



National Health and Nutrition Examination Survey (NHANES)

OGTT: Trutol Administration



January 2011

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1. OVERVIEW OF THE ORAL GLUCOSE TOLERANCE TEST (OGTT)

1.1 Introduction

Because of the increasing occurrence of diabetes in younger ages, NHANES added this component to the examination protocol to reassess the prevalence of diabetes and impaired glucose tolerance (IGT) in the U.S. population.

Diabetes is a large, growing, and costly public health problem in the United States and disproportionately affects racial and ethnic minorities. About 17 million Americans have diabetes and more than 1 million new cases of diabetes are diagnosed each year. Diabetes is the leading cause of kidney failure, nontraumatic lower extremity amputation, and blindness in working-age adults, and an estimated \$135 billion was spent on direct and indirect medical costs for diabetes in 2002. Alarmingly, type 2 diabetes (formerly considered an adult disease) is now being diagnosed in children and adolescents and there has been a large increase in diagnosed diabetes among adults <40 years of age.

Persons with IGT are at high risk for developing diabetes. In addition, IGT is an important risk factor for a number of other adverse health conditions and mortality. IGT is defined on the basis of an abnormal oral glucose tolerance test (OGTT). Persons without diabetes but with an OGTT 2-hour value of 140-199 mg/dl are considered to have IGT.

Recent national and international randomized controlled trials have shown that diabetes can be delayed or prevented among persons with IGT. Furthermore, NHANES III data indicate a tremendous opportunity for the prevention of diabetes—more than 12 million persons aged 45-74 have prediabetes (defined as overweight persons with either IGT or impaired fasting glucose metabolism). These data also indicate that more than 50 percent of persons with prediabetes are detected only by IGT findings. As risk factors for diabetes, IGT, and prediabetes increase (e.g., physical inactivity, obesity, and aging), the prevalence of these conditions is also likely to increase.

The inclusion of OGTTs on NHANES will allow estimation of the prevalence of IGT and, thus, prediabetes in the U.S. population, surveillance of trends in the prevalence and awareness of these conditions, study of the risk factors for IGT and prediabetes, and examination of IGT as a risk factor for health conditions and mortality. Timely data on IGT and prediabetes are particularly important as the

Nation initiates efforts to prevent diabetes among persons with prediabetes. These data on IGT and prediabetes are critical to targeting, designing, and evaluating prevention efforts such as the U.S. Department of Health and Human Services' (DHHS) Steps Program and efforts by the National Diabetes Education Program.

A fasting glucose blood test is performed on all participants 12 years and older who are examined in the morning session after a 9-hour fast. After the initial venipuncture, participants are asked to drink a calibrated dose (generally 75 milligrams) of Trutol® and to have a second venipuncture 2 hours (plus or minus 15 minutes) after drinking the Trutol.

There are minimal risks associated with this procedure. The package label for Trutol lists the following rare but known adverse reactions: nausea, vomiting, abdominal bloating, and headache. In addition, there is a rare incidence of hypoglycemia. The risks associated with venipuncture include excessive bleeding, fainting/feeling lightheaded, hematoma, infection, and multiple punctures to identify veins. Participants eligible for OGTT will have to endure the discomfort of a second venipuncture; however, they will benefit by the report of findings that will inform them if they have impaired glucose tolerance.

The results from the OGTT will be reported to parents of participants 12-17 years old, and directly to participants 18 years and older, in the Final Report of Findings. If the 2-hour blood glucose values are equal to or greater than 140 mg/dL, (i.e., glucose levels consistent with impaired glucose tolerance or diabetes mellitus), an early report will be sent.

1.2 Field Office Responsibilities

The field office is responsible for instructing SPs to fast and for introducing the OGTT during the household interview by using an informational flyer (Exhibit 1-1). There is no change to the existing fasting remuneration.

Oral Glucose Tolerance Test, aged 12 years and older

Why are we asking participants to have an Oral Glucose Tolerance test (OGTT)?

We are asking teenagers and adults who are examined in the morning exam session to have an OGTT so we can learn more about how many people in the United States have diabetes.

Why is the study of diabetes in teenagers important?

Doctors and other health workers have seen an increase of type 2 diabetes in teenagers and adults over the past 20 years. This is an important problem since it can lead to many health problems such as heart disease, poor circulation, and blindness.

What is diabetes?

Diabetes mellitus is a group of diseases that cause high blood sugar levels. Type 1 diabetes was called insulin-dependent diabetes or juvenile diabetes and develops when the body's immune systems destroy the cells that make the hormone insulin that controls blood sugar levels. Type 2 diabetes was previously called non-insulin diabetes or adult-onset diabetes. Type 2 diabetes happens when the cells in our body do not use insulin right. In the past it was seen mostly in old people, overweight people, and people who were inactive. Today, type 2 diabetes is seen more and more in children and teenagers.

What will participants have to do to have the OGTT test?

Participants aged 12 years and older who are examined in the morning will be asked not to eat or drink anything (EXCEPT WATER) 9 hours before coming to the exam center. They will have their blood drawn for laboratory tests that include a fasting glucose test. They will then drink a special sugar drink. After 2 hours they will have more blood drawn to see how their body handled the sugar they drank.

What will this test tell participants about their health?

This test measures how the body handles sugar. We will be able to tell if a person is at risk for diabetes or already has it. The person or his or her parents will be told if the test shows a blood sugar problem.

Consent:

Page 3 of the consent brochure has been modified as follows:

Safety of Tests

We chose the tests and measurements because they are safe. Some of the exams or procedures may cause you slight discomfort. Examples are collecting a blood sample or fasting for 9 hours. For the blood sample, a person will have a small amount of blood drawn from a vein in his or her arm with a needle. Participants 12 years and older with a morning appointment will be asked to drink a sugar solution and have blood taken a second time. Although rare, the sugar solution can cause nausea, vomiting, bloating, or headache. We will not ask you to have any test or procedure that is wrong for you because of a health problem or condition.

1.3 MEC Overview

Diabetics taking insulin who are assigned to morning sessions are asked to fast for 9 hours so these SPs will be assigned to phlebotomy as the highest priority. They are not eligible for the GTT.

SPs aged 12 and older assigned to the morning session who have fasted for 9 hours are eligible for the GTT. It is generally important to assign SPs aged 12 and older to phlebotomy as soon as possible at the start of a session, but it is especially important during a morning session. It is also important to assess the fasting status of SPs aged 12 and older assigned to a morning session because they are not eligible for the GT examination if they have not met their 9-hour fast requirement. The coordinator gives each SP a hard-copy verification form as part of the check-in process. For SPs aged 12 and older who are examined during a morning session, it includes the question, “Did you eat or drink anything, other than plain water, after 11:30 last night?” The SP records “Yes” or “No” in a check box and the coordinator enters this information into the coordinator application (Exhibit 1-2). The coordinator application then highlights (hot pink) the names of SPs who responded “Yes.” The coordinator must queue these SPs after those who have met their fast, although judgment is always required when managing MEC flow.

If the 9-hour fast is not met but it will be met, and 1 hour and 45 minutes remains in the session, then the phlebotomist will wait to draw all the tubes, including the 2-mL gray top for glucose, until the 9-hour fast is met. A message will appear stating the time the SP will meet his or her 9-hour fast. The SP will be returned to the coordinator until his or her 9-hour fast has been met. The phlebotomy status will automatically default to “Not Done” with a comment of “Waiting to Meet Fast.” See Exhibit 1-3.

Exhibit 1-2. Fasting Questionnaire screen

Phlebotomy

File View Utilities Reports Window Help

Phlebotomy: Stand:430 Session:430060 12/09/2004 08:30 am - 12:30 pm

SP ID: 724907 Name: MARTIN#3, JOETTA Age: 46 years Gender: Male Date: 12/04/2009 Time: 01:20 PM


Fasting Questionnaire

When was the last time you ate or drank anything other than plain water? Do not include diet soda or black coffee or tea with artificial sweeteners like Sweet'N Low, NutraSweet, Equal, or Splenda. 01:00 AM 12/04/2009

Have you had any of the following since today at 1:00 AM?

Coffee or tea with cream or sugar? [Include milk or nondairy.]

Return for blood draw

 I will need to have you wait until approximately 10:00 AM before I can collect your blood. I will have the Coordinator bring you back here at the right time.

OK

Antacids, laxatives, or anti-diarrheals? No : //

Dietary supplements such as vitamins and minerals? [Include multivitamins and single nutrient supplements.] No : //

Fasting 7 Hours 23 Minutes

Exhibit 1-3. Phlebotomy Status screen

Phlebotomy

File View Utilities Reports Window Help

Phlebotomy: Stand:430 Session:430060 12/09/2004 08:30 am - 12:30 pm

SP ID: 724907 Name: MARTIN#3, JOETTA Age: 46 years Gender: Male Date: 12/04/2009 Time: 01:20 PM

Phlebotomy Status

Status

Complete

Partial

Not Done

Comments: Waiting to meet fast

Other text:

The SP will continue with other exams until the fast is met. Once the fast is met, the SP will be assigned back into phlebotomy to complete the blood draw. After blood draw, the SP can be assigned to the GT component so that he or she can drink the Trutol and have the second blood drawn 1 hour and 45 minutes later. The phlebotomist must take care not to give the SP juice and crackers at the conclusion of the first blood draw.

The coordinator will use the “GT” component in the coordinator application to assign and track SPs. After the initial phlebotomy examination, the SP will be assigned to the phlebotomy/OGTT, OGTT room in trailer 3, or the MEC Interview/OGTT room in trailer 2 for the first section of the GT component. If the SP is not excluded, then he or she will be instructed to drink a calibrated dose (generally 10 oz.) of a glucose solution (Trutol) immediately after the first venipuncture has been completed. The SP must drink the entire dose within 10 minutes. All MEC staff members, except the physician, have been trained to administer the Trutol. They monitor the time it takes for the SP to

consume the Trutol using the first of two sections in the OGTT application. After the SP has consumed the solution, he or she will continue with the other MEC exams.

The SP is eligible to return to phlebotomy for a second blood draw 2 hours, +/- 15 minutes, after he or she finished consuming the Trutol. (He or she must maintain the fast until the second blood draw is completed.) The coordinator will track the reassignment using the GT component in the coordinator application. After 105 minutes have elapsed since the SP finished drinking the solution, the coordinator will reassign the SP to the phlebotomy room for the second section of the GT component to have a second venipuncture performed. The phlebotomist will draw one additional 2-mL gray top tube for the OGTT test and any tubes that were not drawn during the first venipuncture. The second venipuncture must be complete 135 minutes after the SP finishes drinking the Trutol.

Most SPs will drink the Trutol solution in the OGTT or MEC interview/OGTT rooms. Some SPs may stay in the phlebotomy room to drink the Trutol, but this will generally occur only during lightly booked sessions. The coordinator must exercise judgment to determine the best location for the SP to consume the Trutol solution. Judgment should be guided by the goal to complete all MEC exams for an SP, balance the phlebotomist's workload, and assign the SP to the GT component as soon as possible after the initial venipuncture is complete.

It is critical that the SP drink the entire calibrated dose in 10 minutes as soon as possible after the first venipuncture is complete because he or she must wait at least 100 minutes before being eligible for the second blood draw. SPs must maintain their fast until the second blood draw is complete. Therefore, the entire MEC staff must be aware that the SP must continue the fast and must be sensitive to the discomfort caused by the Trutol and the effect of being around other SPs who may be eating or drinking juice. The SP may drink water. If an SP breaks his or her fast, then he or she is not eligible for the second blood draw but must be reassigned to OGTT in the phlebotomy room to complete the examination.

As noted earlier, drinking 10 oz. of Trutol may have some unpleasant side effects. These side effects may include nausea, vomiting, abdominal bloating, and/or headache. To enhance the palatability, chill enough of each flavor to accommodate all SPs scheduled into the session. Chill the solution in the refrigerators located in the OGTT room, spare room in trailer3, and phlebotomy/OGTT rooms. Protect from light, do not freeze, and discard any remaining solution. After the second blood draw, the phlebotomist will offer the SP animal crackers and juice.

A paper label prints on the Dymo printer in the OGTT, MEC Interview/OGTT, and phlebotomy/OGTT rooms. The label displays the time at which the SP is eligible for the second blood draw. Place this label on the upper-right side of the SP's paper top. All MEC staff members are responsible for monitoring the time on this label and ensuring that the SP is taken to the coordinator in time to be reassigned to phlebotomy for the second blood draw.

The MEC lab staff will process this OGTT vessel (#98) per the glucose protocol. They will use the "GTT" module that is similar to the urine collection module to record the vessel as filled "Yes" or "No." All SPs are listed in the same window in this module. The lab staff ships the samples weekly to the contract laboratory.

2. OGTT: TRUTOL ADMINISTRATION

2.1 MEC Staff Responsibilities

The MEC phlebotomist completes the initial blood collection procedure, which consists of (1) administering a questionnaire to screen for conditions that exclude the participant from the blood draw; (2) determining fasting status; and (3) performing a blood draw.

The OGTT application has been created to (1) calculate and display the amount of Trutol[®] that an SP should drink (calibrated dose); (2) monitor the time it takes for an SP to consume the Trutol solution; and (3) record the second venipuncture results. This application has been installed in the phlebotomy/OGTT, OGTT, and MEC Interview/OGTT rooms. All MEC staff members who administer the Trutol are responsible for using the first section of this application to administer the correct amount of Trutol for the weight of the SP and monitor the time it takes for the SP to drink the Trutol. After 105-135 minutes have elapsed since the SP consumed the Trutol, the phlebotomist is responsible for drawing a second 2-mL gray top tube and for using the second section of the OGTT application to record the results of the second blood draw.

After the first venipuncture is complete, the phlebotomist will escort the SP to the location identified in the message window. All MEC staff members with the exception of the physician are eligible to administer the Trutol in the OGTT room. The coordinator can also assign the SP to phlebotomy or the MEC interview rooms where the respective staff can administer the Trutol. When the SP is reassigned to phlebotomy for the second blood draw, the phlebotomist will draw one 2-mL gray top tube and any tubes that were missed during the first venipuncture.

2.2 Equipment and Supplies

The equipment and supplies used in the OGTT are listed in Exhibit 2-1. The average number of examined SPs aged 12 and older is 232 per stand.

At the start and end of each stand, the phlebotomist will take a complete inventory using procedures described in Chapter 11, Section 11.3 in the *Laboratory Procedures Manual*. The OGTT supplies are included in the phlebotomy start and end of stand inventory sheets.

Exhibit 2-1. Equipment and supplies – OGTT

OGTT	Par level
Trutol	
Orange (part number 401223)	48 bottles
Lemon-Lime (part number 401421)	24 bottles
Fruit Punch	36 bottles
2-mL gray top Vacutainer tube	3 trays of 100
Plastic drinking straws	2 boxes of 100
Dymo labels	7 rolls of 500 (for use in phlebotomy and BM and MEC Interview rooms)
Small graduated medicine cups	2 sleeves

The Trutol can travel from one stand to the next; it does not need to be sent back to the warehouse. Do not store the Trutol in the belly compartments as they are not climate controlled and there is the possibility that the Trutol could freeze. However, it is acceptable to pack the Trutol in boxes in the OGTT exam room.

The Trutol is good through the end of the month listed as the expiration date. If, at the end of the stand, any of the Trutol expires before the start of the next stand, then it should be discarded on site and the end of stand par level adjusted accordingly.

The phlebotomist should empty and clean the GTT refrigerators at the end of each stand and should prepare them for transit (block the door open like the other refrigerators.) The FES will need to secure the refrigerator so that it does not get moved around or get damaged in transit.

It is acceptable to refrigerate the Trutol, let it warm to room temperature, and then refrigerate it again.

2.3 Gaining Cooperation

The coordinator will introduce the SP to the OGTT examination and briefly explain the examination process. The coordinator can answer any general questions the SP has about venipuncture or the OGTT. However, the entire MEC staff must be prepared to answer all the questions the SP poses about the OGTT procedure and must convince the SP of the importance of participating in the OGTT component of the examination.

Prepare to answer questions about the rationale for the OGTT component, the discomfort involved and the side effects, and the composition of the Trutol. It is essential to create a pleasant atmosphere and maintain a pleasant attitude. To address SPs' concerns effectively, know the following information about the procedures used for the study:

Rationale

- Although the SP has provided much useful information in the household and individual interviews, the successful completion of the OGTT component of NHANES is critical to the success of the pilot. This information is contained in the introduction to this chapter. Diabetes is a large, growing, and costly public health problem in the United States and disproportionately affects racial and ethnic minorities. About 17 million Americans have diabetes and more than 1 million new cases of diabetes are diagnosed each year. It is the leading cause of kidney failure, non-traumatic lower extremity amputation, and blindness in working-age adults, and an estimated \$135 billion was spent on direct and indirect medical costs for diabetes in 2002. Alarming, type 2 diabetes (formerly considered an adult disease) is now being diagnosed in children and adolescents and there has been a large increase in diagnosed diabetes among adults <40 years of age.
- Persons with impaired glucose tolerance (IGT) – 15.6 percent of the U.S. population – are at high risk for developing diabetes. In addition, IGT is an important risk factor for a number of other adverse health conditions and mortality. IGT is defined based on an abnormal oral glucose tolerance test (OGTT). Persons without diabetes but with an OGTT 2-hour value of 140-199 mg/dl are considered to have IGT. Recent national and international randomized controlled trials have shown that diabetes can be delayed or prevented among persons with IGT. Furthermore, NHANES III data indicate a tremendous opportunity for the prevention of diabetes - over 12 million persons aged 45-74 have prediabetes (defined as overweight persons with either IGT or impaired fasting glucose metabolism). These data also indicated that over 50 percent of persons with prediabetes are only detected by IGT findings. As risk factors for diabetes, IGT, and prediabetes increase (e.g., physical inactivity, obesity, and aging), the prevalence of these conditions is likely to increase.

- The inclusion of OGTTs on NHANES will allow estimation of the prevalence of IGT and, thus, prediabetes in the U.S. population, surveillance of trends in the prevalence and awareness of these conditions, study of the risk factors for IGT and prediabetes, and examination of IGT as a risk factor for health conditions and mortality. Timely data on IGT and prediabetes are particularly important as the Nation initiates efforts to prevent diabetes among persons with prediabetes. These data on IGT and prediabetes are critical to targeting, designing, and evaluating prevention efforts, such as DHHS's STEPS program and efforts by the National Diabetes Education Program.

Discomfort and Side Effects

- Venipuncture causes only minimal discomfort. A certified, experienced phlebotomist performs venipunctures. A variety of blood collection needles are available so that the most appropriate size can be selected for each SP.
- Side effects of drinking the Trutol can include nausea, vomiting, abdominal bloating, and/or headache. To enhance the palatability, chill before serving. Protect from light, do not freeze, and discard any remaining solution.

Composition of the Trutol

Ten ounces of Trutol contains 75 grams of dextrose and 300 calories. The following items contain approximately the same amount of sugar:

- 2 cans of Pepsi or Coke (66 grams)
10 ounces of Coke or Pepsi has 33 grams of sugar and 121 calories
- 3/4 cup of raisins (86 grams)
1 cup contains 115 grams of sugar and 435 calories
- 1 cup of dried apricots (80 grams)
1 cup contains 80 grams of sugar and 310 calories
- A small McDonald's sundae (61 grams)
A 6.4-ounce McDonald's hot caramel sundae contains 61 grams of sugar and 360 calories

- A small McDonald's M&M McFlurry (90 grams)

A 12-ounce (small) McDonald's M&M McFlurry contains 90 grams of sugar and 630 calories

- A small McDonald's vanilla shake (67 grams)

A 12-ounce (small) McDonald's vanilla shake contains 67 grams of sugar and 430 calories

- A small Dairy Queen Misty slush (56 grams)

A small Dairy Queen Misty slush contains 56 grams of sugar and 454 calories

Creating a Pleasant Atmosphere and Positive Attitude

Gaining the cooperation of an SP is easier if the atmosphere in the examination room is pleasant and makes the SP feel comfortable. Below is a list of suggestions for creating a pleasant atmosphere in the examination room.

- Maintain a clean and uncluttered work area.
- Be aware of body image; a positive body image inspires confidence. Maintain a tidy appearance, erect posture, and a smile.
- Speak face to face with the subject and maintain eye contact. Staring at other areas in the room may cause the SP some uneasiness since it implies that he or she is not important. It also implies disinterest.
- Avoid nervous behaviors such as squirming and tapping that can be distracting. The SP may begin to feel nervous, hurried, and anxious because of such behaviors.

2.4 Exclusion Criteria

There are seven exclusion criteria. The phlebotomist will ask SPs aged 12-59 the shared exclusion pregnancy question if the question has not already been asked elsewhere in the MEC. Hemophilia and chemotherapy safety exclusion questions are asked and fasting status is assessed in phlebotomy as a prelude to the initial venipuncture examination. If the SP refuses one or more of the blood tubes, then he or she is excluded. The other two exclusion criteria are listed in the first screen of the first section of the OGTT examination.

Persons will be **excluded** from this component if they:

- Report that they are taking oral medications for diabetes (asked during the household interview or in OGTT);
- Report that they are taking insulin (asked during the household interview or in OGTT);
- Report that they are pregnant (shared exclusion question);
- Report that they have hemophilia (asked in phlebotomy);
- Report that they have received cancer chemotherapy in the last 3 weeks (asked in phlebotomy);
- Report that they have not fasted at least 9 hours (as determined by the fasting questionnaire in phlebotomy); and
- Refuse one or more blood tubes in phlebotomy during the initial venipuncture or if the phlebotomist is unable to draw at least one tube.

2.5 OGTT Application Overview

The OGTT application consists of two sections and five total screens. The first section contains the safety exclusion questions and monitors the time it takes the SP to drink the Trutol. This application is active in the BM, phlebotomy, and MEC Interview rooms. The second section is used by the phlebotomist to record the results of the second blood collection.

The first Trutol Administration Information section includes three screens. The first Exclusion Question screen includes the two exclusion questions and a “Length of Fast” read-only text box. The second Trutol Administer Information screen contains instructions, a “Length of Fast” read-only text box, a “Your weight is” text box, an “Amount to drink” calculation (in oz. and mL), a ‘Please drink this solution within 10 minutes’ script, a 10:00 timer, Start button, Start and Stop read-only text boxes, a timer Reset button and an “Amount of solution the SP drank” text box. The Trutol Administer Information section status screen displays after the first screen if the SP is excluded or after the second screen if the SP is not excluded.

The second blood draw section contains two screens. The first blood draw screen includes the second 2-mL gray top tube in the upper section and any tubes that were not drawn during the first venipuncture in the lower section. The second screen is the blood draw section status screen.

2.5.1 Introduce Exam to SP

Introduce the OGTT component as the “next component” in the SP’s exam profile. The first section of the OGTT application is used by the phlebotomist, MEC interviewers, health technologists, dietary and MEC interviewers, the medical technologist assigned to workstation 3, and the MEC manager to screen for safety exclusions and to administer and monitor the time it takes the SP to drink the Trutol solution.

The following “Talking Points” in Exhibits 2-2 and 2-3 have been developed to ensure that each examiner provides the same critical information to every SP.

2.6 OGTT Section 1 - Exclusion Questions and Trutol Administration

Two safety exclusion questions are asked in the Trutol administration section of the OGTT application. The first question asks the SP if he or she is taking insulin, and the second question asks if he or she is taking oral medications for diabetes. The insulin question is asked during the household interview. The oral medications question may be asked during the household interview, but in the event that it is not, then it is asked in the OGTT examination. Only a “Yes” response to either question will exclude the SP from the OGTT examination.

SPs who weigh less than 94 pounds must have a calibrated dose of Trutol. If the SP has been weighed in body measures, then the weight is pulled into the Trutol Administration screen and displayed in the “Your weight is” text box. If the SP has not been weighed in body measures, then the self-reported weight will be pulled into the Trutol Administration screen and displayed in the text box. (The self-reported weight is WGQ020 “How much do you weigh without clothes or shoes?”) If the self-reported weight is less than 100 pounds, then weigh the SP on the OGTT room floor scale.

The SP must meet the 9-hour fast requirement before he or she is eligible for the OGTT. The fasting time is based on information given during the fasting interview that was administered before the first venipuncture in phlebotomy.

Exhibit 2-2. Talking Points - English

OGTT Talking Points - English

- This test measures how your body handles sugar.
- We may be able to tell if you are at risk of developing diabetes or if you already have it.
- Diabetes is important because it is the leading cause of kidney failure, heart disease, stroke and blindness in working-age adults. Almost 41 million Americans are at risk of developing diabetes.
- We need you to drink 10 ounces of a chilled carbonated sugar solution. We have three flavors, fruit punch, lemon-lime, and orange.
- You must drink all 10 ounces within 10 minutes, although most people drink the solution in less than 4 minutes. I will use this computer to record the time you start and stop drinking and the amount that you drank.
- It's very important that you do not eat or drink anything, other than plain water, for the next 2 hours.
- In 2 hours you will return to the blood draw room to have one small blood tube drawn. We will give you juice and crackers once the blood tube has been drawn.
- The sugar solution drink can make some people feel thirsty. Feel free to ask any staff member for a glass of water at any time.
- After you finish drinking the solution, I will place a paper sticker on the outside of your top. This is the time at which you are eligible to return for the second blood draw. It helps the staff keep track of when the 2 hours are up and you need to go back and have the second blood draw.

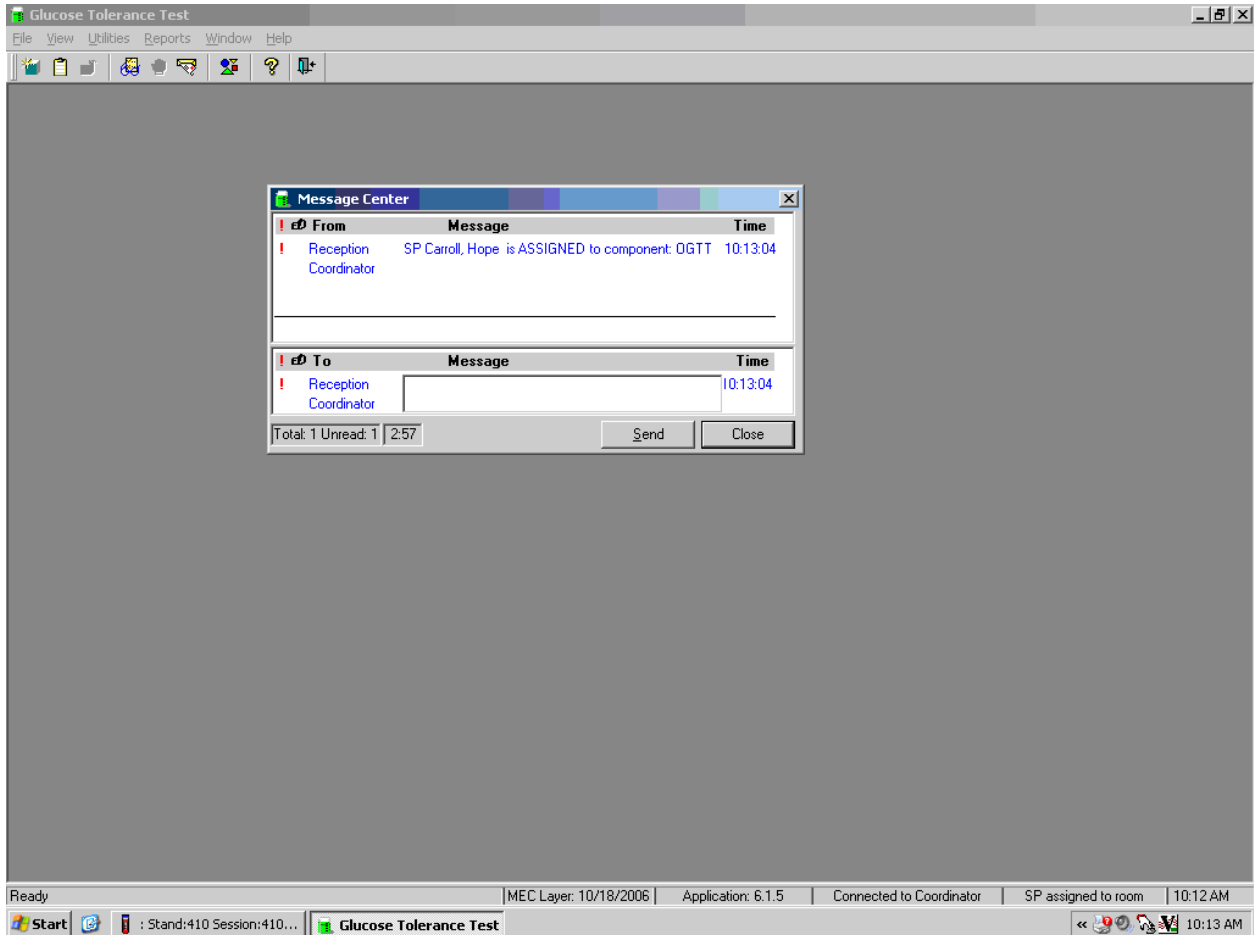
Exhibit 2-3. Talking Points – Spanish

OGTT Talking Points - Spanish

- Esta prueba mide la forma en que su cuerpo procesa el azúcar.
- Posiblemente le podremos decir si usted corre el riesgo de desarrollar diabetes o si ya la tiene.
- Es importante prestar atención a la diabetes porque es la causa principal de enfermedades de los riñones, enfermedades del corazón, ataque cerebral y ceguera en los adultos en edad laboral. Casi 41 millones de personas en Estados Unidos corren el riesgo de desarrollar diabetes.
- Necesitamos que tome 10 onzas de una solución fría de azúcar carbonatada. Tenemos tres sabores, ponche de fruta, lima-limón y naranja.
- Debe tomarse todas las 10 onzas en 10 minutos, aunque la mayoría de las personas se toman la solución en menos de 4 minutos. Usaré esta computadora para anotar el tiempo en que empezó y terminó de tomarla y la cantidad que tomó.
- Es muy importante que por las siguientes dos horas, no coma ni tome ninguna cosa, aparte de agua pura.
- Dentro de dos horas volverá a la habitación dónde se saca sangre para que le saquen la cantidad justa para llenar un tubito. Le daremos jugo y galletas después de sacarle sangre.
- Algunas personas pueden tener sed después de tomar la solución de azúcar. Puede pedirle a algún miembro del personal un vaso de agua en cualquier momento.
- Después de que termine de tomar la solución, le pondré un adhesivo de papel en la parte exterior de su camión. El adhesivo indicará la hora cuando usted debe volver para la segunda extracción de sangre. Esto ayuda al personal a llevar la cuenta de las dos horas y así saber cuándo se le debe sacar sangre por segunda vez.

The Message Center window (Exhibit 2-4) displays once an examiner and SP are assigned to the OGTT component.

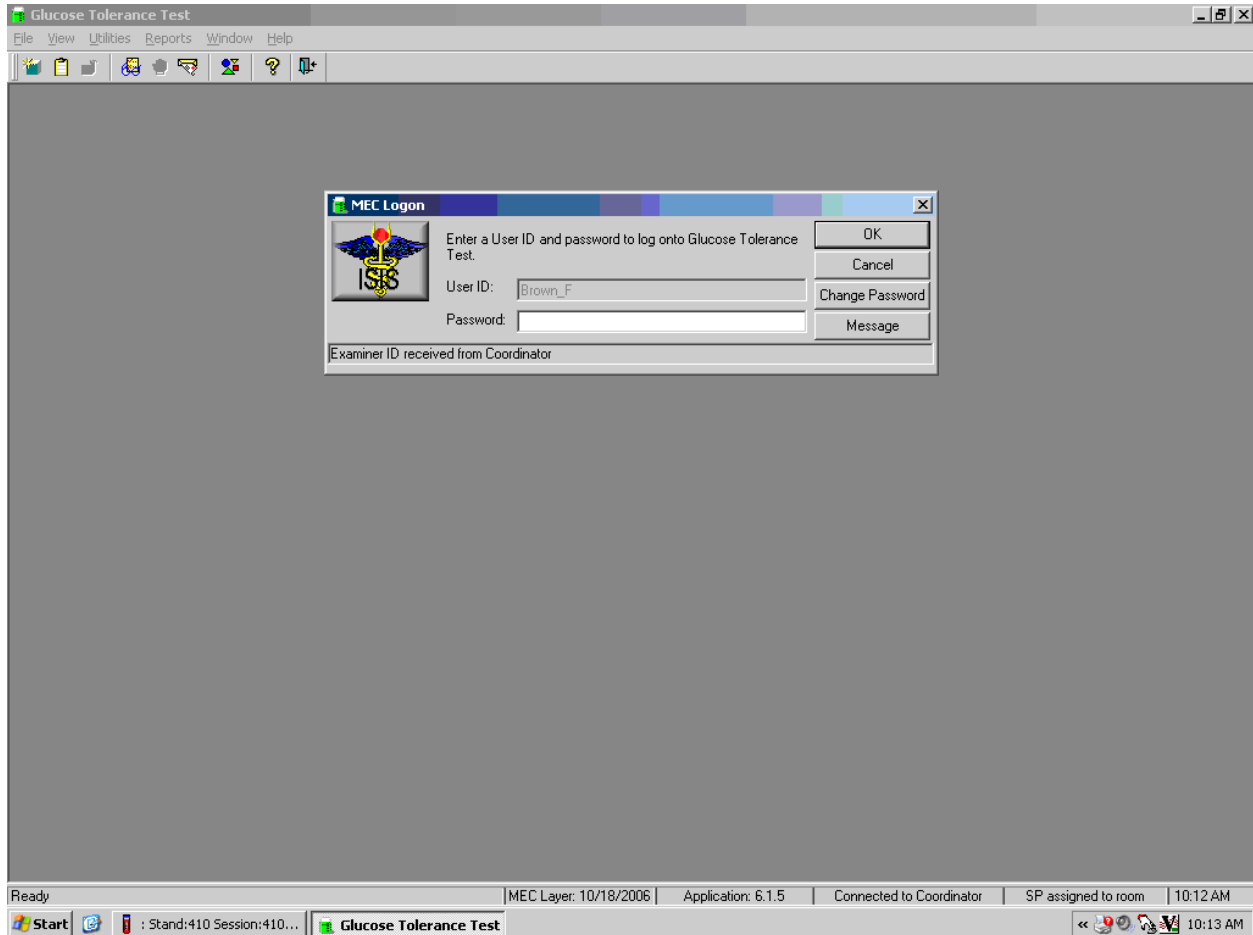
Exhibit 2-4. Message Center screen



A Message Center message text box displays containing a message from the coordinator indicating the name of the SP who is assigned to the OGTT component. Enter an optional text message and, to send the message to the coordinator, use the mouse to direct the mouse arrow to the Send button and left click. To exit without sending a message to the coordinator, use the mouse to direct the mouse arrow to the Close button and left click, or select [Enter].

The logon screen, shown below (Exhibit 2-5), appears after the coordinator assigns the examiner to the component and the assigned examiner accesses the OGTT application.

Exhibit 2-5. MEC Logon screen



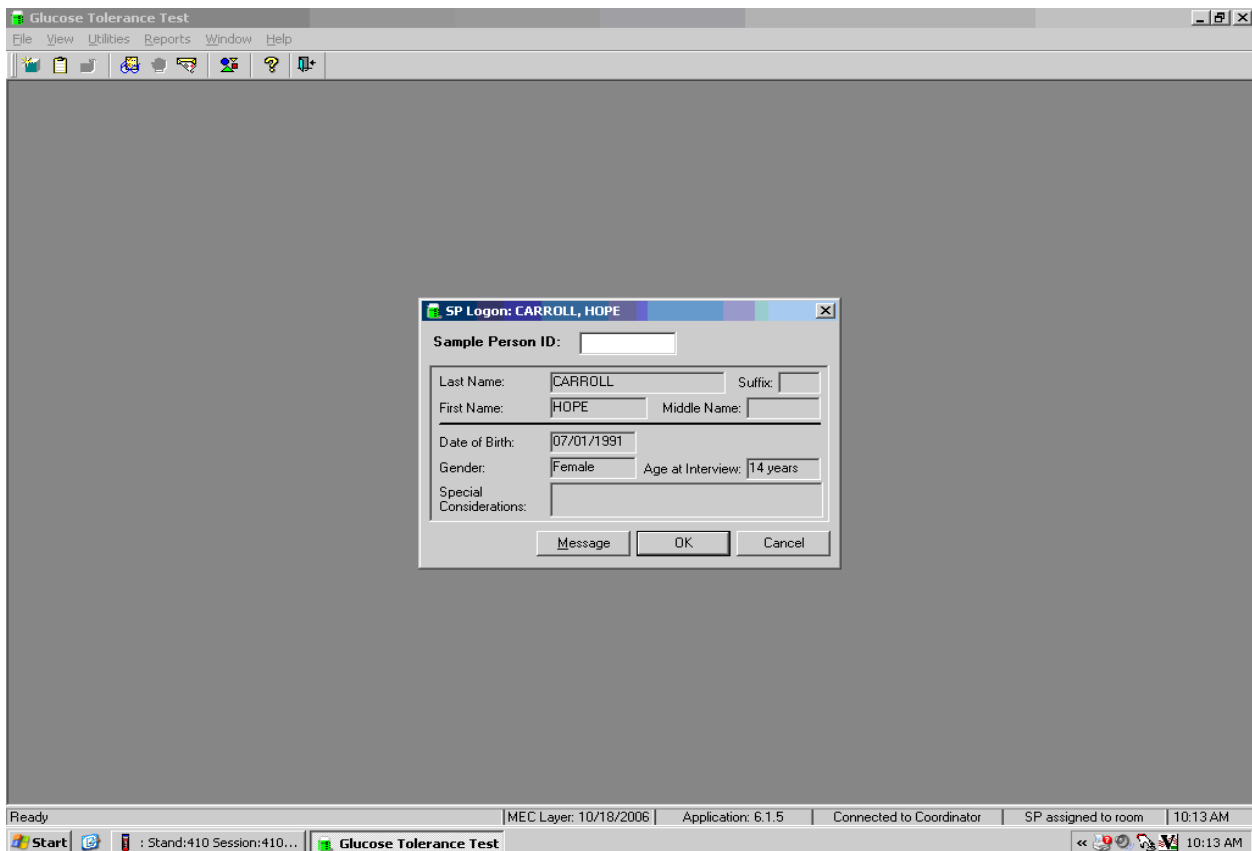
The MEC Logon window displays. The User ID (Last Name_First Initial) will automatically appear and cannot be changed. Type last name, underscore, first initial in the User ID space, and [Tab] or [Enter]. Enter the password using the keyboard keys and press [Tab], [Enter], or use the mouse to direct the arrow to the OK button and left click. To exit this screen without entering a password, use the mouse to direct the arrow to the Cancel button, and left click. Examiner logoff is automatic at the end of each examination.

Open the OGTT exam. To open an exam, use the mouse to direct the mouse arrow to {File} in the menu bar, left click, drag the arrow to {Open} and left click, or type [Alt] [F/f], [O/o], or [Ctrl] [O/o]. Log the SP into the exam component.

The SP Logon window displays (Exhibit 2-6) for the SP assigned to the component. To log the SP into the component, either read the SP ID from the SP's bracelet and manually type this number into the Sample Person ID text box, or use the bar code wand to scan the bracelet bar code. To continue, select [Enter] or use the mouse to direct the mouse arrow to the OK button, and left click. To cancel the logon process and to remove the window, use the mouse to direct the mouse arrow to the Cancel button, and left click.

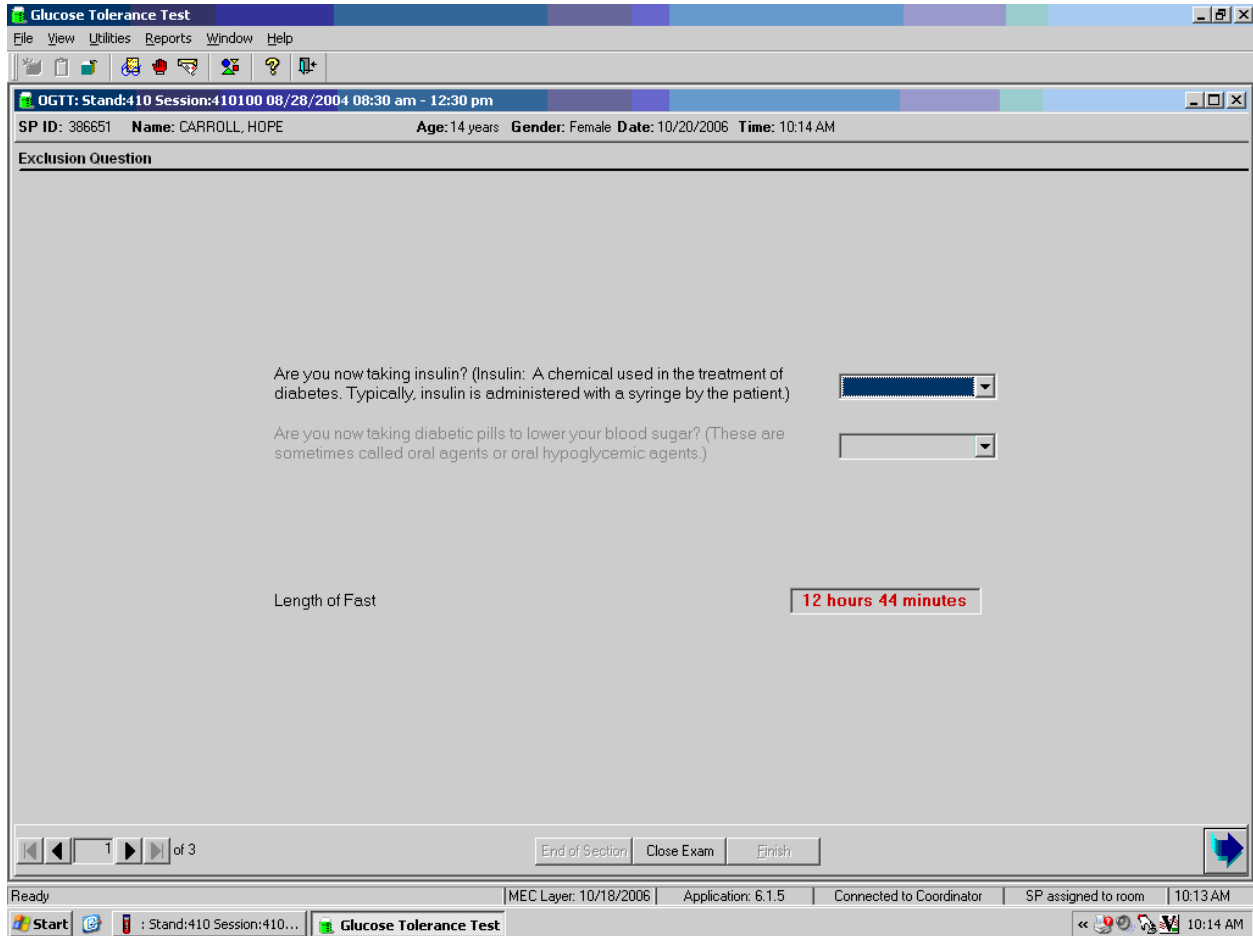
Verify all information that appears on the SP Logon window. If there is an error in any of this information, inform the coordinator immediately. The coordinator will verify and correct the information as necessary.

Exhibit 2-6. SP Logon screen



The Exclusion Question screen displays (Exhibit 2-7).

Exhibit 2-7. Exclusion Question screen (1)



The Exclusion Question screen lists the two safety exclusion questions and displays the Length of Fast timer. If the data for the first two questions was captured during the household interview, then the response is displayed in the text box and the text box is grayed out. The length of fast is initially captured by the fasting questionnaire screen in the phlebotomy application. The Length of Fast timer continues to update until this section is complete.

Use the following Q x Qs to guide the SP through the exclusion question interview.

Q1: Are you now taking insulin? (Insulin: A chemical used in the treatment of diabetes. Typically, insulin is administered with a syringe by the patient.) Yes, No, Refused, Don't know

<p>Q1: This question asks the SP if he or she is taking insulin, which is an exclusion criterion for this procedure.</p>	<p>Explain that SPs who are taking insulin are excluded due to safety concerns.</p> <p>Insulin is a hormone and therefore, a protein. Insulin is secreted by groups of cells within the pancreas called islet cells. The pancreas is an organ that sits behind the stomach and has many functions in addition to insulin production. The pancreas also produces digestive enzymes and other hormones. Carbohydrates (or sugars) are absorbed from the intestines into the bloodstream after a meal. Insulin is then secreted by the pancreas in response to this detected increase in blood sugar. Most cells of the body have insulin receptors, which bind the insulin, which is in the circulation. When a cell has insulin attached to its surface, the cell activates other receptors designed to absorb glucose (sugar) from the blood stream into the inside of the cell.</p> <p>Diabetes is a disease in which the body either fails to produce any insulin (type 1, also called insulin-dependent or juvenile-onset), or the insulin that it does produce is unable to adequately trigger the conversion of food into energy (type 2, also called non-insulin-dependent or adult-onset).</p> <p>SPs are asked to respond to DIQ050, “{Is SP/Are you} now taking insulin” during the household interview. The response choices are, 1=Yes, 2=No, 7=Refused, 9=Don't Know.</p> <p>If the SP answers, “Yes,” the SP is excluded from the OGTT.</p>
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	<p>If the SP answers, “Refused” the SP drinks the Trutol and receives a 2nd venipuncture for the OGTT.</p> <p>If the SP answers “No,” the SP drinks the Trutol and receives a 2nd venipuncture for the OGTT.</p> <p>If the SP answers “Don’t Know,” the SP drinks the Trutol and receives a 2nd venipuncture for the OGTT.</p> <p>Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” [R/r] if they refuse, or [D/d] for “Don’t know.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t Know” and left click. If the response is “Yes,” use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click or select [Enter].</p> <p>If the answer is “No,” “Refused,” or “Don’t Know,” then continue to the next question.</p>
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Q2: Are you now taking diabetic pills to lower your blood sugar? (These are sometimes called oral agents or oral hypoglycemic agents.) Yes, No, Refused, Don’t Know

<p>Q2: This question asks whether the SP is currently taking diabetic pills to lower his or her blood sugar, which is an exclusion criterion for this procedure.</p>	<p>Explain that SPs who are taking pills to lower blood sugar are excluded due to safety concerns.</p> <p>People take pills or capsules to lower the level of glucose in the blood. The pills work for some people with type 2 diabetes if their pancreas still makes some insulin. They can help the body in several ways, such as causing the cells in the pancreas to release more insulin.</p>
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A great deal of research toward the development of more effective ways of treating the disease has led to the development of orally active agents, including the [sulfonylureas](#) and the [biguanides](#). These oral agents have been widely received and are primarily used for the treatment of non-insulin-dependent type of diabetes.

Types of these pills for sale in the United States are:

- [Sulfonylureas](#) (many varieties)
- Biguanides: [metformin](#) (Glucophage)
- Alpha-glucosidase inhibitors: [acarbose](#) (Precose); miglitol (Glyset)
- Thiazolidinediones (or “glitazones”): [rosiglitazone](#) (Avandia); [pioglitazone](#) (Actos)
- Meglitinides: [repaglinide](#) (Prandin); nateglinide (Starlix)

Sulfonylureas

Generic Name: Tolbutamide (*Trade Name*: Orinase)

Generic Name: Acetohexamide (*Trade Name*: Dymelor)

Generic Name: Tolazamide (*Trade Name*: Tolinase)

Generic Name: Chlorpropamide (*Trade Name*: Diabinese)

Generic Name: Glipizide (*Trade Name*: Glucotrol, Glucotrol XL)

Generic Name: Glyburide (*Trade Name*: Diabeta, Micronase, Glynase)

Generic Name: Glimepiride (*Trade Name*: Amaryl)

Metformin

Pioglitazone

Rosiglitazone (Avandia)

Repaglinide (Prandin)

	<p>SPs may be asked DIQ070 “{Is SP/Are you} now taking diabetic pills to lower {his/her}/your} blood sugar? These are sometimes called oral agents or oral hypoglycemic agents” as part of the household interview. However, because this is dependent on a positive response to a previous question, most SPs will not be asked this question before they get to the OGTT component. The response choices are, 1=Yes, 2=No, 7=Refused, 9=Don’t Know.</p> <p><u>If the SP answers “Yes,” the SP is excluded from the OGTT.</u></p> <p>If the SP answers “Refused,” the SP drinks the Trutol and receives a second venipuncture for the OGTT.</p> <p>If the SP answers “No,” the SP drinks the Trutol and receives a second venipuncture for the OGTT.</p> <p>If the SP answers “Don’t Know,” the SP drinks the Trutol and receives a second venipuncture for the OGTT.</p> <p>Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” [R/r] if they refuse, or [D/d] for “Don’t know.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t Know” and left click. If the response is “Yes,” use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click or select [Enter].</p> <p>If the answer is “No,” “Refused,” or “Don’t Know,” then continue to the next screen.</p>
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2.6.1 Recording Responses to the Exclusion Questions

If the text box is not grayed out, then ask the first exclusion question, “Are you now taking insulin?” Record the exact response (Exhibit 2-8).

Exhibit 2-8. Exclusion Question screen (2)

The screenshot displays the 'Glucose Tolerance Test' software interface. The window title is 'Glucose Tolerance Test' and the menu bar includes 'File', 'View', 'Utilities', 'Reports', 'Window', and 'Help'. The main window content shows patient information: 'OGTT: Stand:410 Session:410100 08/28/2004 08:30 am - 12:30 pm', 'SP ID: 386651', 'Name: CARROLL, HOPE', 'Age: 14 years', 'Gender: Female', 'Date: 10/20/2006', and 'Time: 10:14 AM'. The section is titled 'Exclusion Question'. The question text reads: 'Are you now taking insulin? (Insulin: A chemical used in the treatment of diabetes. Typically, insulin is administered with a syringe by the patient.)' and 'Are you now taking diabetic pills to lower your blood sugar? (These are sometimes called oral agents or oral hypoglycemic agents.)'. A drop-down menu is open, showing options: 'Yes', 'No', 'Refused', and 'Don't Know'. Below the question, the 'Length of Fast' is displayed as '12 hours 44 minutes'. At the bottom of the window, there are navigation buttons: 'End of Section', 'Close Exam', and 'Finish'. The Windows taskbar at the bottom shows the system tray with the time '10:14 AM' and the Start button.

Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” [R/r] if he or she refuses, or [D/d] for “Don’t Know.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t Know,” and left click. If the response is “Yes,” use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click or select [Enter]. If the answer is “No,” “Refused,” or “Don’t know,” ask the next question.

If the SP has not been excluded, continue the exclusion question interview by asking the second question displayed on the screen (Exhibit 2-9), “Are you now taking diabetic pills to lower your blood sugar?”

Exhibit 2-9. Exclusion Question screen (3)

The screenshot shows a software window titled "Glucose Tolerance Test". The menu bar includes "File", "View", "Utilities", "Reports", "Window", and "Help". The toolbar contains various icons for file operations and help. The main content area is titled "Exclusion Question" and contains the following text and controls:

Are you now taking insulin? (Insulin: A chemical used in the treatment of diabetes. Typically, insulin is administered with a syringe by the patient.)

Are you now taking diabetic pills to lower your blood sugar? (These are sometimes called oral agents or oral hypoglycemic agents.)
Yes
No
Refused
Don't Know

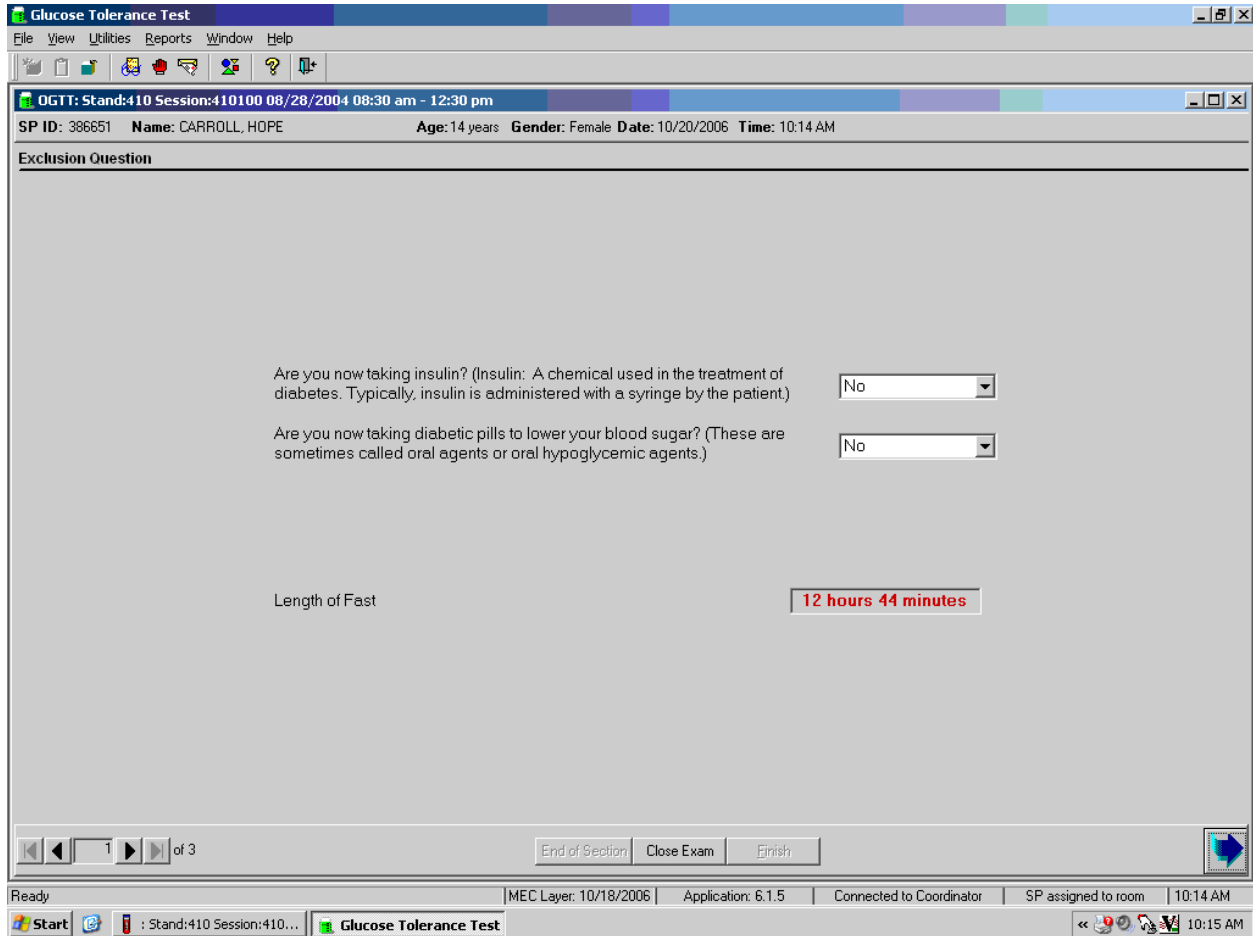
Length of Fast

The bottom of the window features a navigation bar with "End of Section", "Close Exam", and "Einish" buttons, and a blue arrow icon. The Windows taskbar at the bottom shows the Start button, a taskbar with "Stand:410 Session:410..." and "Glucose Tolerance Test", and a system tray with the time "10:15 AM".

Record the response by typing [Y/y] for “Yes,” [N/n] for “No,” [R/r] if he or she refuses, or [D/d] for “Don’t know.” Alternatively, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “Yes,” “No,” “Refused,” or “Don’t Know,” and left click. If the response is “Yes,” use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click. If the answer is “No,” Refused,” or Don’t know,” continue to the next slide.

Review the length of fast; this is informational only.

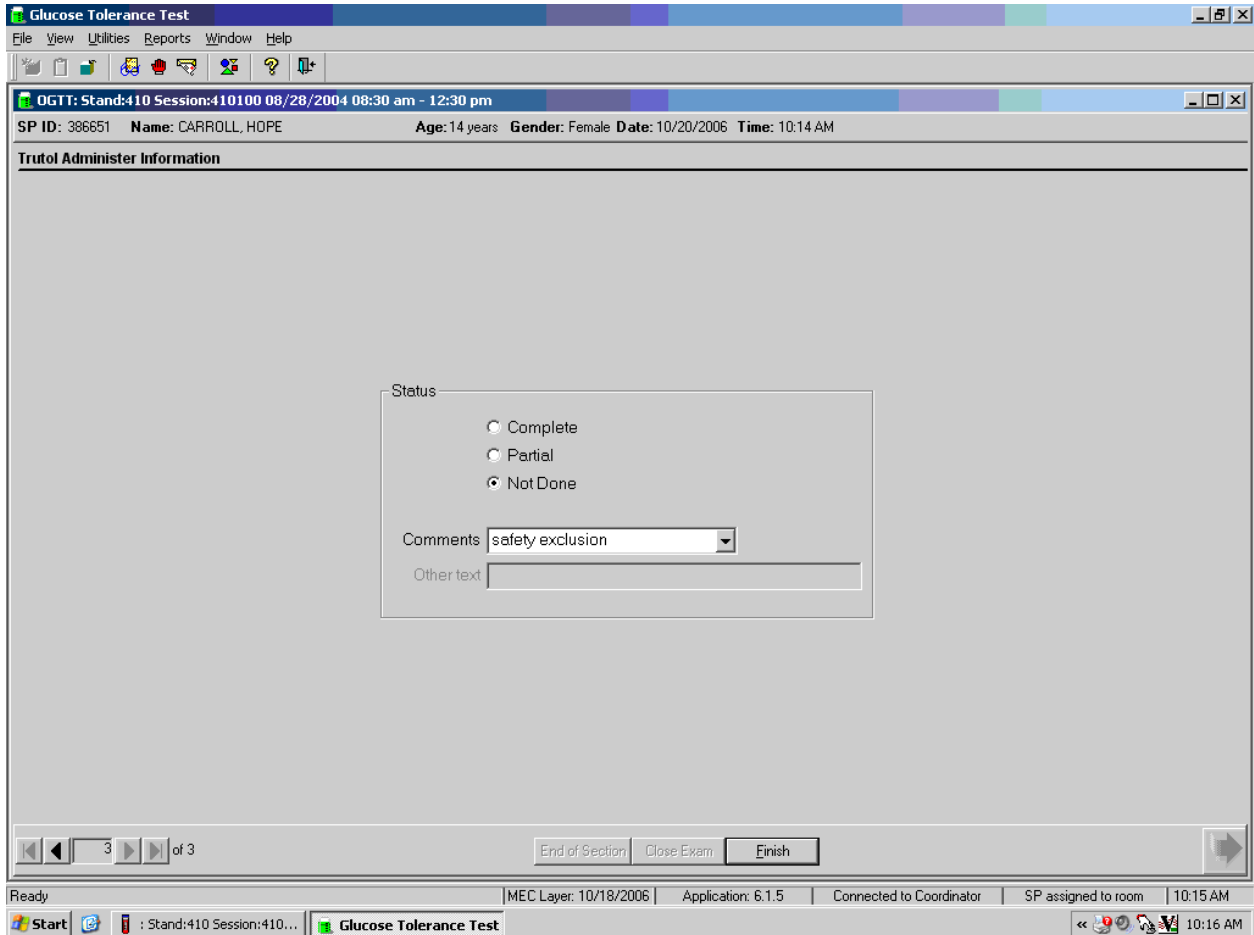
Exhibit 2-10. Exclusion Question screen (4)



To progress to the Trutol Administer Information screen (Exhibit 2-11), use the mouse to direct the mouse arrow to the bright blue arrow in the bottom right corner and left click, or select [Enter].

SPs excluded due to a “Yes” response to either of the two exclusion questions are automatically coded by the application as “safety exclusion.”

Exhibit 2-11. Trutol Administer Information screen (1)



Escort the SP back to the coordinator or to the next component as directed by the Message Center.

2.6.2 Trutol Administer Information

If the SP is not excluded, then the Trutol Administer Information screen displays (Exhibit 2-12). Review the length of fast; this is informational only.

Exhibit 2-12. Trutol Administer Information screen (2)

The screenshot shows a software window titled "Glucose Tolerance Test" with a menu bar (File, View, Utilities, Reports, Window, Help) and a toolbar. The main content area is titled "OGTT: Stand:410 Session:410100 08/28/2004 08:30 am - 12:30 pm" and displays patient information: "SP ID: 386651 Name: CARROLL, HOPE Age: 14 years Gender: Female Date: 10/20/2006 Time: 10:14 AM". Below this is the "Trutol Administer Information" section, which includes:

- Length of Fast:
- Your weight is: LBs
- Amount to drink is 10 oz (295 ml)
- Please drink this solution within 10 minutes.
- Timer: with Start and Reset buttons.
- Start:
- Stop:
- Total:
- Amount of solution the SP drank:

At the bottom of the window, there are navigation buttons (Back, Forward, Home, End of Section, Close Exam, Finish) and a status bar showing "Ready", "MEC Layer: 10/18/2006", "Application: 6.1.5", "Connected to Coordinator", "SP assigned to room", and "10:18 AM". The Windows taskbar at the very bottom shows the Start button, a taskbar with "Stand:410 Session:410...", and the system tray with the time "10:19 AM".

The Trutol Administer Information screen contains a “Length of Fast” timer, a “Your weight is” text box, an “Amount to drink” calculation, a script (“Please drink this solution within 10 minutes.”) to recite to the SP, a 10:00 timer to record the Start, Stop, Total elapse time, and a text box to record the “Amount of the solution” (Trutol) that the SP consumed.

If the SP has been weighed in body measures, then the weight is pulled into the Trutol Administration screen and displayed in the “Your weight is” text box. If the SP has not been weighed in body measures, then the self-reported weight will be pulled into the Trutol Administration screen and displayed in the text box. (The self-reported weight is WGQ020 “How much do you weigh without clothes or shoes?”)

If the self-reported weight is less than 100 pounds, then weigh the SP on the floor scale. SPs who weigh less than 94 pounds must have a calibrated dose of Trutol. Enter the weight into the “Your weight is” text box and select [TAB]. The application will calculate the amount of Trutol to remove from the Trutol bottle. Use a small medicine cup to measure the correct amount to remove and then discard the excess Trutol. Exhibit 2-13 illustrates the correct dosage per lb. or kg.

Exhibit 2-13. Trutol Calibrated Dosage Chart

Body weight		75g concentration		Remove	
lb.	kg	oz.	mL	oz.	mL
94+	42.7+	10.0	295	0	0
90-93	40.9	9.5	283	0.5	12
85-89	38.6	9.0	267	1.0	28
80-84	36.4	8.5	251	1.5	44
75-79	34.1	8.0	235	2.0	60
70-74	31.8	7.4	220	2.6	75
65-69	29.5	6.9	204	3.1	91
60-64	27.3	6.4	188	3.6	107

If the SP consumes the entire dose of Trutol, then the examiner must place a Dymo label on the outside of the SP’s top. The time displayed is the earliest time at which the SP is eligible for the GTT blood draw. The SP is eligible for the second blood draw 1 hour and 45 minutes after the time he or she consumed the Trutol, but the second blood draw must occur within 2 hours and 15 minutes after consuming the Trutol. The entire MEC staff should monitor the SP and the time displayed on the top. Encourage the SP to continue his or her fast.

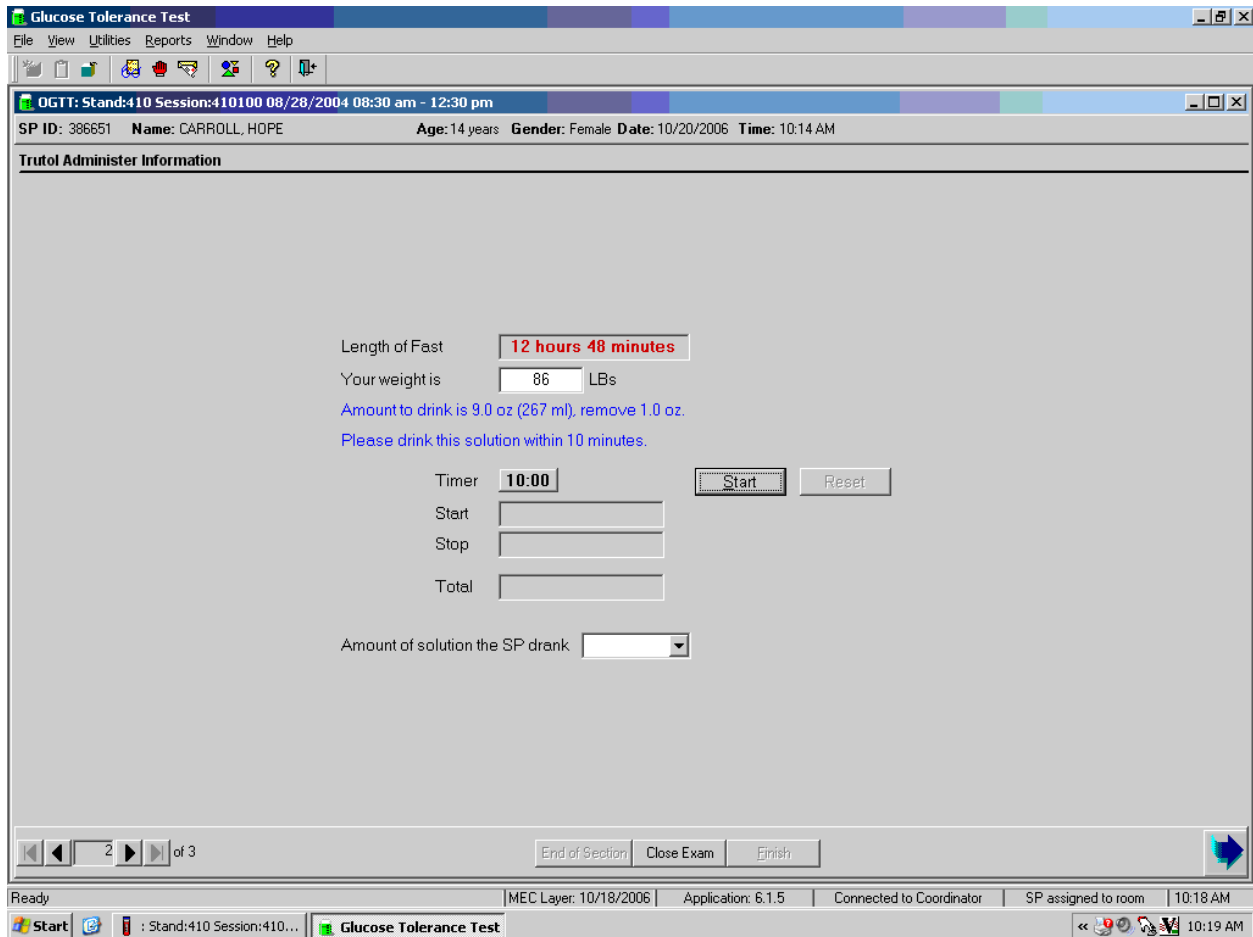
Taking an SP's Weight

Follow these steps to take the SP's weight:

1. Make sure the scale weighs in pounds by checking the switch on the underside of the digital display.
2. Place the scale on the floor.
3. Switch on the scale by pressing the ON button; 888.8 will appear on the digital display.
4. Have the SP remove his or her shoes and any heavy outer clothing such as sweaters, jackets, etc.
5. As soon as the display switches to 0.0, have the SP step on the scale with his or her feet positioned in the center.
6. Ask the SP to stand straight and remain still.
7. Wait about 4 seconds for the weight to display on the digital readout.
8. Record the weight in pounds in the "Your weight is" text box.
9. Ask the SP to step off the scale. The scale switches off automatically after 30 seconds.

Enter the weight into the “Your weight is” text box (Exhibit 2-14) and select [TAB]. The application will calculate and display the calibrated dose of Trutol.

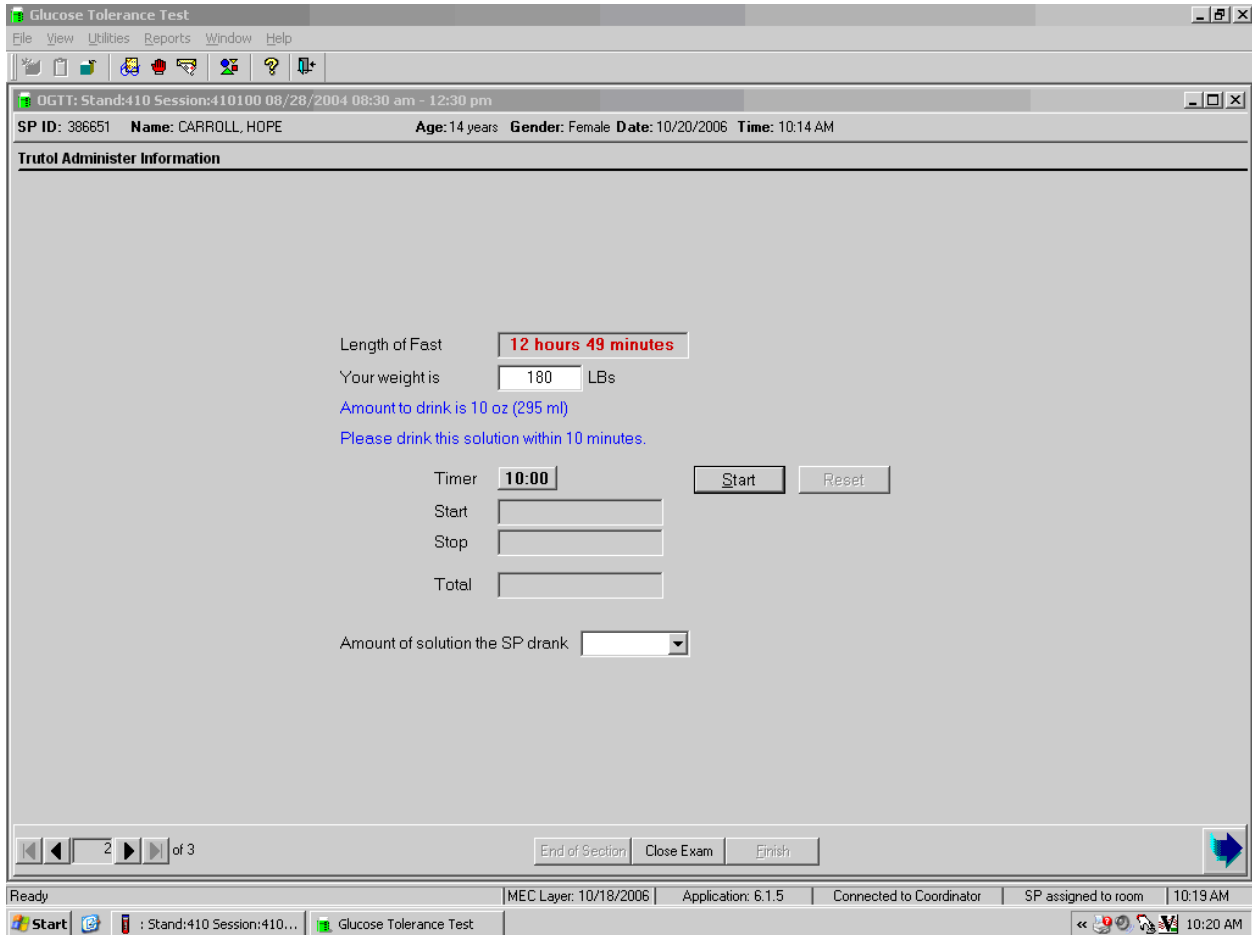
Exhibit 2-14. Trutol Administer Information screen (3)



Ask the SP to indicate a preference for one of the three flavors. Choose the flavor that matches the preference of the soft drink flavor that he or she prefers. Follow the instructions; remove the correct amount of Trutol from the bottle before handing the bottle to the SP. Use a small medicine cup to measure the correct amount to remove and discard the excess Trutol. Hand the SP a cold bottle of Trutol (containing the calibrated dose) and a straw. SPs MUST consume the entire calibrated dose of the Trutol within 10 minutes.

Recite the script “Please drink this solution within 10 minutes” and start the timer (Exhibit 2-15). The timer counts down from 10:00 minutes.

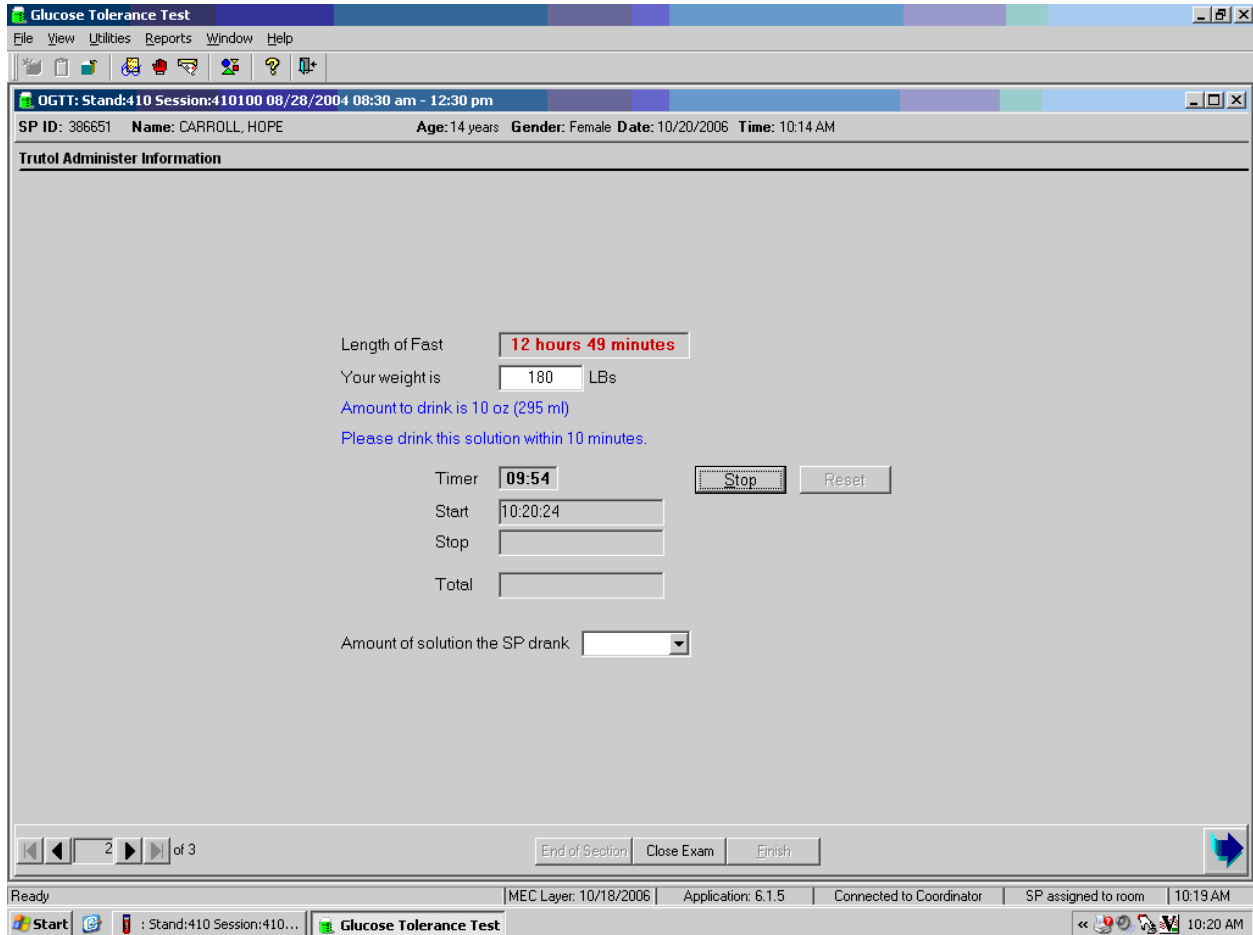
Exhibit 2-15. Trutol Administer Information screen (4)



To start the timer, use the mouse to direct the mouse arrow to the start button and left click or type [Alt] [S/s].

When the SP has finished drinking the entire calibrated dose of Trutol, or cannot continue drinking the Trutol, then select the Stop button (Exhibit 2-16).

Exhibit 2-16. Trutol Administer Information screen (5)

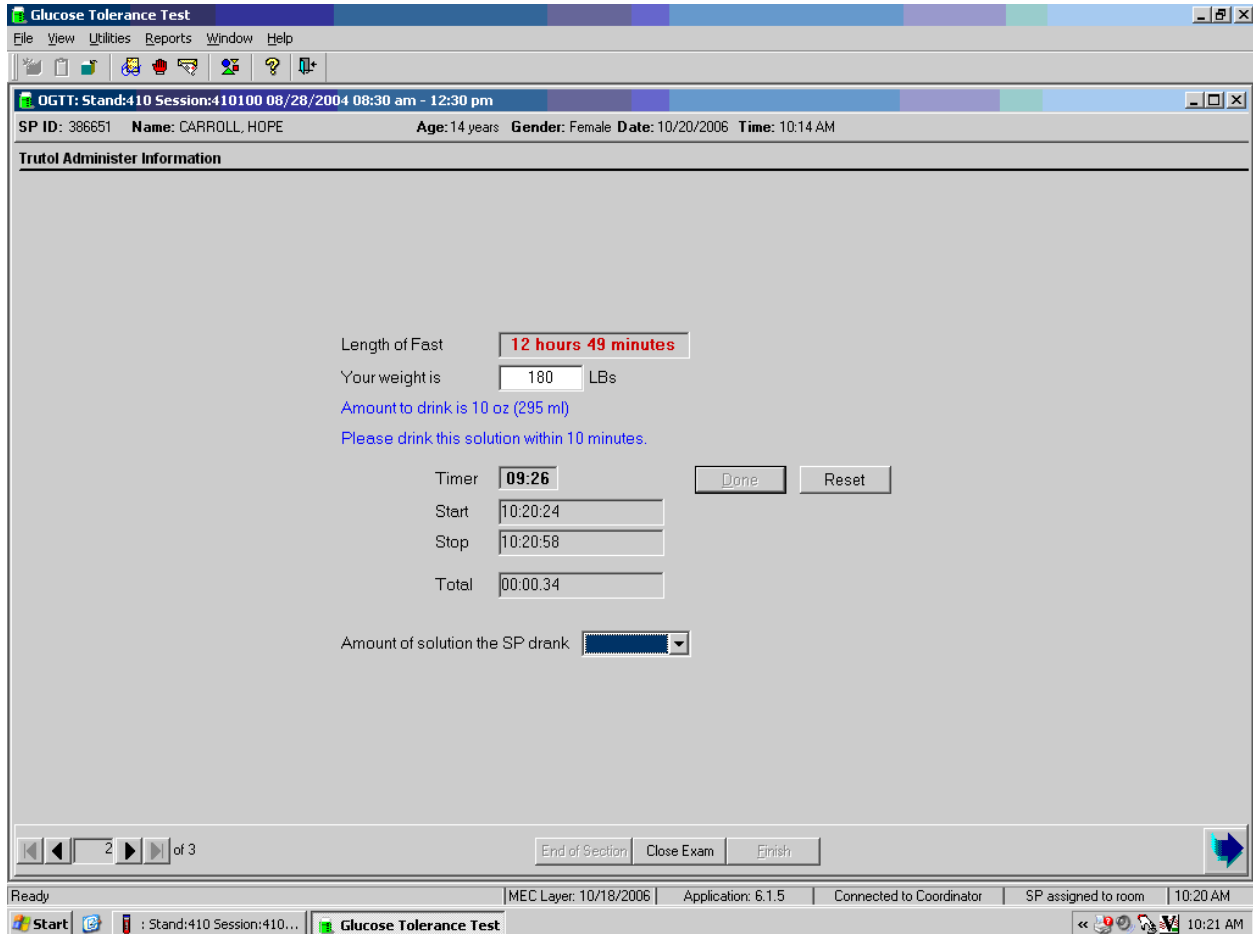


To stop the timer, use the mouse to direct the mouse arrow to the Stop button, and left click or type [Alt] [S/s].

It is possible to restart the timer.

To restart the timer, use the mouse to direct the mouse arrow to the Reset button and left click (Exhibit 2-17). The Start, Stop, and Total fields will be cleared and the Start button will be enabled.

Exhibit 2-17. Trutol Administer Information screen (6)



Record the amount of Trutol that the SP consumed (Exhibit 2-18).

The choices for the amount of solution that the SP consumed are “All,” “Some,” or “None.” To record the amount, use the mouse to direct the mouse arrow to the drop-down arrow on the drop-down list, left click to display the responses, and drag the mouse arrow to “All,” “Some,” or “None” and left click. To progress to the section status screen, use the mouse to direct the mouse arrow to the bright blue right arrow in the bottom right corner of the screen and left click.

Exhibit 2-18. Trutol Administer Information screen (7)

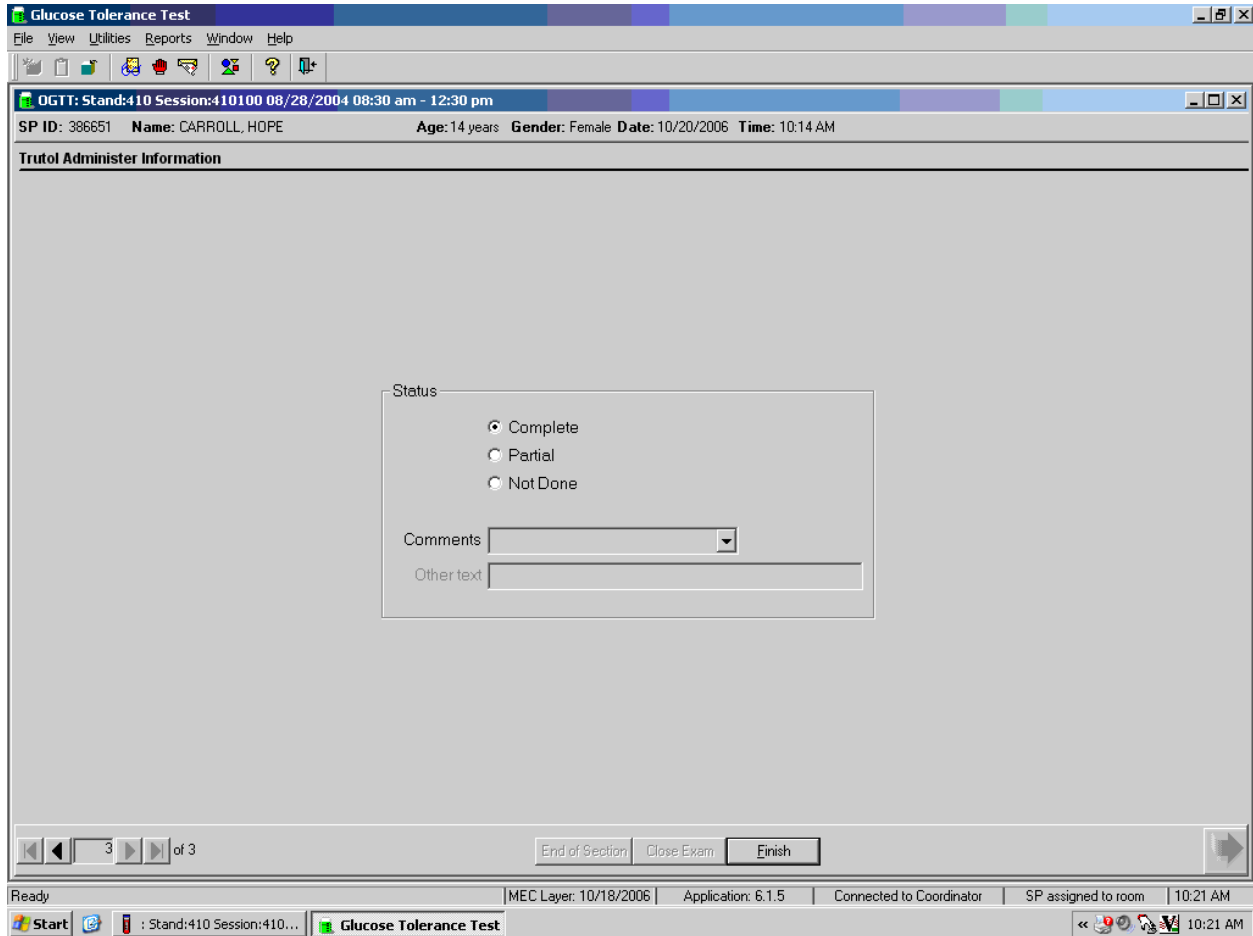
The screenshot displays the 'Glucose Tolerance Test' software interface. The window title is 'Glucose Tolerance Test' and the menu bar includes 'File', 'View', 'Utilities', 'Reports', 'Window', and 'Help'. The main content area is titled 'Trutol Administer Information' and contains the following fields and controls:

- Length of Fast:
- Your weight is: LBs
- Amount to drink is 10 oz (295 ml)
- Please drink this solution within 10 minutes.
- Timer:
- Start:
- Stop:
- Total:
- Amount of solution the SP drank: (dropdown menu open showing options: All, Some, None)

At the bottom of the screen, there are navigation buttons: 'End of Section', 'Close Exam', and 'Finish'. A status bar at the very bottom shows 'Ready', 'MEC Layer: 10/18/2006', 'Application: 6.1.5', 'Connected to Coordinator', 'SP assigned to room', and '10:20 AM'. The taskbar at the bottom of the window shows the 'Start' button, a taskbar icon for 'Stand:410 Session:410...', and the 'Glucose Tolerance Test' application icon.

Verify the Trutol Administer Information section status (Exhibit 2-19).

Exhibit 2-19. Trutol Administer Information screen (8)



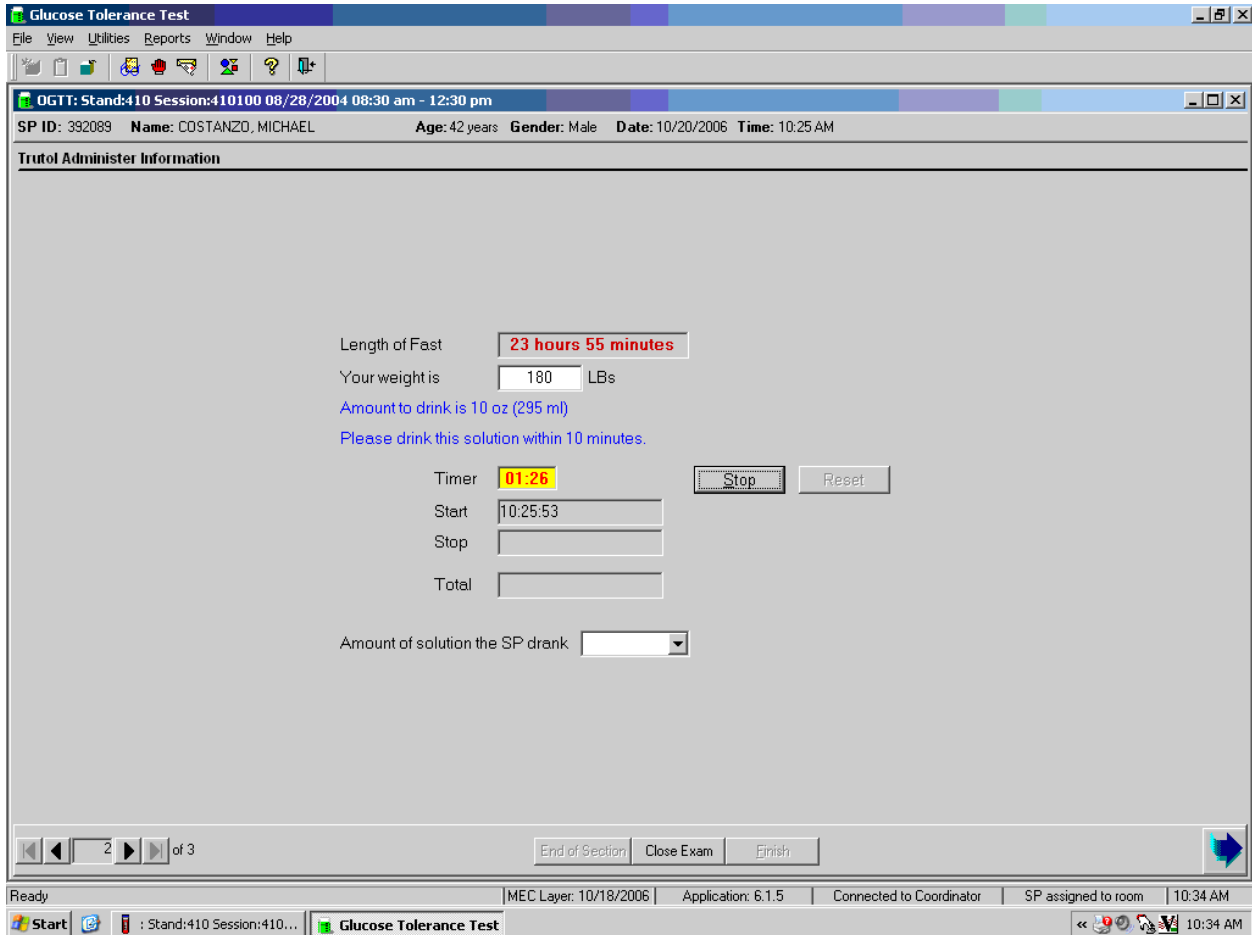
If the SP drank all of the Trutol solution, then the section status is complete. To complete the examination, use the mouse to direct the mouse arrow to the Finish button or type [Enter].

NOTE: Place the Dymo label with the return time on the outside of the SP's top.

Please return this SP for
OGTT Blood Draw at
10:59 am

The timer counts down from 10:00 minutes. When the timer reaches 1:40, the background turns yellow and the numbers change to red (Exhibit 2-20).

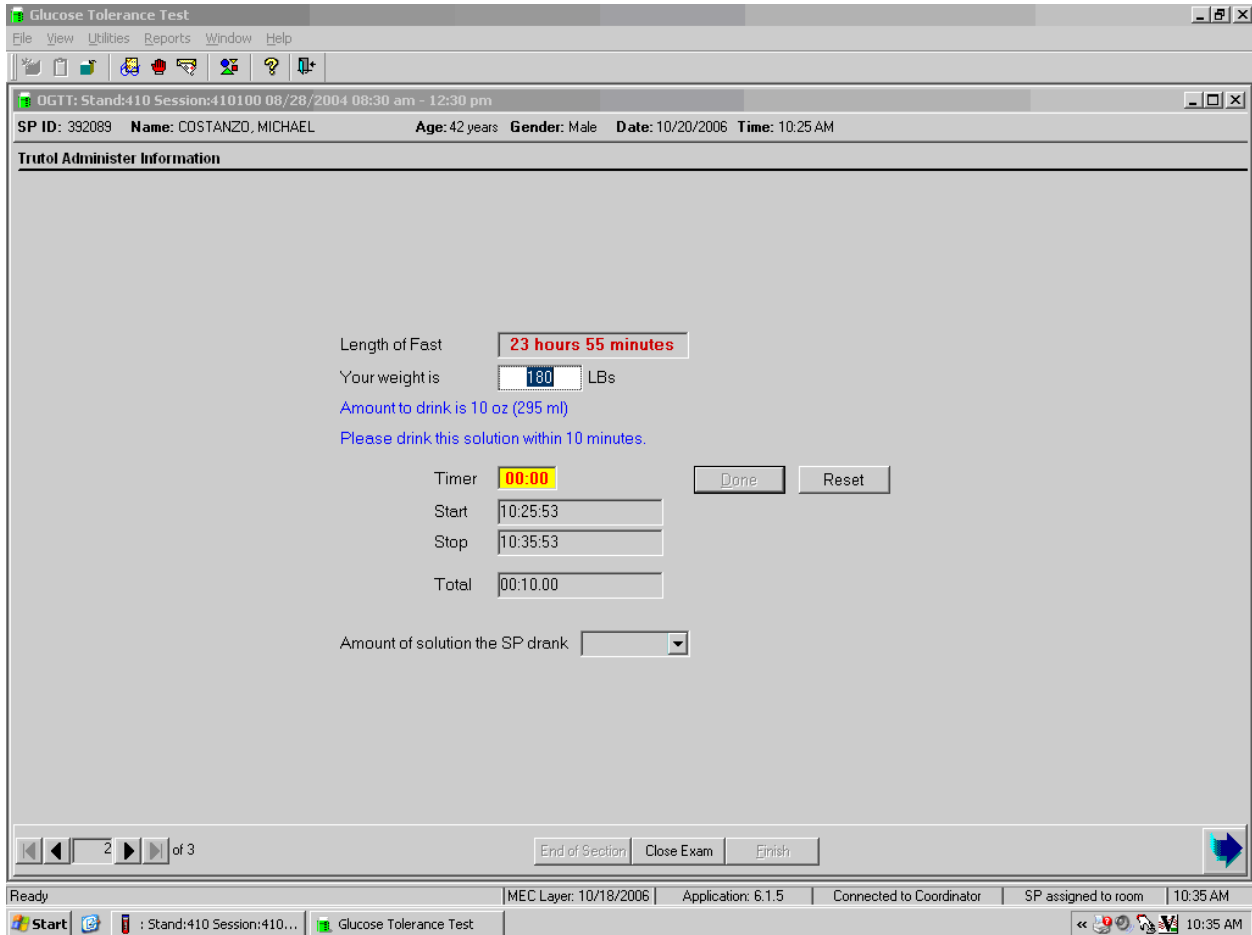
Exhibit 2-20. Trutol Administer Information screen (9)



Monitor the timer display. Coach or encourage the SP to drink the solution before the 10 minutes expire.

If the total time is greater than 10 minutes, then the timer will automatically stop at 00:00 and insert 00:10:00 in the Total field (Exhibit 2-21).

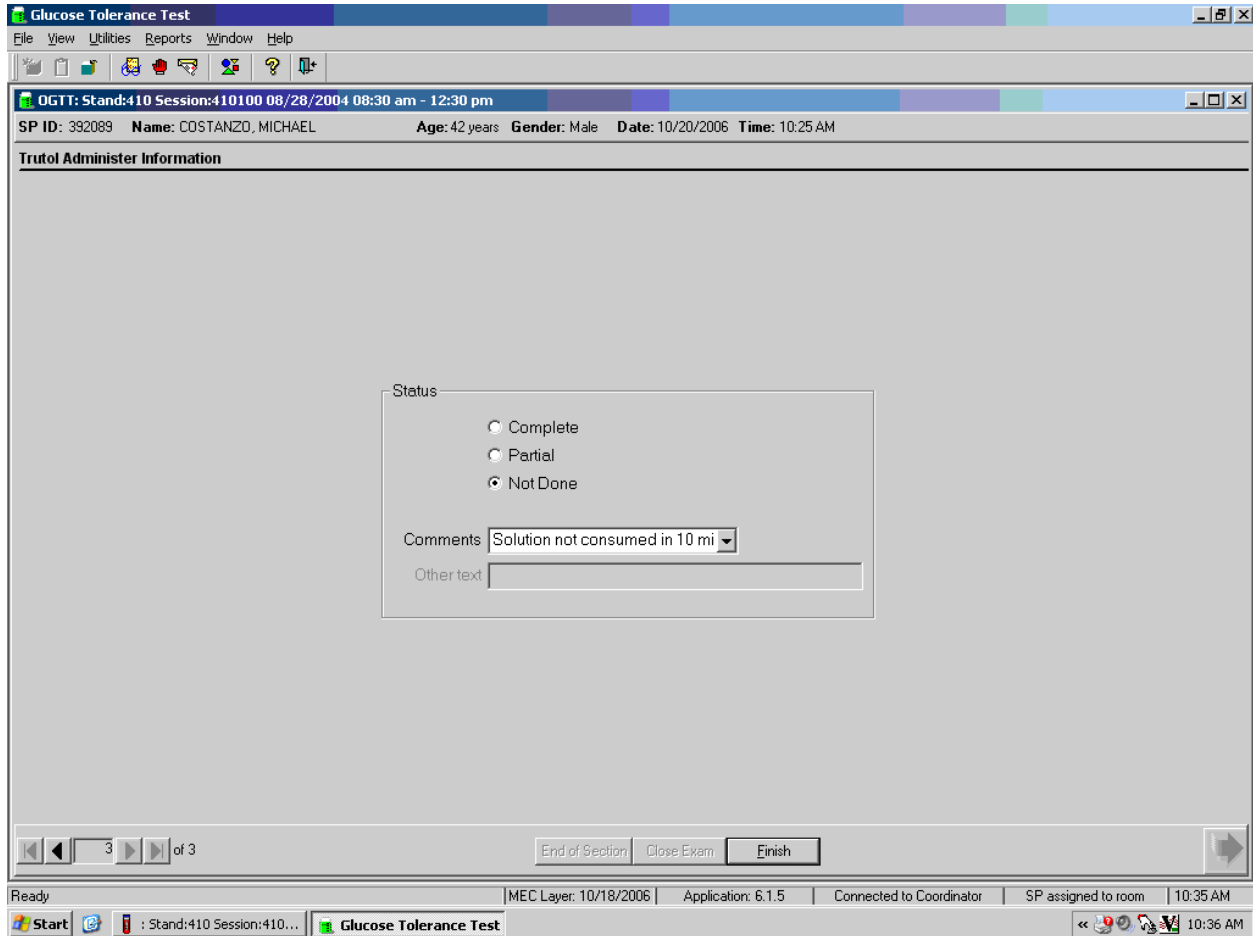
Exhibit 2-21. Trutol Administer Information screen (10)



Record the amount of solution the SP drank and proceed to the section status screen. If the SP drank “some” or “none” of the Trutol solution, then the section status is Not Done.

Review the comment in the section status screen (Exhibit 2-22).

Exhibit 2-22. Trutol Administer Information screen (11)

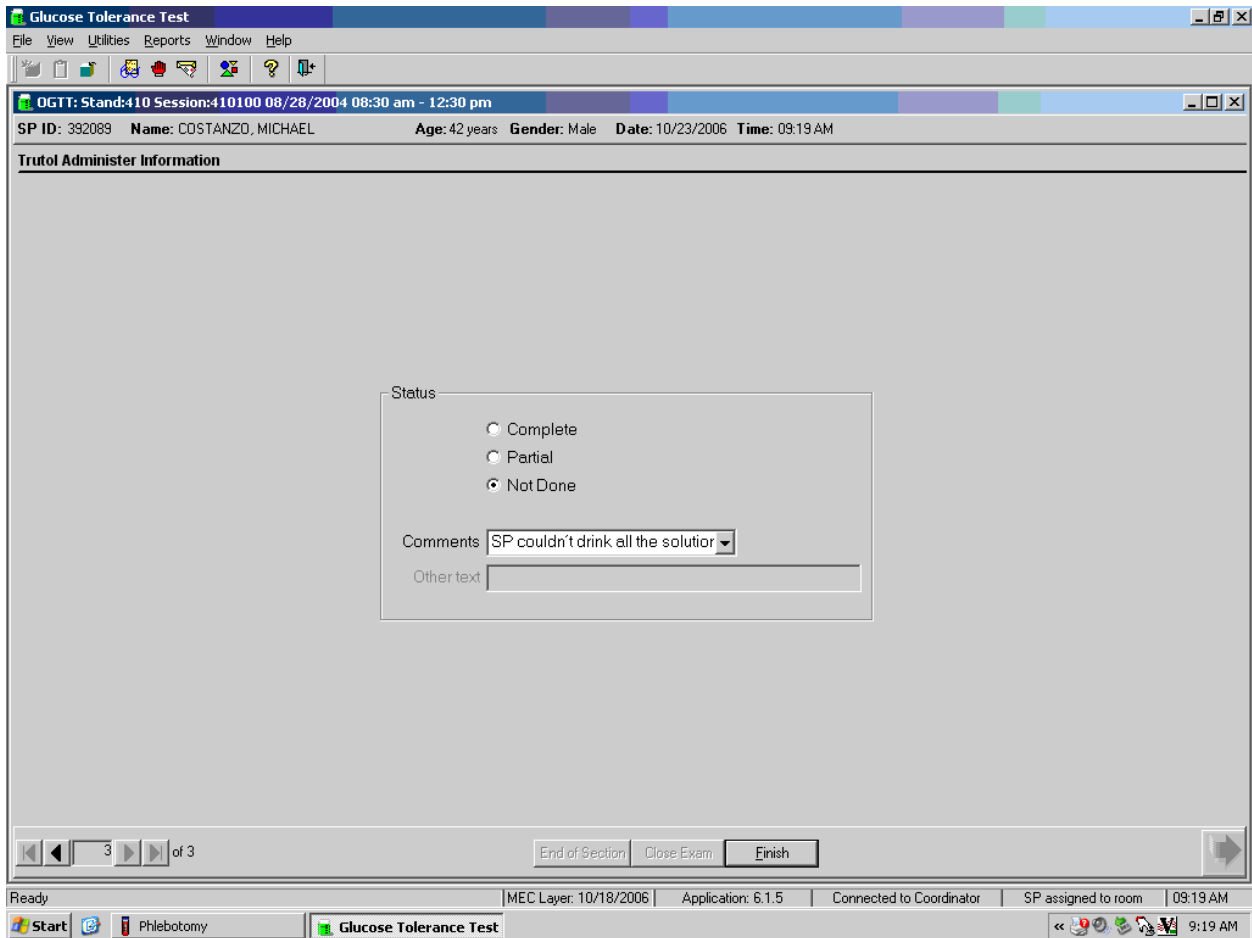


If the total time is 00:10:00, then the comment will default to “Solution not consumed in 10 minutes.”

2.6.3 Section Status

If the SP drank “some” or “none” of the Trutol solution, then the section status is Not Done (Exhibit 2-23). Choose and enter the appropriate comment code when the Trutol Administer Information section status is Not Done.

Exhibit 2-23. Trutol Administer Information screen (12)



To record a comment in the Comment text box, use the mouse to direct the mouse arrow to the scroll arrow on the drop-down list, left click, drag the mouse arrow to the desired choice, and left click. Use the scroll bar to view all choices. Alternatively, use the up and down keyboard arrows to scroll through the choices or type the first letter of the desired comment code (Exhibit 2-24). To complete the examination, use the mouse to direct the mouse arrow to the Finish button or type [Enter].

Exhibit 2-24. Comment codes for Status Not Done

Comment code	Use when:
Safety exclusion	Not applicable This is reserved for positive responses to the insulin, oral diabetic medications, hemophilia and chemotherapy exclusion questions, and positive pregnancy tests. It is automatically coded by the application. The coordinator may code exams using this comment.
SP refusal	The SP refuses to drink the Trutol. This is SP initiated nonresponse due to refusal. The SP refuses the component for any reason other than an illness or emergency. If the SP refuses in the reception area, the coordinator codes the exam. If the SP refuses after starting the exam, the examiner codes the exam.
No time	Not applicable
Physical limitation	Not applicable
Communication problem	Not applicable
Equipment failure	Not applicable
SP ill/emergency	Use this comment to code not done or partial when the SP faints or is about to faint or the SP becomes ill or an emergency occurs and the test cannot be performed on the SP.
Interrupted	Not applicable
SP couldn't drink all the solution	Use this code when the SP cannot consume the entire calibrated dose of the Trutol.
Solution not consumed in 10 minutes	Use this code when the timer expires before the SP has consumed the entire calibrated dose of the Trutol.
SP regurgitated the solution	Use this code when the SP becomes ill and regurgitates the Trutol.
SP broke fast	Use this code if the SP eats anything or drinks anything other than plain water after consuming the Trutol but before completing the second blood draw.
Other, specify	If the above reason for a status Code of Not Done is not explained by one of the Comment Codes, the examiner must choose Other, specify and record a comment in the text field.

3. SPANISH SPEAKING SPs

3.1 Performing the OGTT on SPs Who Do Not Speak English

When the MEC staff must conduct the OGTT procedure with an SP who does not speak English and the staff member does not speak the language of the SP, a translator who does speak the language of the SP assists the examiner.

The translator stays with the examiner and the SP **for the entire procedure**. It is very important that the examiner be able to communicate with the SP if the SP becomes ill during the examination.

3.2 Convert Screen Text to English or Spanish

Convert exam screen text from English to Spanish or from Spanish to English at any time before, during, or after an exam.

To view the exam screen text in Spanish, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {Spanish}, and left click, or type [Ctrl] [S/s]. To return exam screen text to English, use the mouse to direct the mouse arrow to {Utilities} in the menu bar, left click, drag the arrow to {English}, and left click, or type [Ctrl] [E/e].

English <i>Ctrl+E</i>	Toggle option to set exam language to English.
Spanish <i>Ctrl+S</i>	Toggle option to set exam language to Spanish.

The following four screenshots document the English and official Spanish translations for the OGTT component:

- Exclusion Questions English-Exhibit 3-1;
- Exclusion Questions Spanish-Exhibit 3-2;
- Trutol Administration English-Exhibit 3-3; and
- Trutol Administration Spanish-Exhibit 3-4.

Exhibit 3-1. Exclusion Questions screen—English

The screenshot displays a software window titled "Glucose Tolerance Test". The window has a menu bar with "File", "View", "Utilities", "Reports", "Window", and "Help". Below the menu bar is a toolbar with various icons. The main content area is titled "OGTT: Stand:410 Session:410100 08/28/2004 08:30 am - 12:30 pm" and shows patient information: "SP ID: 381736 Name: DELACH, JENNIFER Age: 59 years Gender: Female Date: 10/23/2006 Time: 09:29 AM". The section is labeled "Exclusion Question".

Two exclusion questions are present, each with a "No" dropdown menu:

- Are you now taking insulin? (Insulin: A chemical used in the treatment of diabetes. Typically, insulin is administered with a syringe by the patient.)
- Are you now taking diabetic pills to lower your blood sugar? (These are sometimes called oral agents or oral hypoglycemic agents.)

A "Length of Fast" field shows a value of "11 hours 59 minutes".

At the bottom of the window, there are navigation buttons: "End of Section", "Close Exam", and "Finish". A status bar at the very bottom shows "Ready", "MEC Layer: 10/18/2006", "Application: 6.1.5", "Connected to Coordinator", "SP assigned to room", and "09:29 AM". The Windows taskbar at the bottom shows the Start button, "Phlebotomy", and "Glucose Tolerance Test" application icons, along with the system clock showing "9:29 AM".

Exhibit 3-2. Exclusion Questions screen—Spanish

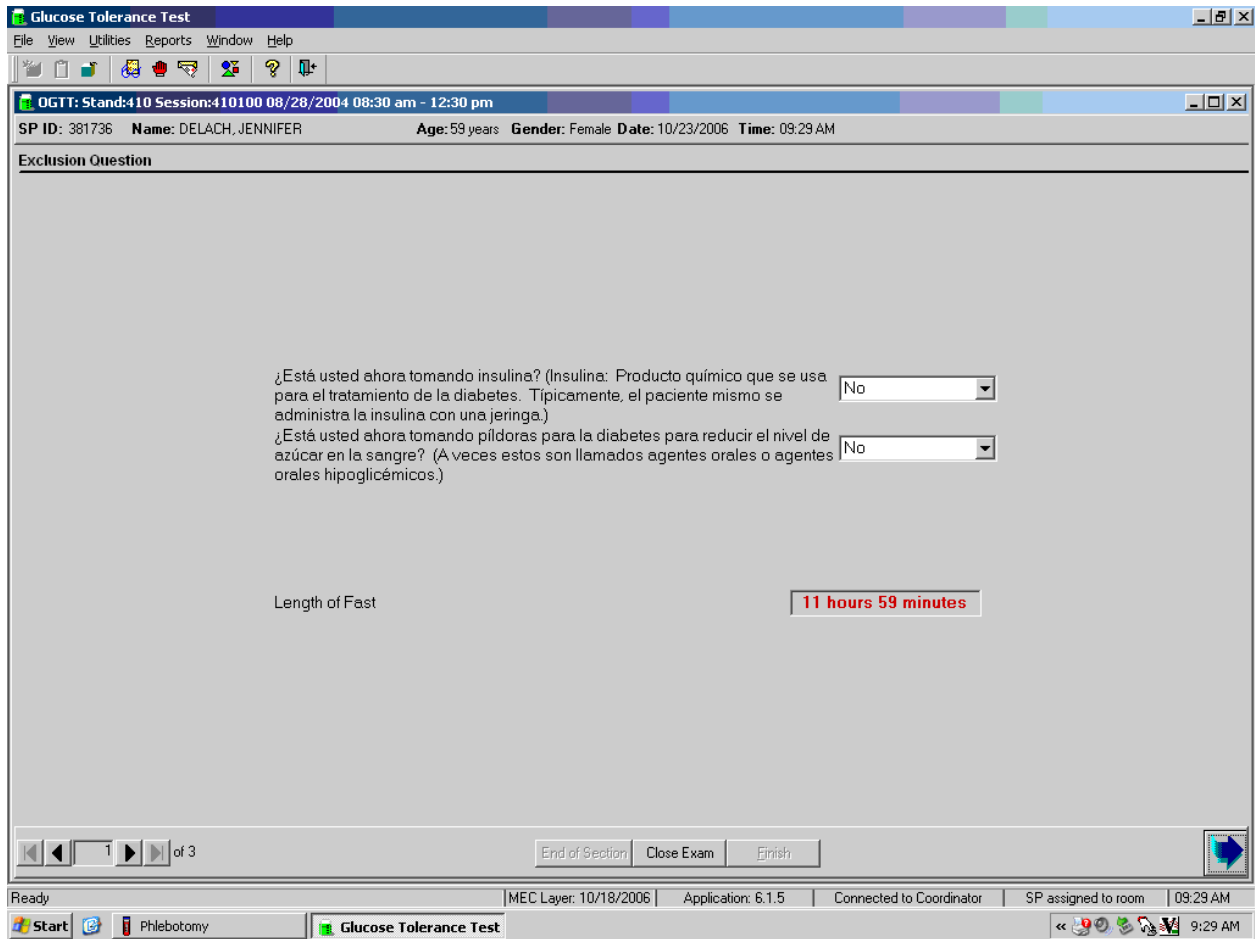


Exhibit 3-3. Trutol Administration screen—English

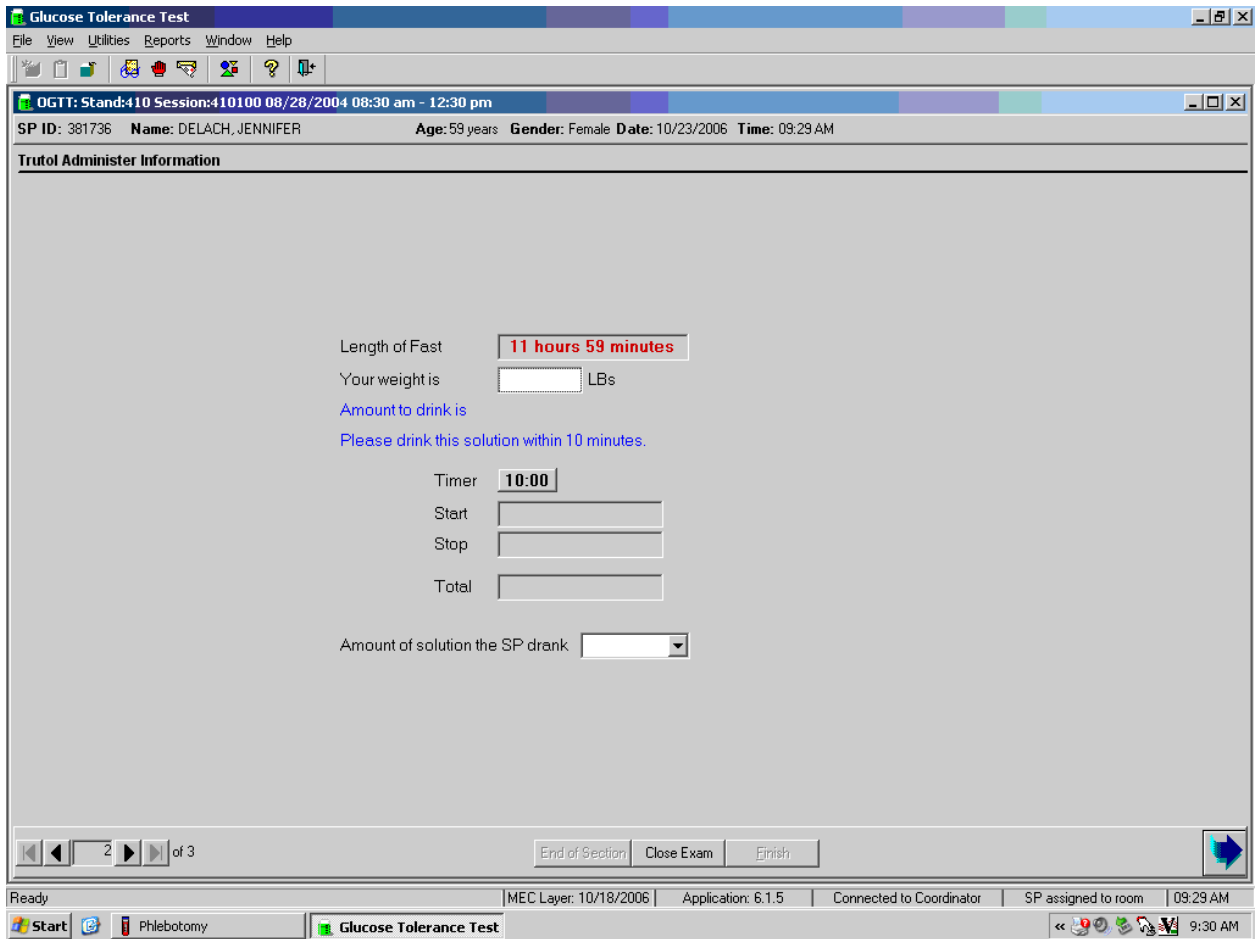


Exhibit 3-4. Trutol Administration screen—Spanish

