NIHR | Lancashire Clinical Research Facility

STANDARD OPERATING PROCEDURE

Management of an Unwell Participant

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RESEARCH AND DEVELOPMENT

LCRF

BACKGROUND

The 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.

Participants attending the facility may attend acutely unwell or may develop symptoms whilst in the facility. The management of an unwell participant is based on clinical assessment by appropriately qualified medical and clinical nursing personnel. The LCRF staff include a team of registered nurses and other allied health care professionals who receive regular training in managing emergencies. LCRF nurses receive training and annual updates on BLS and ILS.

The LCRF is part of the Lancashire Teaching Hospitals NHS Foundation Trust (LTH) emergency resuscitation procedures.

PURPOSE/OBJECTIVE

To describe the process for assessment of patients who arrive in the LCRF with new or worsening symptoms.

SCOPE

This SOP provides a framework for managing patients who complain of new or worsening symptoms. However, it is not a substitute for clinical judgement.

This SOP applies to all qualified medical and nursing staff, Allied Health Professionals and Health Care Support Workers working at the LCRF.

This SOP does not apply to situations of emergency for example, collapse and acutely unwell patients. Refer to LCRF SOP 02 for the management of medical emergencies.

PROCEDURE

1. WHO?

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

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

2. WHEN?

This SOP must be followed in the event a participant becomes unwell.

3. HOW?

1. A medical emergency is any acute event which is or which has the potential to be life threatening. In the case of a medical emergency refer to LCRF SOP 02 for the management of medical emergencies.

2. The PI is responsible for ensuring medical cover is available for the participants within the study at all times as specified in LCRF-SOP-22. Medical cover must be prearranged by the PI and the name and contact information (bleep/pager) of the responsible clinician or team must be given to the nurse responsible for the study. If medical cover is not in place, the LCRF manager can suspend research interventions until this is resolved.

3. If a patient attending the LCRF complains of new or worsening symptom/s, the treating nurse must obtain further details including, but not limited to, a history of the symptoms, timescales and severity. If appropriate, the nurse must obtain clinical observations and document on the NEWS2 form. Clinical staff must follow the NEWS2 escalation procedure (written within the document) or current LTH equivalent assessment. Critical Care outreach must be bleeped, if relevant, according to the policy during the day on 3388 as per LTHTr SOP-34 Critical Care Outreach Service. The PI, or delegated medical clinician, must be informed immediately.

4. If the symptoms are felt due to the underlying disease or treatment for which they are attending the LCRF, this should be documented within the appropriate research AE/SAE log, as required within Good Clinical Practice and a DATIX completed if appropriate according to RDCLI08 Safety Reporting

5. The treating nurse must contact the Principal Investigator (PI), nominated deputy (if they are not already aware) or clinical team (which will have been agreed through the application process) to ensure no further action is required and/or safe to proceed with study interventions. Nurses should use clinical judgement and can escalate to senior nurses/clinical lead within the facility for advice.

6. If the patient requires a medical review, it is the responsibility of the PI or delegated medical individual (or clinical team as agreed) to review the patient and arrange further management, which may or may not include primary care as detailed in LCRF-SOP-22. Transfer to another clinical area must be agreed and organised by the PI or delegated clinician.

7. The clinical team in the LCRF must assist with any investigations such as ECG or venepuncture and arrange any transfer for radiological investigations requested.

8. It is the responsibility of the PI or delegated deputy to give advice on any medical queries to LCRF staff. If patients require further assessment, admission to the hospital or referral to primary care, it is the responsibility of the PI or deputy to arrange transfer or further assessment.

9. If a patient requires transfer for admission/assessment in another LTHTr area then this should be done in accordance with LTH RMP-C-116, Transfer of Patients Common Core Document (most current version). LCRF staff must complete the LTHTr Adult Patient Transfer Information (Inter and intra Hospital/Department) form (MS118) and handover to nursing staff taking responsibility for the patient. It is the PI or delegated medical individuals responsibility to ensure medical handover to the admitting clinician or ED consultant.

10. Patients should be assessed for level of care prior to transfer. The decision on what level of training is required by the team to transfer (nurse/medic or both) will be made by the senior nurse in charge and/or the PI or delegated clinician. See appendix 1

11. If the Defibrillator is needed for transfer, and there are other patients in the facility, please make surrounding departments aware that we may need to use their defibrillator in the event of a second emergency.

Other Related Procedures and Documents;

LTHTr Procedure for the Timely Recognition and Response for Patients at Risk of Deterioration RMP-C-73.
Transfer of Patients Common Core Document Including Adults, Women's and Child Health RMP-C-116.
Adult Patient Transfer Information (Inter and intra Hospital/Department) form (MS118)
Adult and Paediatric – including the current version of the NEWS Escalation procedure
RDCL108 Safety Reporting
LCRF-SOP-22 Management of Medical Cover
LTHTr SOP-34 Critical Care Outreach Service

CONSULTATION WITH STAFF AND PATIENTS

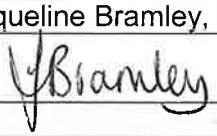
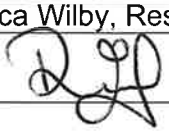
Name	Role
Louise Saynor	LTHTr Resuscitation interim Lead
LCRF Resus Safety Group	Safety Consultation Group
Sally Fray	Consultant Nurse Critical Care Outreach
Dennis Hadjiyiannakis	LCRF Medical Director
LCRF Operational Management Board	Ratify SOP's operationally
Jacqueline Bramley	LCRF Lead
Rebecca Wilby	Research Access Project Manager

Appendix 1

APPENDIX 3 Click here **for Adult Patient Transfer Information (Inter and Intra Hospital) (MS118)**

APPENDIX 4- Intra hospital transfer

	VITAL SIGNS/SPECIAL CIRCUMSTANCES	Minimum ACCOMPANYING PERSONNEL For 2nd and 3rd year student nurses see section 13.6	SKILLS REQUIRED	EQUIPMENT
Level 0 (Normal)	Patient needs can be met through normal ward care. • Patient can meet own needs • Observations less than 4 hourly • No oxygen therapy required by patient	Porter(s) (Dependant on mode and distance of transfer)	BLS	Consider pocket mask
Level 0.5 (Additional level of care specific to LTHTr)	Elderly Confused/agitated patient • Safely discontinued IV therapy for transfer • Observations less than 4 hourly • No oxygen therapy required by patient	Porter(s) (Dependant on mode and distance of transfer) plus HCA	BLS	Consider pocket mask
Level 1 (At risk)	Patients: • Oxygen therapy • On going IV fluids/medications • Recently discharged from a higher level of care • In need of additional monitoring, clinical interventions/input or advice • Requiring critical care outreach support • With Chest drainage	Suitably experienced Nurse/Midwife At least band 4 for the stable level 1 Band 5 for complex unstable patients Appropriate competence to meet the needs of the patient Porter(s) (Dependant on mode and distance of transfer)	BLS and Recognition of Patient Deterioration	Pocket mask or BVM Equipment to meet needs of patient.
Level 2 (Unstable/ At risk)	Any of the above plus: For example Potential for airway compromise – Tracheostomy with copious secretions (As applicable), nerve palsy, reduced L.O.C. >50% Oxygen Vasoactive medications Needing a greater amount of nursing intervention to maintain normal and stable vital signs.	Suitably experienced Nurse/Midwife – Appropriate competence to meet the needs of the patient Consider Need for medical staff Porter(s) (Dependant on mode and distance of transfer)	All of above plus current ILS provider Care of arterial or central venous catheter as applicable	Pocket mask or BVM Equipment to meet needs and potential needs of the patient. Consider transfer defib.
Level 3 (Unstable & at high risk)	Requiring more than 60% oxygen Requiring CPAP. Respiratory or Cardiovascular instability. GCS less than 9. Intubation prior to transfer should be seriously considered	Suitably experienced Doctor and Nurse Appropriate competence to meet the needs of the patient. Porter(s) (Dependant on mode and distance of transfer)	All of above plus An ALS provider and competency as appropriate in advanced airway management techniques	As above and Transfer monitoring equipment as per ICS recommendations (2011)

Sign Off Lancashire Teaching Hospitals			
Lead Author:			
Name and Position	Jacqueline Bramley, LCRF Lead		
Signature		**Date**	25/09/2023
Reviewed and approved by:			
Name and Position	On behalf of LCRF Operational Management Group		
Signature		**Date**	25/09/2023
Authorised for release by:			
Name and Position	Rebecca Wilby, Research Access Project Manager		
Signature		**Date**	25/09/2023

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