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| **TGHN-256x151px**  **Standard Operating Procedure** | | | **SOP No:**  **Version: 1**  **Effective Date:** | |
| **Title: Emergency Scenario Training** | | | | |
|  | NAME | **SIGNATURE** | | **DATE** |
| **PREPARED BY** |  |  | |  |
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| **QA UNIT**  **AUTHORITY** |  |  | |  |
| **APPROVAL**  **AUTHORITY** |  |  | |  |

1. **Purpose/scope**

To describe the procedure for assuring competency in the emergency medical response provided by Malaria Clinical Research Group team members through emergency scenario training. This SOP is based on documentation provided by the UKCRF network (<http://ukcrfnetwork.co.uk/>) and the Guy's and St Thomas' NHS Foundation Trust.

1. **Templates/forms**

EM04.1 Case scenario planning document

EM04.2 Emergency scenario training report

EM04.3 Feedback and action plan

1. **Glossary/definitions**

None

1. **Responsibilities and procedure**

**Training plan**

* 1. All team members who interact with trial participants must be competent in attending to potential emergency medical conditions they (or their family, or other staff members) may experience, according to qualification, experience and/or trial role. See SOP EM02 for details of the minimum number of staff with a particular qualification(s) that should be on duty during a trial.
  2. The Principal Investigator (PI) will assign responsibility for planning, conduct, assessment and follow-up of emergency scenario training to an appropriate member(s) of the trial team (or external consultant if required/contracted) before each trial. This organiser will draw up a case scenario planning document. (example given in EM04.1) that details intended learning objectives/competencies.
  3. Scenario types cover common clinical conditions (training sessions approximately 40 minutes long) and general sessions about how to evacuate a participant from the trial ward or release someone from a locked toilet/shower (approximately 30 and 15 minutes log respectively). NB these 2 broad types of scenarios may be combined if time allows. Possible clinical scenarios include cardiac arrest, anaphylaxis, seizures, acute stroke, arrhythmias, acute myocardial infarction, and acute pulmonary oedema: However, the PI may request different/additional scenarios depending on what is known about the intervention/control being used in the trial, and prioritise the topics accordingly.
  4. Scenario training in evacuation from the trial ward should be prioritised at the start of a trial for all staff, and for any new staff who join the team during the trial.
  5. Clinically qualified staff should attend a clinical scenario training session approximately every 3 months while a trial(s) is active.
  6. Non-clinical staff should be encouraged to join clinical scenario training sessions in order to understand their potential role in supporting the clinical team. They should also be supported to obtain training and/or certification in first aid or basic life support.

**During the scenario training**

* 1. The facilitator(s) will ensure the following are documented in an Emergency scenario training report (example given in EM04.2):
     1. Observed learning notes: a summary of what action was taken, what time it was taken, and by whom the action was performed.
     2. A list of discussion points.
     3. A constructive debriefing session.
     4. Confirmation of the scenario, and record of the date for the next training session.
  2. A training attendance register will also be completed as per SOP AD08.

**After the scenario training**

* 1. The facilitator(s) will send a personalised feedback and action plan form (example given in EM04.3) to each participant, providing constructive feedback and remedial actions needed in terms of points 4.8.2 and 4.8.3 above.
  2. The facilitator(s) will send the training attendance register to the member of team given responsibility for maintaining the Investigator Site File/training file.

1. **Document history:**

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| --- | --- | --- | --- |
| **Version No.** | **Date** | **Reviewer** | **Details of changes** |
| 1 | add | NA | Not applicable, first version this SOP |