SOP History (archived date)  V2.0 (21/05/13) Reviewed by Jo Kadziola, V1.3 (01/11/2010) Reviewed by Alison Jenkins; V1.2 (01/11/2010); V1.1 (20/02/2008); V1.0 (07/11/2006)
SOP Number CRF.C116
Created by Alison Mortimer
Version V3.0
Date 20/11/2013
Review Date November 2018
Related SOPs None
Approved by Mary Stringer

*The master document is available on the CRF I:\ drive and website: print-off of this document by anyone other than the CRF SOP Co-ordinator will be classed as uncontrolled. Researchers and their teams may print off this document for training and reference purposes but are responsible for regularly checking with the CRF Sop Co-ordinator for the most recent version.*
Standard Operating Procedure: NIHR Sheffield Clinical Research Facility  
Blood Glucose Monitoring

This SOP has been written to give general guidance to study personnel on how to obtain a participant's blood glucose reading. There are no GCP Guidelines concerning obtaining a participant’s blood glucose reading.

**Background**

It is important that all clinical staff working in the Clinical Research Facility use the same procedure to perform participant’s blood glucose readings as specified in the trial protocol, to ensure continuity and consistency in recordings.

**Definition**

Monitoring a patient’s blood glucose provides an indication of how the body is controlling glucose metabolism. Conditions where a patient's blood glucose may need careful monitoring are:

a) In order to make a diagnosis of diabetes mellitus.
b) In the acute management of unstable diabetic states, diabetic ketoacidosis, hyperosmolar non-ketotic coma, and hypoglycaemia.
c) In order to make a diagnosis of hypoglycaemia,
d) Where blood glucose levels are not in keeping with the patients clinical status.

**Equipment**

- FreeStyle Precision Pro Monitor
- Freestyle Precision Pro Blood Glucose Test Strips (check expiry date)
- Medisense Glucose and Ketone Control Solutions
- Unistik 3 Normal single use safety lancet
- Sharps bin
- Non sterile nitrile gloves
- Cotton wool & plaster

**Equipment location**

- **RHH CRF**: The BM testing equipment is located in the Phlebotomy room. The orange HYPOBOX is located on the shelf in the drug room (Room C117).
- **NGH CRF**: The BM testing equipment and the orange HYPOBOX are located behind the nurses’ station in the 4 bed bay.

**Procedure**

1. The investigator is responsible for ensuring the blood glucose measurement is recorded according to protocol. This duty can be delegated to other
appropriately qualified members of the research team as recorded on the Project Delegation Log.

2. The investigator or delegated person will refer to the protocol to ensure specific requirements for obtaining a blood glucose measurement are identified. If no specific study requirements are outlined the investigator or delegated person should follow the procedures below.

3. The investigator or delegated person will explain the procedure to the participant.

4. The investigator or delegated person must ensure participant comfort and that the participant is warm enough.

5. The Investigator or delegated person must ensure that all the equipment is clean and appears to be in good working order, and that the Freestyle Precision Pro sensor test strips are in date.

6. The investigator or delegated person will wash their hands according to STHFT Hand Hygiene Policy, then wear a new pair of non sterile nitrile gloves.

7. The investigator or delegated person must ask the participant to wash the area to be used to obtain the sample to remove any potential interfering substances and ask them to keep the identified area (usually the hand) hanging down to aid blood flow.

8. Prior to patient use the investigator or delegated person must ensure that they have had training for the FreeStyle Precision Pro monitor and received their unique barcode.

9. A QC must be performed at least once a week and prior to patient use if it has not yet been done that day. All registered users must perform a QC check of the monitor at least every 90 days or the monitor will not allow them to proceed with a patient BM test.

10. The investigator or delegated person will turn on the Freestyle Precision Pro monitor and follow the on screen instructions, refer to Operator’s manual located with the testing equipment if required.

11. If a BM test is required on a patient or healthy volunteer who does not have a hospital ID number then the Emergency Patient ID barcode located within the testing equipment box should be scanned as the patient ID. As soon as safely possible following the patient visit the Point of Care Team should be contacted (POCT@sth.nhs.uk) and advised that the emergency barcode has been used. The patient’s study number (or STH ID number if it has now been allocated) should be passed on to the POCT so that they can update the Precision Pro system with the patient details to ensure a clear audit trail.

12. The test strip must be inserted without touching the blood testing end. To open the correct way: hold the test strip with blue side facing and nick on right side. Pull down on the packaging from right to left to remove the lower part of the packaging exposing the black and white striped section of the test strip to insert into the monitor.
13. To obtain a blood sample the investigator or delegated person must obtain a new Unistik 3 Normal single use safety lancet.

14. The investigator or delegated person must twist off and discard the grey lancet cap. DO NOT PULL. Press platform firmly against the chosen site and press the release button. Dispose of the used lancet immediately in accordance with STHFT Sharps Disposal Policy.

15. Once the drop of blood has been obtained the investigator or delegated person must apply the blood to the white target area on the test strip. When sufficient blood has been applied --- will display in the screen and then count down from 5 the result will then be displayed.

16. The investigator or delegated person will apply a cotton wool ball firmly to the bleeding site until the flow of blood stops, and if necessary apply a small plaster.

17. If any blood spillage occurs the investigator or delegated person should clean up the spillage in accordance with STHFT Policy for the Decontamination of Hospital Equipment & Medical Devices.

18. The investigator or delegated person must wash their hands according to STHFT Hand Hygiene Policy.

19. The investigator or delegated person must record the result on the relevant study source documentation, and in the participant’s medical notes. The result must also be recorded in the patient notes and Quality Control Record book which is found in the blood glucose test equipment box.

20. In non-diabetics, Venous serum/plasma Glucose should be <11.1 mmol/L (random) or <6.1 mmol/L (fasting).

21. The acceptable lower BM level is not specified in the STH Laboratory Medicine Handbook however STH guidelines for blood glucose monitoring indicate an acceptable lower level of 3.7 mmols after a meal.

22. If the result is below the STH policy normal range, i.e. the patient is hypoglycaemic, the investigator or delegated person must obtain the orange HYPOBOX and follow the guidelines provided within the box for management of hypoglycaemia. The study PI should be informed as soon as possible so that they can determine the appropriate clinical management.

23. The investigator or delegated person must clean the Precision Pro blood glucose monitor and return it to its storage box once testing is complete.

Reference:

http://sthweb/marsden/marsden/rm_28.htm#chapter28_402

http://nww.sth.nhs.uk/NHS/ClinicalGuidelines/

http://nww.sth.nhs.uk/NHS/LaboratoryMedicine/

Related Documentation¹
<table>
<thead>
<tr>
<th>Document Name</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precision Pro Operator’s Manual</td>
<td>Abbott Diabetes Care Ltd 2012</td>
</tr>
<tr>
<td>Project Delegation Log</td>
<td>CRF</td>
</tr>
<tr>
<td>STH Hand Hygiene Policy</td>
<td>STH Infection Control Team</td>
</tr>
<tr>
<td>STHFT Management of Health and Safety at Work Policy</td>
<td>Mr N Riley</td>
</tr>
<tr>
<td></td>
<td>Mrs A Redfern</td>
</tr>
<tr>
<td>STHFT Infection control guidelines</td>
<td>STH Infection Control Team</td>
</tr>
<tr>
<td>Blood and Body Fluid Exposure Incident Management Pack</td>
<td>STH Foundation Trust</td>
</tr>
<tr>
<td>STHFT policy for the Decontamination of Hospital Equipment &amp; Medical Devices</td>
<td>STH Foundation Trust</td>
</tr>
<tr>
<td>STHFT Laboratory Medicine Handbook: Analyte Glucose</td>
<td>STH Foundation Trust</td>
</tr>
<tr>
<td>STHFT Waste Strategy and Policy</td>
<td>STH Foundation Trust</td>
</tr>
</tbody>
</table>

1 The location(s) of any related document(s) are listed in the CRF SOP Referenced Documents Directory.

The CRF SOP Referenced Document Directory and any Related SOPs, listed on page 1 of this SOP, can be accessed electronically at www.sheffield.crf.nihr.ac.uk or can be requested by contacting Sheffield Clinical Research Facility, O Floor, Royal Hallamshire Hospital, Glossop Road, Sheffield, S10 2JF, 0114 2713339.