

4. GUIDELINES FOR BLOOD DRAWING AND HANDLING

4.1 Introduction

The proper handling of blood samples is critical to the outcome of the HAPO Follow-Up Study. Deviations from HAPO Follow-Up Study protocol and procedures can significantly affect the parameter being measured. It is particularly important that time deadlines and transport conditions be strictly adhered to. It is also very important to adhere to the following:

- Before taking any blood specimens, read the procedures carefully and ensure that the correct tubes and labels are available.
- Blood samples may be drawn either by a butterfly, an indwelling catheter, a traditional needle and syringe, or by vacuum present in the sample tube. If a syringe and needle are used **DO NOT FORCE THE BLOOD INTO THE TUBE THROUGH THE NEEDLE.**
- If blood is put into an incorrect tube **DO NOT TRANSFER THE BLOOD TO THE CORRECT TUBE.** A fresh sample must be taken.
- Personnel collecting the child samples should be approved for child phlebotomy.

4.2 General Instructions

There are a number of basic procedures that should be followed for obtaining all blood specimens:

- Greet the participant.
- Confirm that you have the correct set of HAPO ID labels and that the correct labels have been affixed to the correct tubes.
- Locate the appropriate form in the mother or child's form set and check that one of the participant's HAPO ID labels has been affixed to each page of the form.
- Inform the mother and/or child about the procedure. An example might be: "I am going to be drawing some blood from the vein in your arm. The purpose of this is to check the level of glucose in your blood. I will be taking xx tubes—about xx tablespoons of blood. Do you have any questions?"
- Assemble all materials; have tubes within reach.
- Expose the venipuncture site to make it accessible.

- Disinfect the area of puncture with an alcohol wipe. Wipe completely with a sterile gauze pad.
- **DO NOT TOUCH SKIN AFTER CLEANSING.**
- Put gloves on before venipuncture.
- Apply the tourniquet and perform venipuncture and insert cannula or butterfly.
- The same staff member should not attempt a venipuncture on a participant more than twice. If two attempts are unsuccessful, a different staff member must be used for a third attempt.
- When blood drawing is complete, remove the butterfly or cannula, apply direct pressure and bandaid (optional) until bleeding has stopped, remove gloves, wash hands.

Detailed instructions for the individual blood samples are described in later sections of this manual.

4.3 Supplies

Phlebotomy tubes, sample and storage vials, plastic and cardboard freezer boxes, and polyurethane shipping boxes are distributed to field centers by the Clinical Coordinating Center and Laboratory Coordinating Center. The glucose for the OGTT is also distributed to the field centers as 75g bottles of Trutol.

4.4 Sample Processing

Once the appropriate amount of blood is drawn into each tube, prompt processing must be done. Blood specimen tubes should be processed as soon as possible after collection. Samples must be processed within 2 ½ - 3 hours of venipuncture. Before filling specimen cryovials, make sure that the correct Bar-code label has been affixed vertically to the correct vial and that the Bar-code label corresponds to the HAPO ID on the blood sample tube. The details of processing for each type of sample are specified in the “Aliquotting/Labelling” section under each blood draw in later sections of this manual.

Sample aliquots are sent to the Laboratory Coordinating Center for analysis or for storage.

4.5 Recommended Precautions for Preventing Transmission of Bloodborne Infectious Diseases

The collection and processing of human biological specimens presents significant biohazard safety concerns. The individuals involved should work under the assumption that all biological specimens may be infectious and require scrupulous aseptic handling.

Routes of infection:

Infectious microorganisms may be contracted by several primary routes. They are:

- Direct inoculation. Parenteral exposure occurring as a result of a break in the skin barrier or contact with mucous membranes (conjunctiva). Examples are nicks, cuts, scratches, needle sticks, or splashes to the eyes.
- Ingestion. Occurs when infectious microorganisms are taken into the mouth and swallowed. Avoid hand to mouth contact, poor hand washing practices, mouth pipetting of biological specimens and placing objects in the mouth such as pencils, etc.
- Droplet aerosols. These may be formed when liquids are agitated to cause microscopic droplets to leave the surface of the liquid and become airborne. Aerosols may be created by pouring or pipetting liquids, removing tightly fitting caps from test tubes and during centrifuging.

Several ways to assure infection control protection during venipuncture are:

- Gloves are to be worn when drawing all blood samples and when handling blood specimens.
- Needles should be considered as potentially infective and handled with extraordinary care to prevent accidental injuries.
- Disposable syringes and needles should be placed into puncture-resistant containers located as close as practical to the area in which they were used. To prevent needlestick injuries, needles should not be recapped, purposefully bent, broken, removed from disposable syringes, or otherwise manipulated by hand.
- Blood spills should be cleaned promptly with a disinfectant solution such as sodium hypochlorite.

Several ways to assure infection control protection during specimen processing are:

- **Note: All specimens are to be treated as if they are contaminated; that is, a source of hepatitis B or C virus, HIV (AIDS agent), or other disease-producing agents.**
- Protective gloves are to be worn when processing all specimens.
- All specimens must be capped when centrifuged.
- All specimens are separated/aliquotted with transfer pipettes, not by pouring.
- Mouth pipetting is to be avoided.
- Frequent hand washing with an approved antiseptic soap is essential.
- Work areas should be cleaned with phenolic disinfectant or 1% sodium hypochlorite.

4.6 Storage and Shipping

Each field center must identify a -20° C or colder freezer (-70 or -80 is preferred) that can serve for safe storage of blood and urine specimens. The freezer must have a backup power supply in the event of a power outage, or an alarm system for notification of freezer failure. A backup procedure for maintaining specimens in the frozen state should also be available. The temperature of the freezer should be checked each workday to ensure the temperature does not vary significantly. A freezer must be utilized that is **not** the automatic defrost type. These freezers pass through a warm cycle to prevent the build up of frost on the inside. In doing so, this warm cycle may actually thaw the specimens contained therein. **Note: It is very important that specimens not be thawed following initial freezing.** The first thawing should occur at the Laboratory Coordinating Center when the specimens are being prepared for analysis.

Analysis samples are stored in the field center laboratory in a plastic freezer box at -20° C or colder (-70 or -80 is preferred) prior to shipment on dry ice to the Laboratory Coordinating Center every 4 weeks. Backup samples are stored temporarily in the field center freezer as backup samples. Purple top tubes containing DNA samples are stored in the field center laboratory in a cardboard freezer box at -20° C or colder (-70 or -80 is preferred) prior to shipment on dry ice to the Laboratory Coordinating Center.

The details of storage and shipment of specimens are described in MOO Chapter 7 Storage and Shipment of Specimens.