NIHR | Lancashire Clinical Research Facility

**STANDARD OPERATING PROCEDURE**

# Hypoglycaemia in Non-Diabetic Research Participants

| AUTHOR. | AUTHORISED BY | DATE AUTH | RISK MANAGEMENT PROCEDURE NUMBER |
|---|---|---|---|
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**RESEARCH AND DEVELOPMENT**

LCRF

## BACKGROUND

The Lancashire Clinical Research Facility (LCRF) is a purpose built unit at Royal Preston Hospital, where delivery of all research related activity will take place. The unit provides staff with equipment that is required if an emergency situation arises.

One such situation is when participants are required to attend the unit in a 'fasting state', i.e. withholding food or beverages other than water. This can also include medication, depending on the clinical study. The body enters into a fasting state in approximately eight hours after the last meal, the body will then use stored glucose to function. Prolonged fasting can cause the blood sugar levels to drop, triggering hypoglycaemia.

Hypoglycaemia is a condition identified by a low blood glucose reading (BM reading) which, as a rule, is associated with the diabetic population. Hypoglycaemia is recognised when the blood sugar reading falls below 4 mmol/L with or without symptoms (MacArthur and Gibson 2012, Kaushal and Howell, 2013).

Although non-diabetic hypoglycaemia is a rare condition it has been reported in two instances:

1. Reactive hypoglycaemia, occurring a few hours after eating.
2. Fasting, this may be related to a disease or may be in preparation for research or surgery.

## PURPOSE

The purpose of this Standard Operating Procedure is to inform and guide team members on recognising hypoglycaemia and treatment options for all adult participants attending the LCRF regardless of their previous medical history. This document should also be reviewed alongside the current version of the LTHTr Trust policy on hypoglycaemia for adult inpatients.

## SCOPE

This SOP applies to all clinical staff members including all trained nurses and Clinical Trial Support Officers (CTSO's). The administration of therapy ONLY relates to registered nurses, Doctors or other Allied Health Professionals with the required competencies.

## PROCEDURE

1. **WHO?**
    - It is the responsibility of the study nurse, to ensure study related procedures are carried out in a timely manner so a hypoglycaemic episode can be avoided.
    - The study nurse is responsible for monitoring participants to ensure that they are not developing a hypoglycaemic episode.
    - It is the responsibility of the study nurse to ensure help is available if an episode occurred, i.e. other team members, emergency doctor at the LCRF.
    - The responsibility of reporting the hypoglycaemic episode to the participants General Practitioner (GP), Principle Investigator (PI), or if they are diabetic to the diabetes care provider, is with the study nurse.
    - The overall medical responsibility for the patient lies with the PI – please refer to SOP 04 Management of an Unwell Participant

2. **WHEN?**
    - This Standard Operating Procedure must be used in the event a participant experiences a hypoglycaemic episode.

3. **HOW?**

**Pre Study Visit**

- Ensure the participant is aware of the reason they must attend in a fasting state.
- Clinical staff to follow the checklist shown in appendix 1 in preparation for the fasting visit.
- Ask the participant, if they would bring some form of a snack with them, to ensure they receive adequate food intake as soon after the procedure as possible.
- If possible, plan the visit in the morning rather than later in the day.
- Ensure the Precision Pro Blood Glucose and ketone Meter (BG machine) is in correct working order, and available for you to use. This device is stored at the LCRF reception. To use the Precision Pro device please refer to the Trust guidance Medical Devices Competency Assessments Procedure Version7.2 15th August 2017. The study nurse, clinician, or AHP must ensure they have received the appropriate training before using this equipment. If the blood glucose meter is not found to be in

good working order then the nurse, clinician or AHP checking the meter must report to the LTHTr Point of Care Team care.testing@lthtr.nhs.uk or support team ext 3007.

**Study Visit**

- The procedure to identify a hypoglycaemic episode begins with assessing the participant and asking appropriate questions. For example, when was the last time they had something to eat/drink, observing the participants behaviour, and identifying key terms that may be used.

  **Signs and symptoms of non-diabetic hypoglycaemia:**
  - Blurred vision or changes in vision
  - Dizziness, light-headedness, or shakiness
  - Fatigue and weakness
  - Fast or pounding heartbeat
  - Sweating more than usual
  - Headache
  - Nausea or hunger
  - Anxiety, irritability, or confusion

- To determine a hypoglycaemic episode, a finger prick blood glucose (BG) reading should be completed, using the Precision Pro meter.
- Once the BG measurement has been taken, this procedure should be recorded in the participant's medical notes and eCRF if relevant.

## 4. Initial Management of Hypoglycaemia (from NICE guidance on Hypoglycaemia)

- Adults with symptoms of hypoglycaemia who have a blood-glucose concentration greater than 4 mmol/litre, should be treated with a small carbohydrate snack such as a slice of bread or a normal meal, if due.
- Any patient with a blood-glucose concentration less than 4 mmol/litre, with or without symptoms, and who is **conscious and able to swallow**, should be treated with a fast-acting carbohydrate by mouth. Oral glucose formulations are preferred as absorption occurs more quickly. Orange juice should not be given to patients following a low-potassium diet due to chronic kidney disease. Chocolates and biscuits should be avoided, if possible, as they have a lower sugar content, and their high fat content may delay stomach emptying.
- If further management is necessary (or if required in the opinion of the clinical team) consider escalation of patient care as per LCRF SOP Management of the Unwell Participant (see below).
- If necessary, repeat treatment after 15 minutes, up to a maximum of 3 treatments in total. Once blood-glucose concentration is above 4 mmol/litre and the patient has recovered, a snack providing a long-acting carbohydrate should be given to prevent blood glucose from falling again (e.g. two biscuits, one slice of bread, 200–300 mL of milk (not soya or other forms of 'alternative' milk, e.g. almond or coconut), or a normal carbohydrate-containing meal if due). Insulin should not be omitted if due, but the dose regimen may need review.
- If the participant experiences a hypoglycaemic episode, the study nurse must complete the Hypoglycaemic episode record (Appendix 3), to ensure evidence of treatment and procedures carried out as per LTHTr Trust policy.

## TRAINING

Team members are responsible for their own training needs and must be kept up to date. Trainers are available within the LCRF when required. The Trust also provides regular sessions on Diabetes which can be accessed via the intranet.

## OTHER RELATED PROCEDURES

**The documents listed below were reviewed in the writing of this SOP. However, as they are amended regularly, all staff should continue to review the latest versions as they are published.**

| Location of document | Title of Document | Version referred to in writing this SOP |
|---|---|---|
| **LTHTR Policy** | Trust standard EBG/01/08/V7 Hypoglycaemia in adult diabetes inpatients | Version 7 January 2017 |
| **LTHTR Competency** | Medical Device Competency Documentation, Point of care glucose/ketone testing Abbott BLOOD GLUCOSE/KETONE MONITOR FPP/PXP http://intranet.lthtr.nhs.uk/download.cfm?ver=12377 | Version 1.5 November 2017 |
| **LTHTR document** | Research Nurse Checklist for fasting diabetic patients attending the LCRF | Appendix 1 |
| **LTHTR Document** | Algorithm for the treatment of Hypoglycaemia in Adults with Diabetes in Hospital | Appendix 2 |
| **LTHTR document** | Hypoglycaemic Episode Record | Appendix 3 |
| **LCRF SOP** | LCRF-SOP-04 Management of an unwell participant | Version 1.1 3rd October 2016 |
| **LTHTR Observation Charts** | Adults - including the current version of the NEWS Escalation procedure | Version RMP-C-73 2/5/17 |

## CONSULTATION WITH STAFF AND PATIENTS

| Name | Role |
|---|---|
| Dr Rajbhandari | Diabetes endocrinology specialist physician |
| Joanne Byrne | Diabetes Specialist Nurse |
| Deepsi Khatiwada | Chronic Conditions Research Nurse |
| Dennis Hadjiyiannakis | Medical Director LCRF |
| Nichola Verstraelen | LCRF Manager |
| Jacqueline Bramley | LCRF Manager |
| LCRF Operational Management Board | Ratify SOP's operationally |

| Sign Off | | | |
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| **Reviewed and approved by:** | | | |
| **Name and Position** | Dr Dennis Hadjiyiannakis<br>Lancashire Clinical Research Facility Medical Director. | | |
| **Signature** | *Dr Hadjiyiannakis* | **Date** | 07-05-2024 |
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| **Signature** | *R. Davenhall* | **Date** | 07-05-2024 |

| Controlled Copy Authorisation | | | |
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**APPENDIX 1**

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# Checklist Prior to Patients with Diabetes attending the LCRF in a Fasted State
# To be used in conjunction with the Hypoglycaemic SOP

| Action | Details | Staff | Sign and date |
|---|---|---|---|
| Either the day before or the week before discuss with the patient the fasting process | Discussion of eating a complex carbohydrate the evening before the appointment – then following the study specific protocol on fasting appointments. Please encourage sips of water to prevent dehydration (if allowed via the study protocol).<br><br>Encourage light meal or snack before they go to bed.<br><br>Ensure the patient follows their individual routine according to their own diabetic medication regime.<br><br>Advise that the patient brings their own food with them unless the trial provides this.<br><br>Advise patient to bring their medication with them so they can take with breakfast.<br><br>Question the patient regarding recent illness or injury which could affect blood sugars (for a potential hypo). | Nurse | |
| Appointment time | The appointment time should be given as early as practical for the patient.<br><br>If the patient requests an earlier time (before 8am), please log this with the CRF co-ordinator for the day so that they are aware. | Nurse | |
| Check the patient has understood testing BM before journey starts | Ask the patient to test their BG before they set off to the CRF. If the BG is less than 5 ask the patient to call the research nurse to:<br>• cancel the appointment to rearrange for another time<br>• advise not to drive and<br>• to treat the hypo as appropriate. | Nurse | |

| | | | |
|---|---|---|---|
| | Ask the patient what is their normal running BG. If it is normally between 8-10 then anything less than this could be a hypo for them so advise accordingly as to whether it is safe to attend the appointment.<br><br>Ask the patient to bring their own glucometer so that if they experience any of the symptoms of hypoglycaemia whilst not in the CRF they could check and treat accordingly if it is safe to do so. | | |
| Symptoms of hypo | Check that the patient knows the symptoms of their own hypo's so they know what to look out for if there is an issue. | Nurse | |
| Driving | It is preferable that the patient does not drive themselves during the fasting please ask if they can be accompanied and recommend not to drive. | Nurse | |
| Lucozade or glucose tablets | Ask the patient to bring this with them to the facility so that they can treat a hypo if needed. | Nurse | |
| Complex carbohydrates | If there has been a hypo during the CRF appointment ensure that they have a complex carbohydrate such as bread, biscuits, banana which will ensure their BG is maintained and hypoglycaemia doesn't reoccur. | Nurse | |
| Voiding urine | Study specific protocol advise for when to void urine and if a sample is required. | Nurse | |
| Blood sampling | During the sampling it is advisable to have a second support such as the CTSO or other nurse in case of any problems and have the nurse call bell to hand. | Nurse/CTSO | |
| Discharge | Check BG prior to discharge<br><br>BG should be higher than 5 before the patient is discharged<br><br>If there has been any hypoglycaemic episode whilst in the CRF<br><br>Ask the patient to contact you to confirm that they arrived home safely (via phone or text). If they do not contact you then please contact them.<br><br>Please refer to the diabetic specialist nurse if after discussion it appears that they have | | |

| | | | |
|---|---|---|---|
| | been having regular hypo's via LTHTr DSN referral route as detailed below.<br><br>RPH ext 2254<br>diabetesspecialistnurserph@lthtr.nhs.uk<br>CDH ext<br>5350 diabetesspecialistnursecdh@lthtr.nhs.uk | | |

**Notes for medication specific advice prior to fasting**

| Medication | Instructions Prior to fasting visit |
|---|---|
| **Patients on once daily basal insulin**<br><br>**(long acting)** | Take your normal basal insulin at your usual time. |
| **Patients on mixed insulin BD** | Do not take basal insulin in the morning – but bring with you to the appointment to take following food |
| **Patients on basal bolus insulin** | Take long acting insulin (basal) insulin at your usual time. Take your meal time insulin with you to have when your next meal is resumed |
| **Any oral/SC morning dose of hypoglycaemic agents** | To be omitted prior to the visit. These can be taken after the visit with breakfast |

| **This checklist was created in consultation with:** | **Date** |
|---|---|
| Jill Whitaker – Diabetes Specialist Nurse | 14/11/2016 |
| Joanne Byrne – Diabetes Specialist Nurse | September 2018 |
| Dr Rajbhandari | November 2016<br><br>September 2018 |

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# Appendix 2

## Algorithm for the treatment of Hypoglycaemia in Adults with Diabetes in Hospital

Hypoglycaemia is defined as blood glucose of less than 4.0mmol/l (if not less than 4.0mmol/l but symptomatic give a small carbohydrate snack for symptom relief)

### MILD

Patient Conscious, orientated & able to swallow

Give 15-20g of quick acting carbohydrate from **ONE** of the examples below:-

- 1 bottle of Glucojuice liquid drink (15g)
- 1-2 tubes of Glucoboost gel (each tube10gm)
- 200ml original Lucozade
- Small carton fresh orange juice

Check BG after 10-15mins, if still less than 4.0mmol/l repeat carbohydrate + BG up to 3 times
If patient not improving or BG still <4.0mmol/l contact doctor & consider glucagon 1mg IM (can take up to 15 mins to take effect) OR Commence 10% glucose IV at rate of 100ml or as clinically indicated. Escalate care if required

**Check NEWS & Follow 1 & 2 below**

### MODERATE

Patient conscious but confused, disorientated or aggressive & **able to**

If capable and cooperative give 15-20g of quick acting carbohydrate from ONE of the examples below:-

- 1 bottle of Glucojuice liquid drink (15g)
- 1-2 tubes of Glucoboost gel (each tube 10gm)
- 200ml original Lucozade
- Small carton fresh orange juice

**If not capable and cooperative but able to swallow, squeeze 1-2 tubes of Glucoboost into the mouth or give Glucagon 1mg IM**
Check BG after 10-15mins, if less than 4.0mmol/l repeat carbohydrate + BG up to 3 times. If repeat Glucagon is required give 1 single further dose of 1mg after 10min
If BG <4.0mmol/l, after 3 cycles escalate care and commence 10% glucose IV at rate of 100ml per hour or as clinically indicated .

**Check NEWS & Follow 1 & 2 below**

### SEVERE

Patient unconscious, seizures, very aggressive, nil by mouth (NMB) or Enterally fed.

- Complete **ABCDE** assessment including **NEWS**, Glasgow Coma Scale (GCS), BG and Temperature. Administer Oxygen as per policy & contact Doctor/hospital at night practitioner urgently. Administer either:-
  a. **1mg Glucagon IM**. – Up to 15 mins to take effect (less effective in patients on sulphonylureas, malnourished, prolonged starvation or severe liver disease). If < 4 mmols/l after 10 -15 mins give IV glucose as below (ALSO if Glucagon contraindicated)
  b. **100ml 20% Glucose IV** over 10-15 min **or** 150ml 10% Glucose IV over 10-15 min. Repeat BG 10 min later and if still <4.0mmol/l repeat IV glucose. Escalate as indicated.
- To maintain BG treat if possible as 1. **POST EVENT** below **OR** prescribe 10% Glucose IV 100ml/hr or as clinically indicated.

**Check patient ABCDE, NEWS, GCS, BG & Temperature & Follow 1. & 2. below**

### FOR ENTERALLY FED PATIENTS ONLY

a. **If tube is patent:** give 15-20g quick acting carbohydrate: 1 bottle of Glucojuice liquid **OR** 50-70ml of Ensure plus juice. Flush tube with water afterwards.
b. If tube is NOT patent: Give 1mg Glucagon IM **OR** 100ml 20% glucose IV over 10-15 mins.
   - Recheck BG 10-15 min in still <4.0 mmol/l repeat above up to **3** times, consider further escalation.
   - If tube is patent restart feed. If tube is not patent or has been removed, continue IV infusion of **10% glucose at 100ml per hour** until tube is patent or has be replaced.
   - If tube cannot be replaced change to Variable Rate Insulin Infusion

### VARIABLE RATE INTRAVENOUS INSULIN

For Patients on Variable Rate Intravenous Insulin ensure regime is reviewed to prevent further hypoglycaemic episodes

1. **POST EVENT** - Once BG above 4mmol to prevent recurrence MUST follow with 20g long acting carbohydrate e.g. one of the following - . 2 biscuits, 1 slice bread , 200-300 ml milk or next meal if due( ensure contains carbohydrate) If IM glucagon has been used GIVE EXTRA 20g **( TOTAL 40g)** of long acting carbohydrate in order to replenish glucose stores. **Document on hypoglycaemia episode record and clinical record.**

2. **DO NOT OMIT subsequent doses of insulin & continue regular BG monitoring for 24-48 hours** as reactive hyperglycaemia is common. Medical staff to consider if reduction in treatment is required. Avoid 'stat' doses of Actrapid. Refer to **diabetes specialist nurse** for advice as insulin dose adjustment may be required. Diabetesspecialistnursecdh@lthtr.nhs.uk; **OR** diabetesspecialistnurserph@lthtr.nhs.uk

Hypoglycaemia Pathway V7 1st Jan 2017

## APPENDIX 3

| HYPOGLYCAEMIA EPISODE RECORD | | | | |
|---|---|---|---|---|
| **Date** | **Time** 24 hr clock 00:00 | **Blood Glucose** (BG mmol/l) | **Type of Treatment administered** | **Signature/Initials & Counter-initials/Signature** |
| Starting BG | | | | |
| BG after 10-15 mins | | | | |
| BG after further 10-15mins (if required) | | | | |
| BG <4.0mmols after 45 mins. **Escalate care** | | | **Escalated to:-** | |