

**Lancashire Clinical Research Facility
STANDARD OPERATING PROCEDURE**

MANAGEMENT OF MEDICAL EMERGENCIES

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RESEARCH AND DEVELOPMENT

LCRF

BACKGROUND

1. The NIHR Lancashire Clinical Research Facility (LCRF) provides a dedicated unit to support multidisciplinary clinical research. The facility provides a safe and quality environment for the delivery of clinical research. Participants attending the facility suffer from all disease areas and will be from all age ranges.
2. A medical emergency is any acute event which is, or which has the potential to be life threatening. The LCRF supports a number of clinical trials of investigational medicinal products (CTIMPs) where there is a risk of a medical emergency resulting from adverse reactions to the investigational medicinal product (IMP). The most likely problems are anaphylactic shock, cardiac arrest, respiratory arrest, serious cardiac arrhythmias, seizures, cytokine release syndrome and hypoglycaemia. The LCRF also supports other studies of a non-interventional nature; emergencies in these situations cannot be excluded.
3. This SOP must be followed for all emergencies including in the event of a member of the public entering the LCRF seeking urgent medical attention (whether involved in a research study or not, which may or may not include relatives or visitors attending with patients) when the LCRF is open.
4. In Phase I accredited units there are certain standards for managing medical emergencies required by the Medicines and Healthcare products Regulatory Agency (MHRA). The LCRF,

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although not currently an accredited unit, seeks to ensure the appropriate arrangements are in place to manage medical emergencies.

The management of a medical emergency is based on clinical assessment by appropriately qualified healthcare professional and is determined by clinical judgement, current best practice as set out in the Resuscitation Council (UK) recommendations and guidelines, and the study protocol.

5. The LCRF is supported by the Lancashire Teaching Hospitals NHS Foundation Trust (LTHTr) emergency resuscitation teams and the main hospital buildings are accessed via 2 lifts and a link corridor. Therefore, the LCRF adopts the LTHTr emergency resuscitation policies and staff in the LCRF must be trained according to LTH guidance.

PURPOSE/OBJECTIVE

To describe the LCRF emergency infrastructure (e.g., resuscitation trolley, emergency alarms) and the procedures for responding to an emergency based on Resuscitation Council (UK) guidelines and LTHTr Policy.

SCOPE

This SOP provides a framework for managing medical emergencies. However, clinical judgement must be used where applicable.

This SOP applies to all qualified Medical, Nursing and Midwifery staff, Allied Health Professionals, Radiographers and Health Care Support Workers working regularly at the LCRF.

This SOP does not apply to non-clinical LCRF staff who may be present during a clinical emergency; a separate instruction document is available for these staff, which highlights the details of this SOP that may be relevant to those in a non-clinical role.

PROCEDURE

1. WHO?

It is the responsibility of all clinical staff using the LCRF to:

- Have read and understood this SOP.
- Have read and understood documents related to the topic as specified in the SOP.
- Follow the procedures in the SOP and use clinical judgement where applicable.
- Maintain and update their knowledge and skills in the management of medical emergencies

2. WHEN?

This SOP must be followed in the event of any medical emergency within the LCRF.

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3. HOW?

1. Resuscitation Trolley

- 1.1 The LCRF is equipped with an LTHTr standard resuscitation trolley, which contains emergency medicines for adults and paediatrics, as detailed in the Resuscitation Policy. The resuscitation trolley and its contents must be checked and maintained according to LTHTr policies and guidelines
- 1.2 The resuscitation trolleys must be maintained according to the LTHTr Resuscitation Policy. It is the responsibility of the delegated staff, as per the rota system, (available on MS Teams Off Duty) that the resuscitation trolley is checked daily and a full check is performed weekly in line with the Resuscitation policy, while the facility is open for patient visits. If patient visits occur on a weekend, then the responsibility lies with the clinical staff on duty.
- 1.3 The Resuscitation Trolley is audited through the Audit Management and Tracking (AMaT) System.

2. Emergency Alarms

- 2.1 An emergency alarm panel is located in the reception/nurses' station / and large agile working area and in the Large Meeting Room in the administration area. In the event of an alarm sounding, this panel will highlight where the alarm has been initiated. Outside each room there is a light on the ceiling. Once the emergency alarm is pulled, this will illuminate to easily identify where the alarm has been triggered.
- 2.2 Once the emergency alarm is activated, (please refer to Emergency Alarm Guidance Document for further guidance), all available clinical staff must respond immediately. The first responder must initiate management using the ABCDE (Airway, Breathing, Circulation, Disability, and Exposure) approach as outlined in the LTHTr trust standard P284 Resuscitation Policy. The appropriate resuscitation, severe reaction or anaphylaxis algorithm must be initiated by the clinical staff as soon as practically possible, according to their training and competency. Non-clinical staff must refer to LCRF_SOP 11 for their roles and responsibility during an emergency.

3. Training

The LCRF staff includes a team of registered nurses, midwives and other allied health care professionals who receive regular training in managing emergencies. Resuscitation training is currently provided at three levels for clinical staff (Level 1 is for non-clinical staff):

- Level 2 refers to Adult and Paediatric Basic Life Support (BLS).
- Level 3 refers to Adult Immediate Life Support (ILS) or Emergency Life Support (ELS) which can be considered equivalent for the purposes of this document.
- Level 4 refers to Advanced Life Support (ALS).

Clinically trained staff (core NIHR CRF team) based within the LCRF will receive annual training in Level 2 and Level 3 resuscitation along with regular scenario training. Other staff using the LCRF may be asked to complete Level 2 or Level 3 resuscitation training depending on the risk assessment of the study. Level 2 resuscitation training can also be accessed via other organisations such as

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Lancashire and Cumbria NHS Foundation Trust for those employed there and must be updated annually through their own organisation.

All staff who will use the Automated External Defibrillator (AED) for its intended medical purpose of cardioverting or pacing, must have completed the AED online LTHTR training. This would include, but is not limited to, nursing staff who have current level 3 resuscitation training and medical staff who have current level 3 or level 4 resuscitation training or anaesthetists.

All clinical staff must complete the anaphylaxis training annually via the trust blended learning be that LTHTr or LSCFT.

All staff must be familiar with LCRF_SOP_06: Hypoglycaemia in Non-Diabetic Research Participants and all equipment available to diagnose and treat hypoglycaemia as required.

All staff must be familiar and skilled to use the hypersensitivity kit and contents competently (e.g., nebuliser use and IM injections)

4. Guidelines for managing emergencies

4.1 If the first responder assesses that the resuscitation team is required, then s/he must delegate a person to dial the emergency number 2222. This could be done by any member of staff delegated by the first responder.

4.2 Stating clearly “double two double two” to avoid ambiguity.

For adult cardiac arrest clearly state: “ADULT CARDIAC ARREST, RESEARCH FACILITY, AVONDALE UNIT”

For paediatric cardiac arrest, clearly state: “PAEDIATRIC CARDIAC ARREST, RESEARCH FACILITY, AVONDALE UNIT”

The first responder must delegate any member of staff to stand outside the facility to guide the resus team to the LCRF and open the front clinical door.

4.3 In an emergency, LTHTr guidelines and LCRF procedures must be followed. All documents can be found on either R&I Q-Pulse, LTHTr trust intranet or on the external internet. They must be read by clinical staff and acknowledged as applicable along with this SOP.

4.4 If an adult patient is causing clinical concern within the LCRF the qualified member of the team must perform a full set of observations, document the vital signs accurately on the appropriate NEWS2 and escalate findings to a senior member of the team.

NEWS2 guidelines for the management of a raised score must be followed.

In the event that the critical care outreach team are required, they must be contacted on bleep 3388 during the hours of 7.30am to 8pm. Overnight between the hours of 8pm and 7.30am hours the Hospital at Night team can be contacted on bleep 9090.

Refer to relevant policies available on LTHTr trust intranet:

Trust Standard P281_Procedure for the Timely Recognition and Response for Patients at Risk of Deterioration RMP-C-73.

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Clinical Escalation Plan for Acutely Unwell Children and Young People in the Outpatient Department SOP-27

- 4.5 If the emergency is assessed as due to anaphylaxis, reaction or severe reaction, the administration of any drug, blood product or fluid that could be attributable to the reaction must be discontinued immediately.

If the patient is exhibiting signs of life-threatening anaphylaxis (e.g., airway compromise, circulatory collapse) then LTHTr trust anaphylaxis policy must be followed.

- 4.6 For anaphylaxis, a registered healthcare professional that is trained in the administration of intramuscular (IM) medications is able to administer adrenaline intramuscularly without either a medic being present and / or a medical prescription.

- 4.7 If the situation is deemed life threatening by the admitting clinical team, the resuscitation team must be contacted, as above. It must be decided and clearly communicated who is the emergency lead for the emergency situation.

Ideally this would be the practitioner identified in the morning safety huddle, where a backup emergency lead will also be identified to support the main lead. This person must co-ordinate emergency resuscitation procedures and give clear instructions to other staff that are assisting until the resuscitation team arrives.

Clear communication must then be handed over to the resuscitation Team Leader of the Adult or Paediatric Cardiac Arrest Team using the SBAR (Situation, Background, Assessment and Recommendation) approach and it must be established who will take over control as lead.

- 4.8 For Research Participants, the Principal Investigator (PI) of the research study must be informed as soon as possible and attend the LCRF to facilitate hand over. If unavailable, their nominated deputy or LCRF medic must attend. Information regarding patient's wishes, existence of any community DNAR and appropriate escalation of care must be given to the resuscitation team leader.

- 4.9 A 2222 audit form must be completed for all 2222 emergency calls by the first responder in the LCRF and these are located in the top drawer of the Resuscitation trolley.

5. Participant transfer

- 5.1 Transfers to other hospital departments for ongoing care must be performed in accordance with the current LTHTr Trust standard P178 - Policy and Procedure for the Transfer of patients Common Core Document Including Adults, Women's, and Child Health.

- 5.2 The nurse/midwife/AHP must complete the Lancashire Teaching Hospitals Adult Patient Transfer Information (Inter and Intra Hospital/Department) sheet (Form MS118). This must be handed over along with any supporting documentation and communicated to the receiving nurse/midwife.

- 5.3 The nurse/ midwife / AHP looking after the participant must remain with the medical responder and / or resuscitation team until the participant is stabilised and/ or transferred.

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- 5.4 The non-medical lead for the emergency situation must ensure porters have been booked to transfer any patients. This is done via the LTHTr Intranet page. The icon is displayed on the trust desktop page. For an urgent patient transfer, the Task Type must be Transfer Priority. Comments must include your name/number and that a trolley is required.
- 5.5 It is the responsibility of the resuscitation medical team to ensure medical handover to the admitting clinician or ED consultant as per LTHTr trust policy.
- 5.6 It is the responsibility of the nurse/midwife/AHP to provide a thorough verbal handover to the nurse/midwife/AHP in the admitting department/ward or unit.
- 5.7 Medical and nurse/midwife/AHP handovers must be clearly documented.

6. Follow Up Procedures

The nurse or midwife looking after the participant must ensure that:

- 6.1 The team must follow LTHTr trust policy in terms of reporting mechanisms following the event.
- 6.2 For research participants, inform the PI (if not present at the time of the medical emergency) of the event as soon as possible.
- 6.3 Document all events and actions related to the event in the participant's medical notes /communication sheets.
- 6.4 Contact the participant's next of kin to inform them of the participant's condition, if not already present.
- 6.5 Complete a serious adverse event (SAE) report and submit as per study protocol.
- 6.6 If necessary (e.g., delay in crash team arrival, lack of correct equipment, training issues), complete an incident report through the incident reporting system (Datix).
- 6.7 Ensure LCRF manager and medical director are informed that there has been a medical emergency in the LCRF.
- 6.8 The clinical lead for the shift must co-ordinate with the senior clinical staff, leading an informal debrief session for staff involved in the emergency to identify and record any lessons learned. Details must be added to the emergency scenario training database on the quality management drive for the LCRF and CRF Manager for people to be able to review and reflect on lessons learned.

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4. Other Related Procedures and Documents reviewed and to be reviewed.

The documents listed below were reviewed in the writing of this SOP. However, as they are amended regularly, all staff must 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 P284 - The resuscitation policy	Version 11 10/11/2020
LTHTR Policy	Trust standard P178 - Transfer of Patients Common Core Document Including Adults, Women's, and Child Health RMP-C-116,	P178 Version 3 12/03/2020
LTHTR Document	Adult Patient Transfer Information (Inter and intra Hospital/Department) form (MS118)	Standard Centralised document
LTHTR Policy	Trust standard P281 - Procedure for the Timely Recognition and Response for Patients at Risk of Deterioration RMP-C-73	Version 6.6 04/12/2018
LTHTR Policy	Trust standard P315 -Medicines management policy	Version 3.1 18/06/2019
LTHTR Document	NEWS2	
LCRF Document	Nurse Call Alarm Guidance	Version 1 13/4/16
UK Guidelines	Resuscitation Council (UK) Guidelines	2015
UKCRF Tool	Risk assessment Tool with guidance (for review by lead nurse or LCRF Manager)	Version 1 4/11/14
UKCRF	Early phase Risk Assessment Tool	
LTHTR Policy	Risk Management Procedure/Strategy (for review by lead nurse or LCRF Manager)	Version 10 06/08/2020
LTHTR Policy	Clinical Escalation Plan for Acutely Unwell Adults in the Outpatients Department	Version No:1.3 07/08/2018
LTHTR Policy	Clinical Escalation Plan for Acutely Unwell Children and Young People in the Outpatient Department SOP-27	Version No: 2 26/06/2019
LCRF SOP 06	Hypoglycaemia in Non Diabetic Research Participants	

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CONSULTATION WITH STAFF AND PATIENTS

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