to transmit the infection when they have symptoms, but they can also transmit when they don't have symptoms. In rare instances, a mother can give herpes to her infant during childbirth.

Table A-1. Reproductive Health/Sexually Transmitted Diseases (continued)

STD	Symptoms	Treatment	Things to know
Bacterial Vaginosis (BV) (bacterial growth)	**Women:** Most women have no symptoms. Others have a gray, thin vaginal discharge with an odor.	Can be cured with antibiotics. May recur and require repeat or long-term treatment.	If not treated, can lead to more serious problems. It is very important for pregnant women to get treated. Women who have never had sexual intercourse can get BV.
Trichomonas (protozoan)	Many women have no symptoms. Some women have a yellow gray or green vaginal discharge with an odor. Burning, irritation of the vaginal area.	Can be cured with antibiotics. Sex partners need to be treated.	It is very important for pregnant women to get treated.
Syphilis (bacterium)	Many women and men have no symptoms. Painless ulcers in the genital area. New infection may produce sore genitals, an unusual rash, fever, or swollen lymph nodes.	Can be cured with antibiotics.	If not treated, syphilis can lead to long-term health problems, including heart disease and nerve problems. It is very important for pregnant women to get treated.
Human Papillomavirus (HPV) (virus)	Many people have no symptoms. Symptoms and signs of infection are genital warts, abnormal Pap smear, cervical lesions, and cervical cancer.	HPV is not cured with medicine, but symptoms can be treated.	Some types of HPV are linked to cervical cancer, others to genital warts. HPV infection can resolve on its own.

For information and/or test results, call the NHANES Health Educator: 1-888-301-2360, Monday-Friday, 9 AM to 6 PM Eastern Standard Time.

Your participation is giving researchers valuable information about the number of people in this country who are infected with sexually transmitted diseases (STDs). In order to get accurate numbers, we test all survey participants in your age group, even if you are not at risk for getting these diseases.

Your test results are completely confidential and will not be reported to your family, employers, insurers, or intimate contacts. Your doctor can receive results only with your permission. Test results are given only to you. Four weeks after the exam, you may call our health educator toll-free at 1-888-301-2360 for your STD results (including HIV testing for those aged 18-49 years). You must provide your password before any results are given out. Please make sure you remember this password when you call. If a health problem is identified, you will be told how to get evaluated and treated.

Other phone numbers you can call:

- National STD Hotline – 1-800-227-8922
- AIDS Hotline – 1-800-342-AIDS

Role Play—Scenario 1

Client

Sam is a 45-year-old divorcé who left his former wife about a year ago. He was married for 20 years and has two children. He has never had an STD, just a urinary tract infection once. He has heard much about HIV/AIDS and is worried about how to date safely in the '90s. He is a sample person for the NHANES survey and is willing to be tested for STDs. He is in general good health and looks forward to developing a new romantic relationship.

Counselor

You will be counseling Sam, a 45-year-old divorcé who has recently rejoined the dating scene. He is worried about HIV/AIDS and wants to become romantically involved again, but safely. He is not very aware of the various types of STDs and their associated symptoms.

You will need to provide a smooth segue into this part of the clinician's exam. Discuss the purpose of testing for STD/HIV and why these special tests have a different mechanism for reporting. Assure confidentiality of the survey and test results. If asked, explain and educate Sam on the various STDs, risk behaviors associated with transmission, complications, testing methods, and possible treatments available if found to be infected. In closing, you will arrange for Sam to call to obtain his results, if he wishes, in a confidential manner.

Observer

As the observer, you are not to interrupt or engage in the counseling session. Take side notes of the counselor's ability to cover the major points listed:

- Smooth segue into STD/HIV component of physician's exam;
- Assure confidential manner of testing and obtaining results;
- When asked, explain the various types of STDs, risk behaviors, testing methods, associated symptoms, and treatments available if found to be infected; and
- Mechanisms for client to obtain results.

Did the counselor listen to the client to assess risk and knowledge level of the client about STDs?

Did the counselor use open-ended questions to better assess the client's level of understanding?

Did the client appear to understand the level of communication that the counselor was speaking from?

Did the counselor adequately cover the bullets highlighted above?

Role Play—Scenario 2

Client

Julie is a 19-year-old college student. She has never had an STD and has recently become sexually involved with her boyfriend, Bob, whom she has been dating for 1 year. She has heard about STDs but is not very familiar with symptoms or ways to be tested for them. She is in general good health and looks forward to a happy and healthy future with Bob when she finishes college.

Counselor

You will be counseling Julie, a 19-year-old college student, who has recently become sexually active with her boyfriend Bob. She is not very aware of the various types of STDs and their associated symptoms.

You will need to provide a smooth segue into this part of the physician's exam. Discuss the purpose of testing for STD/HIV and why these special tests have a different mechanism for reporting. Assure confidentiality of the survey and test methods involved. If asked, explain and educate Julie on the various STDs, risk behaviors associated with transmission, sequelae, testing methods, and possible treatments available if found to be infected. In closing, you will arrange for Julie to call to obtain her results, if she wishes, in a confidential manner.

Observer

As the observer, you are not to interrupt or engage in the counseling session. Take side notes of the counselor's ability to cover the major points listed:

- Smooth segue into STD/HIV component of physician's exam;
- Assure confidential manner of testing and obtaining results;
- When asked, explain the various types of STDs, risk behaviors, testing methods, associated symptoms, and treatments available if found to be infected; and
- Mechanisms for client to obtain results.

Did the counselor listen to the client and address specific questions about STDs?

Did the counselor use open-ended questions to better assess the client's level of understanding?

Did the client appear to understand the level of communication that the counselor was speaking from?

Did the counselor adequately cover the bullets highlighted above?

Role Play—Scenario 3

Client

Jack Williams is 42-years-old and married with two children. He has been married for 12 years and works for a new car dealer. He spent 4 years in the Navy and was once infected with gonorrhea while on leave in Japan. While in the Navy, he had to attend presentations about STD/HIV and is familiar with their symptoms and treatment.

Counselor

You will be talking to Jack about the NHANES project and seeking his permission to test him for STDs and HIV.

You will provide a smooth segue into this part of the examination, assure him that everything is confidential, and explain the test procedures. Explain why he is being tested, the purpose of the project, and what your role is with the project. If Jack agrees to be tested, make arrangements for him to call back for his test results.

Observer

Do not interrupt the session. Take notes of the following:

- Smooth segue into STD/HIV component of physician's exam;
- Assure confidential manner of testing and obtaining results;
- When asked, explain the various types of STDs, risk behaviors, testing methods, associated symptoms, and treatments available if found to be infected; and
- Mechanisms for client to obtain results.

Did the counselor address the above checklist?

Did the counselor address questions the client may have asked?

Appendix B

Liver Genetics Protocol

Appendix B
Liver Genetics Protocol

Funding Sources

The costs of the targeted genetic testing for the NHANES Liver Ultrasound Transient Elastography Component will be covered by NCHS interagency agreements with NIDDK and NIAAA.

1.1 Introduction

This component is to test for targeted genetic variants hypothesized to be related to chronic liver disease and co-morbid conditions with liver disease such as obesity, type 2 diabetes mellitus, chronic kidney disease, and cardiovascular disease and methylation sites. DNA methylation is one mediator that cells use to control gene expression and patterns have been associated with liver disease. Targeted genetic variants and methylation sites would be able to be combined with information from NHANES measures of liver steatosis/stiffness measures, current/past alcohol consumption, and co-morbid conditions.

1.2 Study Protocol

This component will be conducted on NHANES participants 18 years of age and older during NHANES 2020–2021. We will approve eligible participants who attend their scheduled exam at the MEC. All eligible individuals will be asked to participate.

1.2.1 Blood Collection

5-milliliter blood samples will be collected from participants aged 18 years and over by a phlebotomist at the MEC. EDTA purple top tubes are recommended. Whole blood will be processed and aliquoted into vials for storage in the MEC. The vials will then be refrigerated at 4 degrees Celsius and shipped overnight twice a week to the contract laboratory (TBA with address).

1.2.2 SNP List

A custom assay will be developed using the approved SNP list. The list does not contain SNPs from the American Society of Clinical Medical Genetics updated list of recommended SNPs for the return of secondary findings list v2. The list also does not contain SNPs that have clinical significance categorized as "pathogenic" or "likely pathogenic" in the U.S. National Library of Medicine, National Center for Biotechnology Information's database of genetic variation (dbSNP).

1.2.3 Methylation

850,000 methylation sites per participant will be accessed using Illumina Infinium Methylation EPIC BeadChip Kit by the contract laboratory.

1.2.4 Testing Period

All testing to be completed within 18 months of the end of the 2020-2021 cycle. Two to three batches may be required to conduct testing during the survey cycle. After testing is completed, DNA samples will be discarded. DNA samples will not be stored for future use.

1.3 Exclusion Criteria

Participants 18 years or older are excluded if they do not consent to the MEC examination or if they are unwilling to give blood or have an exclusion for a blood draw.

1.4 Informed Consent

Information about genetic testing will be added to the NHANES 2020-2021 Health Measurements List to inform participants about this testing prior to consent. No additional consent for genetic testing will be obtained as samples will not be stored for future testing. Participants will not receive results of genetic testing.

During the consent process in the home, field interviewers will have on hand an information handout about the genetic testing (in the form of questions), Attachments A and B. The interviewers will provide the handout to potential participants if they have questions. The home interviewers will

receive training about the information in the handout and how to respond to further questions, and will be instructed to explain that a clinician will be available at the MEC to answer further questions.

All participants will receive the information handout when they go to the clinician component at the MEC. The clinician will give the participants the handout and answer any questions. We will also add an opt-out box for the genetic testing to the clinician's application screen. This process will follow the current STD model that is used by the clinicians. A permanent copy of the handout will be included in the packet of materials participants receive when they leave the MEC. We think it most appropriate for the participants to review questions with the clinician at the MEC rather than in the home.

1.5 Report of Findings

All genetic variants and methylation sites will not be reported since they are not clinically actionable at this time. Resulting genetic data will be released to and only accessible through the NCHS Research Data Center (RDC).

1.6 Remuneration

Persons will not receive any additional remuneration beyond their current ERB approved remuneration for participating in the NHANES.

Attachment A
Genetic Testing FAQ Handout (English)

NATIONAL CENTER FOR HEALTH STATISTICS
National Health and Nutrition Examination Survey

Questions about Genetic Testing for Liver Health in NHANES

What is genetic testing for liver health in NHANES?

We do genetic testing by taking DNA from your blood and from the blood of other NHANES participants to look at genes, or segments of DNA, to see how genes affect liver health.

How will you collect my DNA?

We will use the DNA that is in the blood sample you provide in our Mobile Exam Center.

What are the risks?

There is no risk to genetic testing procedure. However, the risk of having blood drawn is minimal. You may have mild pain and some bruising at the site where blood is drawn.

What kind of genetic tests will be done on my DNA sample?

Your DNA sample, and samples from other NHANES participants, will only be used by researchers to look at specific genes that may be related to liver disease and related health conditions.

Will you store my DNA or use it for future research?

No, your DNA will only be used for current testing. Once this testing is complete the remaining DNA sample will be destroyed. Your DNA will **NOT** be stored after testing is complete and will **NOT** be used for any future research.

Who will use the genetic data obtained from testing?

The data will only be available to researchers whom access your data at the National Center for Health Statistics Research Data Center, which is a secure location. Your personally identifiable information (such as name, address, social security number, etc.) will never be given to researchers.

Will I get results of this testing?

No, we will not provide you with results from this testing. The tests will be used only for research. Your genetic data will not be tested for anything known to require medical care or treatment.

Can I say no to this testing but still participate in the NHANES?

Yes. You can refuse genetic testing at any time and still participate in NHANES. You can also still have your blood drawn for non-genetic tests. Please tell an NHANES staff member if you refuse to have the genetic test done on your blood sample.

Can the genetic information from this testing be used to identify me?

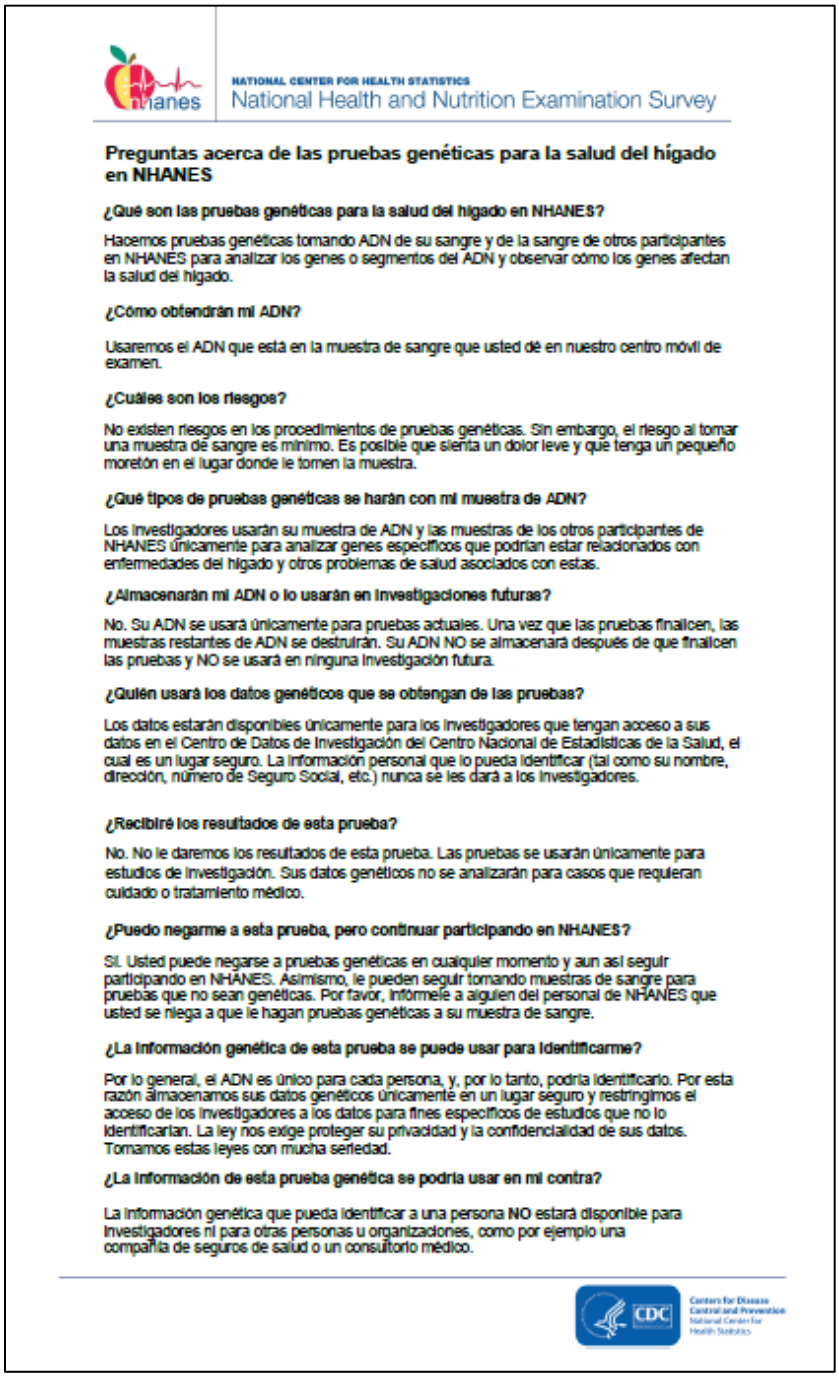
In general, DNA is unique to only you and therefore may identify you. For this reason, we only store your genetic data in a secure place and restrict researchers' access to the data for specific research purposes that would not identify you. We are required by law to protect your privacy and the confidentiality of your data and we take these laws very seriously.

Could information from this genetic testing be used against me?

Individual identifiable genetic information will **NOT** be available to researchers or anyone such as a health insurance company or doctor's office.

CDC Centers for Disease Control and Prevention National Center for Health Statistics

Attachment B
Genetic Testing FAQ Handout (Spanish)



NATIONAL CENTER FOR HEALTH STATISTICS
National Health and Nutrition Examination Survey

Preguntas acerca de las pruebas genéticas para la salud del hígado en NHANES

¿Qué son las pruebas genéticas para la salud del hígado en NHANES?

Haremos pruebas genéticas tomando ADN de su sangre y de la sangre de otros participantes en NHANES para analizar los genes o segmentos del ADN y observar cómo los genes afectan la salud del hígado.

¿Cómo obtendrán mi ADN?

Usaremos el ADN que está en la muestra de sangre que usted dé en nuestro centro móvil de examen.

¿Cuáles son los riesgos?

No existen riesgos en los procedimientos de pruebas genéticas. Sin embargo, el riesgo al tomar una muestra de sangre es mínimo. Es posible que sienta un dolor leve y que tenga un pequeño moretón en el lugar donde le tomen la muestra.

¿Qué tipos de pruebas genéticas se harán con mi muestra de ADN?

Los investigadores usarán su muestra de ADN y las muestras de los otros participantes de NHANES únicamente para analizar genes específicos que podrían estar relacionados con enfermedades del hígado y otros problemas de salud asociados con estas.

¿Almacenarán mi ADN o lo usarán en investigaciones futuras?

No. Su ADN se usará únicamente para pruebas actuales. Una vez que las pruebas finalicen, las muestras restantes de ADN se destruirán. Su ADN NO se almacenará después de que finalicen las pruebas y NO se usará en ninguna investigación futura.

¿Quién usará los datos genéticos que se obtengan de las pruebas?

Los datos estarán disponibles únicamente para los investigadores que tengan acceso a sus datos en el Centro de Datos de Investigación del Centro Nacional de Estadísticas de la Salud, el cual es un lugar seguro. La información personal que lo pueda identificar (tal como su nombre, dirección, número de Seguro Social, etc.) nunca se les dará a los investigadores.

¿Recibiré los resultados de esta prueba?

No. No le daremos los resultados de esta prueba. Las pruebas se usarán únicamente para estudios de investigación. Sus datos genéticos no se analizarán para casos que requieran cuidado o tratamiento médico.

¿Puedo negarme a esta prueba, pero continuar participando en NHANES?

Sí. Usted puede negarse a pruebas genéticas en cualquier momento y aun así seguir participando en NHANES. Asimismo, le pueden seguir tomando muestras de sangre para pruebas que no sean genéticas. Por favor, infórmele a alguien del personal de NHANES que usted se niega a que le hagan pruebas genéticas a su muestra de sangre.

¿La información genética de esta prueba se puede usar para identificarme?

Por lo general, el ADN es único para cada persona, y, por lo tanto, podría identificarlo. Por esta razón almacenamos sus datos genéticos únicamente en un lugar seguro y restringimos el acceso de los investigadores a los datos para fines específicos de estudios que no lo identificarían. La ley nos exige proteger su privacidad y la confidencialidad de sus datos. Tomamos estas leyes con mucha seriedad.

¿La información de esta prueba genética se podría usar en mi contra?

La información genética que pueda identificar a una persona NO estará disponible para investigadores ni para otras personas u organizaciones, como por ejemplo una compañía de seguros de salud o un consultorio médico.

CDC Centers for Disease Control and Prevention National Center for Health Statistics

Appendix C

National Health and Nutrition Examination Survey Consent to Obtain Hepatitis B/Hepatitis C/HIV Testing and Consent to Release Results

Appendix C
National Health and Nutrition Examination Survey Consent to Obtain Hepatitis B/Hepatitis C/HIV Testing and Consent to Release Results

I understand that a Westat employee, working on the National Health and Nutrition Examination Survey, was accidentally exposed to a sample of my blood. To follow U.S. Government regulations and guidelines, _____ has explained the importance of having my blood tested for Human Immunodeficiency Virus (HIV), hepatitis B virus, and hepatitis C virus and of reporting the results of my tests to the Westat employee's workman's compensation adjuster at Liberty Mutual Insurance Company. The adjuster will notify the employee's caregiver.

I understand that my participation in this process is voluntary. There will be no penalty to me if I do not participate. I also understand that all results of my HIV, hepatitis B, and hepatitis C tests will be kept confidential to the fullest extent of the law.

I agree only to the statements marked below, which describe the procedure for testing my blood and reporting the results:

HIV Testing

☐ I agree to have a blood test for HIV by a physician of my choice at no charge to me. I also agree to release the results of my test to the exposed employee's physician. The names of my physician and the physician of the exposed employee are listed below on this consent form.

Hepatitis B Virus Testing

☐ I agree to have a blood test for hepatitis B surface antigen (HBsAG) by a physician of my choice at no charge to me. I also agree to release the results of my test to the exposed employee's physician. The names of my physician and the physician of the exposed employee are listed below on this consent form.

Hepatitis C Virus Testing

☐ I agree to have a blood test for hepatitis C antibody (Anti-HCV) by a physician of my choice at no charge to me. I also agree to release the results of my test to the exposed employee's physician. The names of my physician and the physician of the exposed employee are listed below on this consent form.

Reimbursement of the cost of the physician visit and testing can be accomplished by contacting the Director of MEC Operations using the information below.

If I have any questions, contact Beryl Carew, BN, MPH, Director of MEC Operations at 240-620-6591 or berylcarew@westat.com.

Signature of Survey Participant: _____

Printed Name of Survey Participant: _____

SP ID Number: _____

Date: _____

Physician of Choice for Survey Participant to Perform Testing

Name (Printed): _____

Address: _____

City, State, ZIP code: _____

Telephone: _____

Liberty Mutual Insurance Adjuster for Reporting Results

Send results to: WCDocs@LibertyMutual.com

Subject of Email: ***Name of Westat Employee*** Bloodborne Exposure Source Test Results

Witness: _____

MEC Clinician or MEC Manager

Signature: _____

Title/Date: _____