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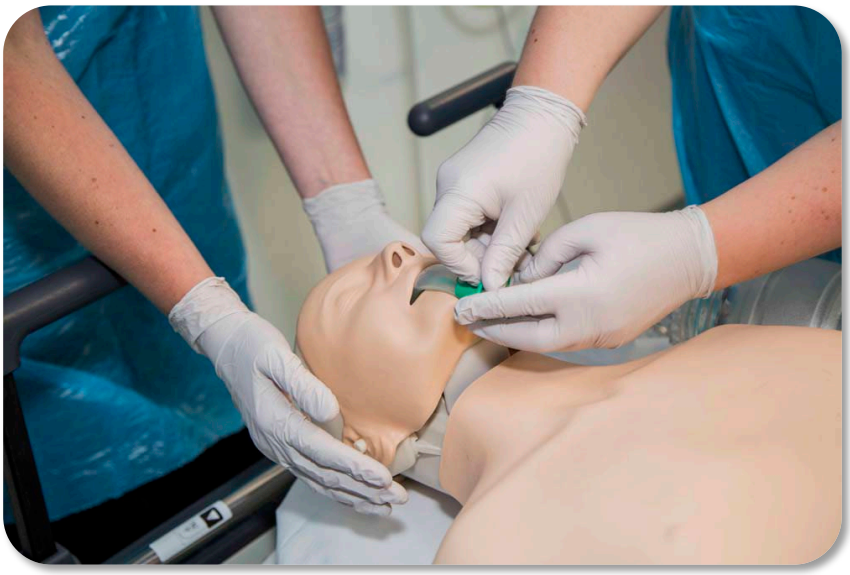
UKCRF NETWORK

Emergency Scenario Training Guidance Document

Version 6.0 – June 2026



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Emergency Scenario Training Guidance Document

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Intended audience

This guidance has been designed for the UKCRF Network workforce but is applicable to all clinical research staff.

Disclaimer

This document provides guidance to support clinical research staff and managers in the delivery of emergency scenario training. While every effort has been made to reflect current safe practice through expert review, this guidance is for general use only and should be adapted to meet local requirements. It must be used in conjunction with local policies, resuscitation procedures, and regulatory requirements, which take precedence. It does not replace individual clinical judgement. The UKCRF Network accepts no responsibility for actions taken based on this guidance.

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How to use this Document

Although the training criteria in this document has been set at Phase I accreditation level, it is important to emphasise that this is for guidance only; the document and associated tools and templates can be used or adapted to suit local needs and in conjunction with local resuscitation team documentation for training. Local policies should be referred to in relation to managing emergency situations.

Document Updates

- Version 2.0 (2013) incorporates updates relating to the MHRA Good Clinical Practice Guide (MHRA 2012) and addition of paediatric scenarios. All references and documents have been checked as current.
- Version 3.0 (2015) reflected changes as part of the review process for the document.
- Version 4.0 (2017) includes additional adult and two paediatric scenarios. All references and documents have been checked as current and updated as necessary.
- Version 5.0 (2019) updated all scenarios where necessary and includes additional adult and paediatric scenarios. The group have also amalgamated appendix 1 and 2 as requested by document users to avoid repetition (appendix 2) and have added a blank template (appendix 1).
- Version 5.1 (2020) made a minor change to the concomitant medications in scenario 6 (page 55) adding Gliclazide along with Metformin.
- Version 6.0 (2026) updates adult and paediatric scenarios, including the removal of two scenarios (syncope with BBB and hypoglycaemia in known diabetic) and the addition of three new scenarios (adult seizure, paediatric CRS and paediatric DKA). Additional debriefing tools have been included, and appendix 6 (Emergency Simulation Training Annual Report Template) has been added. The full document has been reviewed, with references checked and updated in line with current clinical guidance.

Abbreviations

ABG	Arterial blood gas
ABPI	Association of the British Pharmaceutical Industry
ACS	Acute coronary syndrome
AE	Adverse event
AED	Automated external defibrillator
ALS	Advanced Life Support
AR	Adverse reaction
ACVPU	Alert Confusion (new) Voice Pain Unresponsive
BBB	Bundle branch block
BD	Twice daily medications
BM	Blood glucose measurement
BNF	British National Formulary
BP	Blood pressure
BPM	Breaths / Beats per minute
BVM	Bag Valve Mask
CAPA	Corrective action & preventative action
CCU	Coronary care unit
COPD	Chronic Obstructive Pulmonary Disease
CPR	Cardio-pulmonary resuscitation
CRF	Clinical Research Facility
CRP	C-reactive protein
CRT	Capillary Refill Time
DKA	Diabetic Ketoacidosis
DM	Diabetes Mellitus
ECG	Electrocardiogram
EPLS	European Paediatric Life Support
ET	Endotracheal tube
FBC	Full Blood Count
FIH	First In Human
GCS	Glasgow Coma Scale
GCP	Good Clinical Practice
GTN	Glyceryl trinitrate
HDU	High dependency unit

HR	Heart rate
ICU	Intensive care unit
IHD	Ischaemic heart disease
ILS	Immediate Life Support
IM	Intramuscular
IMP	Investigational medicinal product
IV	Intravenous
IVAB's	Intravenous antibiotics
JVP	Jugular Venous Pressure
kg	Kilogram
mcg	Microgram
MDI	Metered dose inhaler
MDT	Multi-Disciplinary Team
mg	Milligram
MHRA	Medicines and Healthcare products Regulatory Agency
MI	Myocardial Infarction
mmol	Millimole
NEWS2	National Early Warning Score 2
NKDA	No known drug allergies
NIV	Non-invasive ventilation
NRB	Non-rebreathe mask
O_2 Sats	Oxygen saturation
O_2	Oxygen
OD	Once daily
PCI	Percutaneous Coronary Intervention
PEA	Pulseless electrical activity
PEARL	Puplis Equal And Reactive to Light
PEWS	Paediatric Early Warning Score
PI	Principal Investigator
PILS	Paediatric Immediate Life Support
PIS	Participant information sheet
PMHx	Past medical history
PO	Per oral
PRN	Pro re nata (as needed)
Resps	Respirations

RR	Respiratory rate
SAE	Serious adverse event
SBAR	Situation, Background, Assessment, Recommendation
SOB	Shortness of breath
SOP	Standard operating procedure
STAT	Immediately
Trop I/T	Troponin
U&E	Urea & Electrolytes
VF	Ventricular fibrillation
VT	Ventricular tachycardia
WOB	Work of breathing

Introduction to Training in Clinical Emergencies

Background

The very serious adverse reactions that occurred in the First in Human (FIH) non-therapeutic clinical trial of a monoclonal antibody, TGN1412, in March 2006, resulted in the Expert Scientific Group on Phase I Clinical Trials being set up by the Secretary of State for Health. The group was tasked with the remit of making recommendations to increase the safety of future clinical trials involving first in human agents. These recommendations have informed the Phase I accreditation process put in place by the UK Regulatory Authority, Medicines and Healthcare products Regulatory Agency (MHRA 2007).

Following these recommendations, the UKCRF Network Quality Assurance Theme Group identified a need for guidance in the planning and management of clinical emergency training within Clinical Research Facilities (CRFs). The Education Theme Group was approached to take forward this initiative, and members nominated a sub-group of individuals with the appropriate skills and knowledge in education, resuscitation and critical care to develop a guidance document.

The Emergency Scenarios Delivery Team undertook an initial scoping exercise in 2011 and a further scoping survey in 2015 to collect information on current training for clinical emergencies in CRFs throughout the UK. The results of the surveys, the recommendations from the MHRA (2007) and guidelines issued by the Association of the British Pharmaceutical Industry (ABPI, 2007 and 2012) are reflected in this document. The MHRA Good Clinical Practice Guide (2012) has also informed subsequent versions of this document.

Levels of Training

The 2011 scoping survey revealed 63.6% of respondents are currently undertaking emergency scenario training; this number has marginally increased to 68% in 2015. All staff working within a CRF setting should receive some level of training for clinical emergencies and this should be set as appropriate to their role (ABPI 2007 and 2012, MHRA 2007 and 2012). Consideration should be given to the timings of scenarios to include agency, bank and outreach staff (MHRA 2009 and 2012).

The 2011 survey identified that 75% of qualified nurses in CRFs are trained in Immediate Life Support (ILS); this has increased to 89% in 2015. This is the recommended level of training for clinical staff and annual updates should be performed as a minimum (MHRA 2007 and 2012, ABPI 2007 and 2012). If this level of training is not possible due to availability and/or funding, it is recommended that a risk assessment be performed prior to studies being accepted to start in the CRF.

The level of cover in the event of a medical emergency must be appropriate for the level of risk of harm from the Investigational Medicinal Product (IMP), study procedure or intervention and this will define the level of resuscitation cover appropriate for the level of risk (ABPI 2007 and 2012, MHRA 2012). ILS is an absolute requirement for clinical staff working on Phase I studies in accredited units.

Methods and Scope of Training

There are several methods of training that can be used. The MHRA (2007 and 2012) and ABPI (2007, 2012 and 2018) expect research staff to be trained and competent to deal with a medical emergency. A recommended method of testing emergency training is to create scenarios that allow staff to simulate what they would do in an emergency. The scenarios should cover a variety of common emergency situations, and it is also useful to consider the specific types of studies undertaken in the CRF and to design scenarios accordingly, e.g. studies involving pregnant women.

The different types of scenarios must be rotated with documented evidence (MHRA 2007, 2009 and 2015) available for internal and external inspection. For Phase I accredited units, this evidence must include a CRF policy that specifies the number and nature of scenarios that staff are expected to attend, and there must be a clear record of who attended and when. This would be recommended as best practice for all facilities to demonstrate programme of training. In addition, management of any anticipated trial specific adverse events could be incorporated into training scenarios prior to the start of the study (MHRA 2012, 2015 and 2025).

Scenarios may be announced or unannounced (these may also be referred to as planned or unplanned). In an announced scenario, learners are made aware in advance that an emergency scenario training session has been arranged, are informed about what will be involved and required of them by the Scenario Facilitator before the scenario begins. The announced scenario could be part of ILS or in-house training. In an unannounced scenario, learners only become aware of the scenario when the alarm is raised.

Training in clinical emergencies should include appropriate information about the IMP and study protocol including use of known antidotes and unblinding procedures. For Phase I Accreditation, it is expected that unblinding will be incorporated into some emergency scenarios - an anaphylaxis scenario can be a useful time to test knowledge of unblinding procedures (MHRA 2012, 2015 and 2025).

During a Phase 1 Accreditation Scheme inspection, the MHRA will usually ask for a demonstration of an emergency scenario, along with testing of a transfer to hospital, (MHRA 2012, 2015 and 2025), and this applies whether the unit is on the hospital site or if an ambulance transfer is required. Emergency training should therefore include preparation for, and transfer to, hospital/ critical care, considering local logistics.

If facilities are available, a video recording of an announced transfer would be appropriate evidence of a rehearsed transfer. This may also present an opportunity to have involvement and support from the hospital resuscitation team and Critical Care.

Simulation training laboratories may be accessible within some hospitals/ universities. This experience can provide simulation of a variety of emergency scenarios, with a formative and reflective review of the entire scenario with the simulation education staff.

Ten core adult scenarios and eight core paediatric scenarios are included in this guidance; these are based on the requirements of the MHRA Phase I Accreditation Scheme (2007, 2015 and 2025). Some of the core scenarios are divided into parts (a + b) to allow for either improvement or deterioration in an emergency.

Frequency of Training

The MHRA (2007, 2012, 2015 and 2025) and ABPI (2012 and 2018) suggest training for clinical emergencies should occur 'regularly'. The 2011 and 2015 scoping exercise conducted by the UKCRF Education Theme Group identified that most staff are updated in emergency training annually and many CRFs undertake one unannounced and one announced scenario training session within a twelve-month period. However, the Resuscitation Council (2015) state the maximum number of learners in a session should be at a ratio of 1 instructor to every 6 learners, hence there may be a need to increase the number of sessions locally to accommodate all staff in training opportunities. The MHRA (2012) Good Clinical Practice (GCP) Guide states an expectation that all clinical staff working in an accredited Phase I unit will be involved in regular emergency scenario testing as well as annual emergency training. All areas conducting clinical research should follow local and CRF policy.

Delivery of Training

Most CRFs have support from the resuscitation officers and this is a positive asset in the delivery of training when debriefing is not available, it may be possible for the resuscitation team to invest time in training designated CRF nurses in the skills necessary for the delivery of training. This may result in less demand on the resuscitation team in the long term.

The ABPI (2007) recommend using appropriately trained people such as doctors and resuscitation officers in training in resuscitation. However, access to doctors with the appropriate level of expertise in resuscitation may not be possible.

Unannounced scenarios need careful preparation, and responsibility for coordinating scenarios should be given to appropriately qualified staff. The respondents in both scoping surveys identified these as CRF nurses with appropriate experience/expertise, CRF education/professional development staff, and resuscitation officers. Where possible, rotation of the CRF nurse involved would facilitate more members of staff being involved in preparing for and facilitating emergency scenario training.

Debrief Mechanisms

A debriefing session should follow all emergency training scenarios, whether announced or unannounced, adult or paediatric (Fanning and Gaba 2007). The 2015 survey recorded 100% response that post-scenario debriefing occurs. To assist those who are managing the scenario in providing a structured debriefing, debriefing delivery tools are included at the end of this guidance document (page 119). A template for recording details of the training session that can be used to support the debriefing session is included in Appendix 2. The Generic Instructor course run by the Resuscitation Council (UK) includes training in providing structured debriefing (http://www.resus.org.uk/pages/infoMain.htm). However, there are set criteria for course candidates and the appropriateness of undertaking this course should be assessed locally.

Documentation of Training

Emergency scenario training sessions should be seen as learning opportunities and as such, they should be documented and distributed to all staff, in order that any learning points can be shared, whether they have taken part in the scenario or not. For accredited units, the MHRA expect to see a formal process for sharing observations and outcomes (MHRA 2009 and 2015), such as an SOP detailing electronic sign off, e-mail distribution to external staff. Documentation should include timings of the response to the alarm call, delivery of appropriate equipment, interventions, and transfer to Critical Care (if required).

Any corrective and preventative actions (CAPA) following the scenario should also be documented and followed up (MHRA 2009, 2012 and 2015). The CAPA information should include:

- description of the learning outcome
- the corrective and preventative action
- timeframe for completion
- responsibility for delivering the CAPA
- circulation list to staff for distribution of CAPA
- record of receipt of the CAPA information
- evaluation of effectiveness of CAPA

Appendices 1 - 6 contain templates (both blank and completed with example observations and actions) that can be used to facilitate the documentation of training.

Summary of Recommendations

- Accredited Phase I units require qualified nursing staff to be trained in Immediate Life Support (ILS) or Paediatric Immediate Life Support (PILS) as a minimum with annual updates. Qualified doctors should be trained in Advanced Life Support (ALS) or European Paediatric Life Support (EPLS) or equivalent with four yearly updates.
- All CRF staff whether clinical or non-clinical should receive training appropriate to their role for clinical emergencies, to be decided locally.
- All staff should be involved in at least one announced or unannounced emergency scenario training session annually.
- The maximum numbers of learners involved in emergency scenario training should be at a ratio of 1 instructor: 6 learners.
- ILS, PILS, ALS and EPLS training, emergency scenario training, and simulation training laboratories are all methods of training that provide staff with the skills to manage medical emergencies.
- Resuscitation officers, doctors with appropriate levels of expertise, appropriately qualified CRF staff and simulation laboratory staff are all appropriate to be involved in the delivery of emergency scenario training.

- A debriefing session should follow an emergency training scenario whether announced or unannounced.
- Emergency scenario training should be documented and a summary of the training distributed to all relevant staff, whether they attended those scenarios or not, so that any learning points can be shared. Any corrective and preventative actions following the scenario should be followed up, documented, effectiveness evaluated and disseminated to all appropriate staff.
- NHS England and NHS Improvement endorse the use of a National Early Warning Score (NEWS) within acute and ambulance settings. The National Early Warning Score 'NEWS' was developed by the Royal College of Physicians. In 2017 a revised version of the Early Warning score was published: NEWS2 and has been rolled out nationally. Use of the tool should be incorporated into scenarios for deteriorating adult patients if in use locally in line with local policies. Similarly, the Paediatric Early Warning Score (PEWS) should be incorporated if in use within Paediatric settings, completing the scenario-based training.

Frequently Asked Questions (FAQs)

Q. Should CRFs have a Standard Operating Procedure (SOP) in training and refresher training in emergency resuscitation procedures?

A. The MHRA Phase I Accreditation Scheme (MHRA 2007) lists this as one of the criteria required; there should be written procedures for emergency resuscitation training and refreshers which could be a training policy that covers frequency of ILS, PILS, ALS and EPLS & scenario training.

Q. Should the training scenarios be planned to coincide with quieter periods?

A. No. Do not always select a quiet period, as this will not demonstrate a realistic scenario. Vary the situation, for example make the scenario within a locked toilet or in the waiting area.

Q. How often should staff check the emergency trolley, alarms and bed tilts?

A. The emergency trolley should be checked at least weekly (MHRA 2007 and 2012, ABPI 2012), however this may be determined by local policy and be performed more frequently to ensure familiarity with equipment.

Q. Should all researchers receive an orientation to emergency equipment, oxygen cylinders, alarm call bells?

A. Yes, this should form part of the orientation to the CRF before the study starts. It may be useful to complete and sign a checklist to record that staff have been made aware of appropriate medical equipment.

Q. Who should be checking the emergency trolley?

A. All clinical staff (including medical staff) should be involved in the checking of the emergency trolley as part of their role in the CRF. As the likelihood of using the resuscitation within a CRF is small, it is recommended that checking is performed weekly to retain familiarity with equipment location/use.

Q. Should Emergency Scenarios Training be limited to one staff group?

A. No, all clinical staff, of all professions and grades, working on the CRF should be involved in the emergency scenarios training sessions.

Q. Are there any logistical preparations that need to be undertaken prior to emergency scenario training?

A. There should be a plan with the relevant CRF Manager to ensure appropriateness of any announced sessions, to prepare and educate staff to understand what is expected of them and set the ground rules (Fanning and Gaba 2007). In unannounced sessions, the sound of alarms and staff rushing may cause anxiety for some participants and carers; it is important that any participants or visitors who may be in the CRF during the emergency scenario training are warned. It is also important to consider staffing levels and ensure participant safety is not compromised during scenario training.

Q. Should separate scenarios be planned for adult trained and paediatric trained staff within a CRF?

A. Separate scenarios can be run but it is useful for both groups of staff to be involved in scenarios with the other patient group.

Scenario Delivery Tool

Simulation allows learners to take an active role in developing their knowledge and skill base (Fanning & Gaba 2007) and should be designed to challenge learners and allow mistakes in a safe and supportive learning environment without harming participants or others (Arafeh et al 2010).

Simulation training can be designed to target specific learning needs and creates an opportunity for learners to practice numerous attempts (as required) to achieve the desired level of competence (Perkins 2007).

The facilitator role is to plan, coordinate and deliver a simulated scenario experience and ensure learners have enough time to reflect on their learning experience. To achieve this, it is important to set time frames for each stage of the scenario and stick to them.

It is vital that simulated scenarios are coordinated by suitably qualified and experienced facilitators to ensure the experience has a positive change in the learners' behaviours (Fanning & Gaba 2007).

Debriefing is well documented as the most important feature of simulation-based medical education (Fanning & Gaba 2007). It is therefore essential that enough time is allocated to the debrief session to ensure the learner has time to reflect on their learning experience. Ideally, a facilitated debrief should account for approximately double the time set for the scenario.

Scenario Delivery Stages

Stage 1: Pre-Scenario Preparation

Initial planning

Begin scenario planning approximately 1 week prior to performing the scenario. However, more time may be needed if the scenario is complex and/or if other departments are going to be involved. (e.g. participant transfer to Critical Care).

During this time, create a scenario plan – you may choose to use one of the Core Scenarios described in this document, or to create your own (a template scenario plan with guidance notes is available at Appendix 2 to help you). As part of the scenario plan, you will need to:

- Identify the scenario and learning objectives.
- Decide where you are going to hold the scenario (location).
- Identify what you will use to represent the participant - a manikin or a facilitator? If the latter, you will need a crib sheet for the facilitator to follow.
- Start preparing the props needed for the scenario (e.g. O_2 delivery devices, bag-valve-mask, IV lines, monitoring equipment, cardiac arrest trolley, drug/ observation charts, ECGs, medical notes, blood results).
- Set the time frame for each section of the scenario (e.g. pre-scenario 15-20 minutes, during scenario 8-10 minutes and post-scenario 15-20 minutes). Times may vary depending on the complexity of scenario.

Day of scenario training – scenario set-up

1. Environment

- Have a copy of the scenario plan to refer to.
- Prepare the location where the scenario is going to take place.
- If using a manikin, position it as described in the scenario plan.
- If using a facilitator, ensure they know exactly what is expected of them during the scenario and have a copy of the facilitator's crib sheet.

2. Props

- Put props in position (as required) and make sure you have all other props to hand if and when they are requested (e.g. O2 delivery devices, bag-valve-mask, IV lines, monitoring equipment, emergency trolley, drug/ observation charts, ECGs, medical notes, blood results).
- Make copies of the template for recording activities during the scenario (Appendix 1) and identify a facilitator to time and document relevant events during the scenario as they occur.

Stage 1: Pre-Scenario Preparation (continued)

3. Briefings

Brief the facilitators on:

a. The scenario narrative (read it out) and intended learning objectives.

b. Specific instructions for each facilitator involved in the scenario (e.g. observer, scribe, participant).

c. Learners' experience levels.

If the scenario is announced, brief the learners on:

d. The scenario in the context of the training and the process (brief, scenario, debrief).

e. The scenario narrative (read it out) and intended learning objectives (e.g. improve technical and non-technical skills).

f. Who is facilitating the scenario and who is not.

Stage 2: During scenario delivery

Record events as they occur including the time, individual involved (e.g. nurse, doctor, etc.) and event – for example:

- 09:46:45 – Call bell pulled by relative
- 09:46:55 – First Responder
- 09:47:24 – Second Responder, followed closely by Third Responder, etc.

Record technical and non-technical skills of learners that you could use during debriefing.

Keep the learning objectives in mind.

A copy of the template for recording details of the training session, completed with example observations, is available at Appendix 3.

Stage 3: Immediately Post-Scenario

Structured debriefing via facilitated debrief enables the group to reflect on and discover what happened during the scenario.

Immediately regroup learners in a different area to allow vital reflection (i.e. place of action vs. place of reflection).

Ensure the room is set up appropriately – arrange the seating so that everyone can see each other with a minimum of two facilitators present (ensure the facilitators sit opposite, where they can see each other).

Introduce the facilitators involved in the scenario if you have not already done so.

Explain that debriefing will follow a structured process and facilitate the debrief as a learning conversation. For more detailed guidance, refer to the Debriefing Delivery Tool (p.119).

Core Adult Scenarios

Core Adult Scenario 1: Recognition and Initial Treatment of Acute Coronary Syndrome (ACS)

Case scenario	Recognition and initial treatment of Acute Coronary Syndrome (ACS)
Intended clinical (technical) learning objectives	• ABCDE approach to assessing and treating participants at risk of cardiac arrest • Identify the increased risk of cardiac arrest secondary to MI • ACS recognition and initial treatment and management
Intended non-technical learning objectives	**Communication** • Structured and effective team communication **Leadership and teamwork** • Managing cardiac arrest • Appropriate and timely allocation of personnel • Managing the needs of relatives **Decision making** • Appropriate call for help

Participant's name and age/ DOB	• Peter Fox • 55-year-old male
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced** A 55-year-old man has just finished a 3-minute shuttle walk for the (specify) study (an observation study)
Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	A 55-year-old man has just finished a 3-minute shuttle walk for the (specify) study (an observation study). He is now complaining of having dull chest pain radiating to his left arm. He looks pale and sweaty. **If asked for:** • PMHx: MI one year ago with recurrent angina,hypertension and type 1 DM • NKDA, Ex-smoker 30/day until 6 months ago, 10 units alcohol/ week • Medication list with participant

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	1. To run the scenario 2. To role play as the relative (optional) 3. To role play as the participant (optional) 4. To observe and document scenario events
Learner (Options according to availability)	• Clinical roles (maximum 6 learners) • Learners should assume their own clinical role during the scenario
Area setup for scenario	**Environment** • Participant sitting in a chair in an examination room in the CRF **Specific set-up** • Can use a facilitator or a manikin as the participant
Equipment setup and possible props needed for scenario	**Equipment immediately available** • Whatever is normally available in the examination room where the scenario is taking place **Equipment available on request** • Emergency trolley, AED, cardiac monitor, O2 and masks, suction, emergency drugs etc
Participant/ manikin preparations for scenario	**Gender** • Male participant **Participant's position** • Sitting on a chair in the examination room **Appearance** • No monitoring, no IV lines • Medications: Sublingual GTN spray (if asked) **Concomitant medications** • Metformin, Insulin, GTN spray (in his pocket), Aspirin, Omeprazole (the participant has this list)

Medical documentation needed for scenario	**Available** • Concomitant medications list in the participant's pocketCase Report Forms currently being completed **Not available** • Clinical records not immediately available

Scenario Clinical Course

Observations on initial assessment	**Verbal handover to first responder as they enter:** Participant is complaining of radiating chest pain and appears pale and sweaty. • A: Clear • B: SOB, RR 24bpm, SpO_2 91% in air, symmetrical chest movement, normal breath sounds, trachea central, percussion normal resonance • C: HR 110 min, regular (ECG: shows sinus tachycardia), BP 140/80mmHg, temp 37.0°C, capillary refill time (peripherally and/or central) 2 secs, 12 lead ECG (attached) if requested • D: Verbal response, Blood Glucose (if asked) 6.3 mmol/L, both pupils reacting equally to light • E: Persistent central chest pain radiating to the left side, pale and clammy to the touch

Initial clinical interventions required in response to the above	• Shout for help (staff in reception; emergency buzzer) • Recognition of need for urgent medical help (calls appropriately) • Immediate ABCDE assessment • Start obtaining history • Cardiac monitoring • Requests 12 lead ECG (attached) • IV access as skills appropriate • Bloods: Trop I/T (specific to area), U&E, FBC, Clotting, Glucose • Initial treatment: • O_2 with appropriate delivery device if indicated as result of low O_2 Sats • GTN (in participant's pocket – 2 puffs) • Aspirin – treatment dose – 300mgs PO Stat (crushed or chewed) • Consider small doses of IV opioid drug (as per local practice)
Clinical course progression	If initial interventions given as above, then participant's breathing and pain remains the same until help arrives – Doctor or Resuscitation Officer If initial interventions are not given, then the participant deteriorates but remains conscious – allow for further assessment below

Further clinical interventions required in response to above progression	**Reassess:** • A: Clear • B: SOB, RR 25bpm, SpO_2 98% (if on O_2), symmetrical chest movement, and normal breath sounds • C: HR 120min, Regular (ECG: shows sinus tachycardia with ST segment changes noted on cardiac monitoring. • Request 12 lead ECG (in patient's notes if requested) • ST elevation noted on 12 lead ECG, BP 150/105mmHg (BP would drop with GTN 130/70mmHg), temp 37.0°C, capillary refill time (peripheral) 2 secs – this would not be delayed • D: Verbal response, BM (if asked) 6.3mmol/L • E: Persistent central chest pain, pale and clammy to the touch • Check if help has been requested • Doctor/ Resuscitation Officer arrive • Hand over using Situation, Background, Assessment, Recommendation (SBAR)
Further clinical course progressions (as required)	Insert / Delete as required
Further clinical interventions (as required)	ST elevation MI identified on 12 lead ECG: Refer to local chest pain pathway and arrange primary PCI transfer; take advice regarding dual-antiplatelet therapy and LMWH. NICE guideline: NG 185 Acute Coronary Syndromes (2020).; Resuscitation Council UK Guidelines (2021).
Post-emergency care (Time dependent)	• Reassess using ABCDE • Request ECG, ABG, Chest X-ray • Handover of participant • Situation Background Assessment Recommendation(SBAR) • Transfer of minimum records required to accompany participant to CCU, or other department as defined in local SOPs

Post-Scenario Discussion

Possible discussion points	• Using a systematic approach (ABCDE assessment) • Recognise presentation of ACS. • Be aware of initial treatment options in ACS • The importance of a good team leader in the management of ACS • Emphasises importance of effective debriefing as a learning tool • Use of SBAR tool • Transfer of patient with the appropriate equipment and notes to the right clinical destination. Knowledge of CCU/ HDU/ICU/PCI Lab/ Admissions/ward location locally

Appendices

Attach any background information and supporting documents for the scenario as required, e.g. Clinical records, x-rays, observation chart, drug chart, ECG, fluid balance chart, peak flow chart, blood results, ABGs results etc.

Core Adult Scenario 1a: Assessment and Initial Treatment of a Critically Ill Participant in Cardiac Arrest

Case scenario	Assessment and initial treatment of a critically ill participant in cardiac arrest
Intended clinical (technical) learning objectives	• ABCDE approach to assessing and treating participants at risk of cardiac arrest • Cardiac arrest recognition and management demonstrating safe defibrillation (manual defibrillator or AED) • Knowledge of resuscitation shockable and non-shockable treatment algorithms as appropriate
Intended non-technical learning objectives	**Communication** • Structured and effective team communication • Utilisation of SBAR structured handover structured handover **Leadership and teamwork** • Management of cardiac arrest • Appropriate and timely allocation of personnel to specific required roles • Managing the needs of relatives **Decision making** • Timely call for appropriate help

Participant's name and age/ DOB	Joe Sparrow 56-year-old male
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced** A 56-year-old man arrives in the CRF reception to attend a screening visit for the (specify) study

Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	A 56-year-old man arrives in the CRF reception to attend a screening visit for the (specify) study. While waiting in Reception, he develops dull central chest pain, shortness of breath (SOB) and looks pale and sweaty. **If asked for:** • PMHx Ischaemic heart disease with MI one year ago and recurrent angina, type 1 DM, gastroesophageal reflux disease • NKDA, ex-smoker 30/day until 6 months ago, 10 units of alcohol per week. Medications list with relative

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	1. To run the scenario 2. To role play as the relative (optional) 3. To role play as the participant (optional) 4. To observe and document scenario events
Learner (Options according to availability)	• Clinical roles (maximum 6 learners) • Learners should assume their own clinical role during the scenario to ensure they work within their scope of practice
Area setup for scenario	**Environment** • Participant sitting in the reception area of the CRF **Specific set-up** • Can use a facilitator as the participant initially, changing to manikin at cardiac arrest
Equipment setup and possible props needed for scenario	**Equipment immediately available** • None, as the location is the reception area **Equipment available on request** • Emergency trolley, AED, cardiac monitor, O_2 and masks, suction, emergency drugs, vital signs monitoring, blood glucose monitoring equipment

Participant / manikin preparations for scenario	**Gender** • Male participant **Participant's position** • Sitting in the CRF Reception **Appearance** • No monitoring, no IV lines, a few basal crepitations **Concomitant medications** • Metformin, Insulin, GTN, Aspirin, Omeprazole (relative has this list)
Medical documentation needed for scenario	**Available** • Concomitant medications list with relative • GTN spray in patient's pocket **Not available** • Clinical records (participant not local to this Trust)

Scenario Clinical Course

Observations on initial assessment	**Verbal handover to first responder as they enter:** Participant is complaining of central chest pain, appears to be short of breath (SOB) and looks pale and sweaty. A. Clear B. SOB, RR 28bpm, SpO_2 96% on O_2, symmetrical chest movement, normal breath sounds, use of accessory chest wall muscles C. HR 110 min, regular (ECG: shows sinus tachycardia with ST segment changes), BP 140/68mmHg, temp 37.0°C, capillary refill time (peripheral) 2 secs, request 12 lead ECG (attached) D. Verbal response, BM (if asked) 6.3 mmol/L E. Persistent central chest pain, pale and clammy to the touch

Initial clinical interventions required in response to the above	• Shout for help (staff in reception; emergency buzzer) • Recognise need for urgent medical help (calls appropriately) • Immediate ABCDE assessment • Start obtaining history • Cardiac monitoring • Request 12 lead ECG (attached) if has not already • IV access if skilled personnel available • Bloods: Trop I/T (specific to area), U&E, FBC, Clotting, Glucose Initial treatment: • O_2 with appropriate delivery device if indicated • GTN (in participant's pocket) • Aspirin • Pain relief
Clinical course progression	While treatment is being administered, the participant stops talking and collapses on the floor Cardiac arrest (VF/ VT)

Further clinical interventions required in response to above progression	Reassess: • A: Clear • Check participant – no breathing and no pulse • Confirm cardiac arrest • Call resuscitation team • Start CPR • Attach self-adhesive pads while continuing chest compressions • Pause CPR to confirm rhythm - VF on monitor • Restart CPR whilst defibrillator is charging • Manage airway and ventilation (depending on skill level) • Alert rescuers to stand clear, remove O2 • When defibrillator charged – Stop CPR – Stand clear – Deliver 1st shock (energy specific to defibrillator) • Promptly restart CPR (30:2) do not re-check rhythm • Continue CPR 2 min • During CPR • IV access/ advance airway (as appropriate) • 2 min – Check monitor (confirm VF) • 2nd shock (energy specific to defibrillator) • Continue CPR for 2 min • During CPR • Change person providing compressions • 2 min – Check monitor (confirm VF) • 3rd shock (energy specific to defibrillator) • Continue CPR for 2 min • During CPR - Give adrenaline 1 mg and amiodarone 300mg IV • 2 min – Check monitor (confirm PEA) • Check participant for signs of life • Continue CPR for 2 min • During CPR - Consider causes • 2 min – Check monitor (confirm rhythm) • Check participant for signs of life

Further clinical course progressions (as required)	Insert / Delete as required
Further clinical interventions (as required)	Insert / Delete as required
Post-emergency care (Time dependent)	• Return of spontaneous circulation - initiate post- resuscitation care • Reassess using ABCDE • Request ECG, ABG, chest x-ray • Handover of participant • Situation, Background, Assessment, Recommendation (SBAR) • Transfer of minimum records required to accompany participant to ICU or other department as defined in local SOPs • Be able to transfer patient in real time to appropriate destination

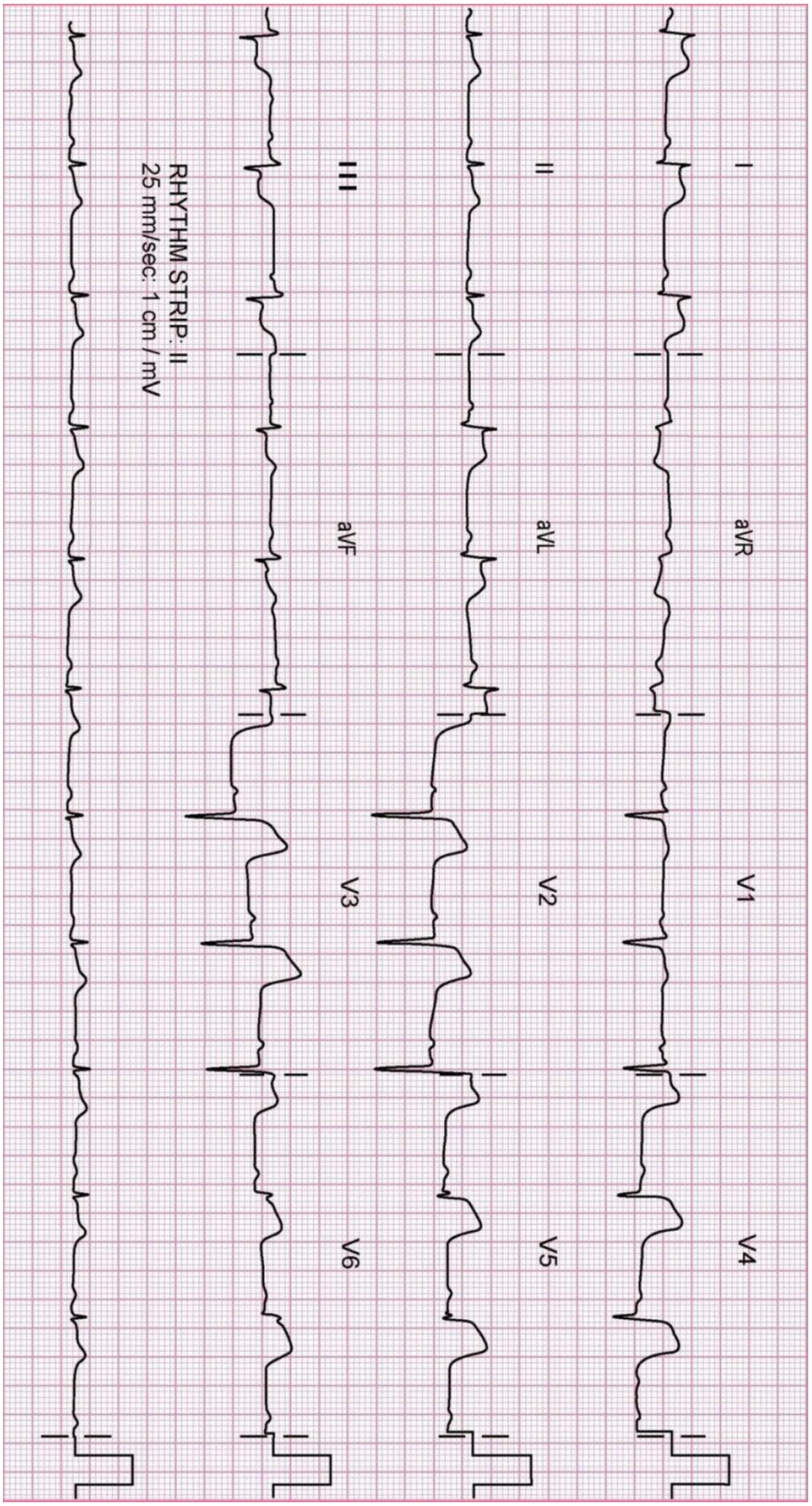
Post-Scenario Discussion

Possible discussion points	• Using a systematic approach (ABCDE assessment) for the assessment of a participant at risk of cardiac arrest • Resuscitation Council (UK) 2021 Resuscitation Guidelines (Resuscitation Council (UK) 2021 ALS algorithm) - shockable and non-shockable algorithms • The importance of teamwork and leadership in the management of cardiac arrest • Safe defibrillation – use of manual defibrillators or AED (specific to what is used in the department) • ECG analysis if appropriate • Post-emergency care and transfer

Appendices

Attach any background information and supporting documents for the scenario as required, e.g. Clinical records, x-rays, observation chart, drug chart, ECG, fluid balance chart, peak flow chart, blood results, ABGs results etc.

ECG recording for use with scenario 1a



Core Adult Scenario 2: Recognition and Treatment of Syncope-Vasovagal

Case scenario	Recognition and treatment of syncope-vasovagal
Intended clinical (technical) learning objectives	ABCDE approach to assessing and treating a collapsed participant • Call for help at appropriate time • Appropriate use of interventions / emergency equipment (positioning of participant, O_2, monitoring equipment, emergency drugs) • Understand the causes of syncope
Intended non-technical learning objectives	• To demonstrate good leadership and communication within the team and with the participant • Clear handover to medical team using SBAR approach or equivalent

Participant's name and age/ DOB	Hilda Wood Age 26 years old
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced** Hilda is attending a phase II clinical trial. Hilda feels dizzy during venepuncture and collapses in the phlebotomy chair/ bed Past medical history of asthma with prescribed inhalers. Nil other significant history, nil drug allergies
Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	History as above NB: The participant will resume consciousness within 30 seconds of positioning. Vital signs will come back as normal after implementation of clinical course 1 required interventions.

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	1. To run the scenario 2. To role play as the relative (optional) 3. To role play as the participant (optional) 4. To observe and document scenario events
Learner (Options according to availability)	• Clinical roles (maximum 6 learners) • Learners should assume their own clinical role during the scenario
Area setup for scenario	**Environment** • CRF **Specific set-up** • Manikin or facilitator playing participant sitting upright on a chair/ bed
Equipment setup and possible props needed for scenario	**Equipment immediately available** • O_2, equipment to measure vital signs **Equipment available on request** • Emergency trolley, suction machine
Participant/ manikin preparations for scenario	**Gender** • 26-year-old female **Participant's position** • Sitting upright on a chair/ bed **Appearance** • Pale, sweaty and clammy **Concomitant medications** • Salbutamol inhaler

Medical documentation needed for scenario	**Available** • Local study data file containing research study consent form, PIS, brief PMH and current medications. • Written entry by PI stating the consent process and brief medical history • Set of baseline medical observations **Not available** • Medical records

Scenario Clinical Course

Observations on initial assessment	Participant has collapsed and looks pale, sweaty and clammy. A. Patent B. RR 16bpm C. Pale and clammy. HR 112bpm, regular BP 80/52mmHg D. Unconscious E. Nil
Initial clinical interventions required in response to the above	• Shout for help, emergency buzzer • Contact study doctor if present • Assess participant using ABCDE approach: A. Maintain airway B. O_2 therapy – non-rebreathe with 15L/min O_2 or similar C. Raise participant's legs, monitor BP D. Vital signs - BP, HR, RR, temp, BM E. Reassure participant • Optimum positioning • Communicate findings to attending colleagues
Clinical course progression	Participant improving; examination findings: A. Patent B. RR 14, SpO_2 98% on room air C. HR 90bpm, BP 109/70mmHg D. AVCPU - alert and oriented E. Nil

Further clinical interventions required in response to above progression	• Reassess: ABCDE • Offer fluids when participant regains consciousness • Medical review before discharge • Report as an AE
Further clinical course progressions (as required)	Participant is now breathing and has a central pulse
Further clinical interventions (as required)	Reassess using ABCDE assessment tool
Post-emergency care (Time dependent)	The participant can be discharged after medical review

Post-Scenario Discussion

Possible discussion points	• Include technical and non-technical points: • Assessment using ABCDE approach • Draw out attributes of a good team leader – roles planned in advance; identification of team leader; non-technical skills (task management, team working, situational awareness, decision making, structured communication) • Hand over to medical staff • Causes of syncope

Appendices

Attach any background information and supporting documents for the scenario as required, e.g. Clinical records, x-rays, observation chart, drug chart, ECG, fluid balance chart, peak flow chart, blood results, ABGs results etc.

Core Adult Scenario 3: Recognition and Treatment of Anaphylaxis

Case scenario	Recognition and treatment of anaphylaxis with recognition to un-blind
Intended clinical (technical) learning objectives	• Performance of the patient assessment using systematic ABCDE approach • Staff can recognise and initiate treatment of anaphylaxis in line with resus council UK 2021 guidelines • Staff recognise the need to call for help early and the requirement for follow up care and reasons why • Staff demonstrate that they understand and can safely follow the process for un-blinding
Intended non-technical learning objectives	**Communication:** • Staff communicate effectively within the team • Clear SBAR handovers given **Leadership and teamwork:** • Staff have clearly defined roles within the team • Staff consider the needs of family – contact the next of kin • Clear leadership by a team member • Appropriate and timely delegation of tasks **Clinical Outcomes:** • Safe management of Anaphylaxis • Recognise the signs and symptoms of anaphylaxis and life-threatening problems • Know how to manage the patient with anaphylaxis • Understand the appropriate treatment of anaphylaxis • Understand what refractory anaphylaxis is and how this is managed **Decision Making:** • Quick decision made regarding diagnosis and status as an emergency • Appropriate and timely initiation of treatment • Appropriate and timely escalation and involvement of medical emergency team • Appropriate decision making to perform un-blinding

Participant's name and age/ DOB	Sam Claus Age 21
Initial Clinical Picture – this is given to the scenario participants	**Use only if scenario is announced** • Sam is taking part in a phase 1 study – This is Sam's first infusion of the trial's investigational medicinal product (IMP). Sam is not taking any regular medications and has no known drug allergies. • After 5 minutes Sam starts to complain of feeling generally unwell; faint, abdominal pain and pins and needles in their fingers – on initial assessment there is nothing to note other than a slightly increased respiratory rate.
Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	Sam is experiencing an anaphylaxis reaction relating to the IMP intravenous infusion. Sam is usually well with no known allergies and has no past medical history. Sam will continue to deteriorate, until the first dose of adrenaline administration. Recognition and treatment should be based on Resuscitation Council (UK) (2021) Emergency Treatment of Anaphylactic Reactions Guidelines: • Staff use ABCDE approach • Discontinue the intravenous infusion • Initiate treatment • Call made to CRF Physician, medical emergency team and request for an anaesthetist • Handover using SBAR or similar communication tool • Consider transfer to ICU • Complete adverse event report

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	1. To run the scenario 2. To role play as the relative (optional) 3. To role play as the participant (optional 4. To observe and document scenario events

Learner (Options according to availability)	Clinical roles (maximum 6 learners) Learners should assume their own clinical role during the scenario
Area setup for scenario	**Environment** • The CRF ward area **Specific setup** • Sam is sitting up in bed with the IMP infusion running • Vitals signs and ECGs are scheduled to be recorded every hour
Equipment setup and possible props needed for scenario	**Equipment immediately available** • Oxygen • Cardio / respiratory monitoring for blood pressure, SpO_2, pulse, respirations, temperature **Equipment available on request** • Emergency trolley, defibrillator • Anaphylaxis kit containing adrenaline and algorithm • Intravenous fluids and IV administration sets • Blood glucose monitoring equipment
Participant/ manikin preparations for scenario	**Gender** • Male/Female **Participant's position** • Sitting up in bed **Appearance** • Anxious, pale, clammy • Concomitant medications nil
Medical documentation needed for scenario	**Available** • Case report form or patient workbook containing relevant medical notes • IMP Prescription chart • NEWS2 observation chart • Anaphylaxis algorithm

Scenario Clinical Course

Observations on initial assessment	**(If applicable) Verbal handover to first responder as they enter the scenario:** A. Clear B. RR 18bpm C. HR 90bpm, BP 110/60mmHg D. Alert, anxious E. Normal
Initial clinical observations and actions	Over the next 10 minutes, Sam becomes very short of breath, has a widespread wheeze, develops an urticarial rash, and feels lightheaded.
Clinical progression	A. Complains of tightness in throat B. RR 28 min, widespread wheeze C. HR120 min, BP 80/60mmHg D. Alert, although very anxious E. Widespread urticarial rash
Further clinical interventions required in response to above progression	• Discontinue the intravenous infusion • Contact the medical emergency team • Repeat ABCDE use deteriorating patient guidelines • Oxygen via non-rebreather • Treat anaphylaxis in accordance with Resus council guidelines • Monitoring (pulse oximetry, non-invasive blood pressure, 3-lead ECG) • Lay flat, with legs raised or semi recumbent position if breathing problematic • Recognise potential need for IV fluids and not using the same cannula as the drug • Handover using SBAR • Consider the requirements of un-blinding • Contact the Principal Investigator/Sponsor • Consider transfer to ICU • SAE report
Further clinical course progressions (as required)	Anaphylaxis resolves with appropriate treatment

Further clinical interventions (as required)	• Review by a senior clinician
	• Mast cell tryptase should be measured in all patients with suspected anaphylaxis where the diagnosis is uncertain
	  ○ initial sample as soon as feasible after initial treatment
	  ○ second sample 1 – 2 hr (but no later than 4 hr) symptom onset
	  ○ third sample at least 24 hr after complete resolution
	• Observed in a clinical area with facilities for treating life-threatening ABC problems for following lengths of time
	  ○ 2 hrs – single dose, good response, complete resolution, has auto injector and trained previously, adequate supervision on discharge
	  ○ At least 6 hours – 2 doses needed or prior biphasic reaction
	  ○ At least 12 hrs - > 2 doses, severe asthma or respiratory reaction, continued allergy absorption, late night admission, access to emergency care difficult if discharged
	• All patients should be referred to a specialist clinic for allergy assessment.
	• Offer patients an appropriate adrenaline injector as an interim measure before the specialist allergy assessment (unless the reaction was drug induced).
	• Patients prescribed adrenaline auto-injectors must receive training in their use and have an emergency management or action plan.
	• Anaphylaxis reactions should be reported to the UK Anaphylaxis Registry at www.anaphylaxie.net (to register, email anaphylaxis.registry@ic.ac.uk)
	• Refractory anaphylaxis (no improvement after 2 doses of IM adrenaline) refer to algorithm

Post-emergency care (Time dependent)	• Arrange appropriate transfer of participant for further observation – ICU/ HDU • Handover of participant to an appropriate area using Situation Background Assessment Recommendation (SBAR) • Transfer of minimum records required to accompany participant to ICU or other department as defined in local SOPs

Post-Scenario Discussion

Possible discussion points	Anaphylaxis is a severe, life- threatening, generalised or systemic hypersensitivity reaction. This is characterised by rapidly developing life-threatening airway and/or breathing and/or circulation problems usually associated with skin and mucosal changes. • Discuss the importance of an ABCDE approach and why interventions should occur as you find problems. • Discuss the approach to management: O_2, IM adrenaline, lying flat, legs raised or semi recumbent (if breathing issues) - 2021 Resuscitation Anaphylaxis Algorithm • Discuss reason other drugs have been removed from the initial treatment of anaphylaxis • Reason to call for help early and who should be contacted first in this scenario • Refractory anaphylaxis – what this is and how treated • What airway problems you would anticipate with the patient • Tools available to help make decisions • Equipment locations • Discuss the merits of intramuscular compared with intravenous adrenaline • What are the dangers of excessive doses of IV adrenaline in the patient with spontaneous circulation?

Appendices

Attach any background information and supporting documents for the scenario as required, e.g. Clinical records, x-rays, observation chart, drug chart, ECG, fluid balance chart, peak flow chart, blood results, ABGs results etc.

Core Adult Scenario 4: Recognition and Treatment of Asthma

Case scenario	Recognition and treatment of Asthma
Intended clinical (technical) learning objectives	• ABCDE approach to assessing and treating a participant with bronchospasm • Appropriate use of emergency equipment, drugs and monitoring • Identify increased risk of respiratory arrest/sudden deterioration • Understand escalation protocols in a research setting
Intended non-technical learning objectives	• Communication (with patient, patient's relatives & colleagues/team) • Leadership • Decision-making • Timing • Structured handover using SBAR

Participant's name and age/ DOB	Ali Mitchell 25-year-old
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced** Ali has agreed to participate in an observational study of exercise tolerance in well-controlled asthmatics The learners enter the room following a call for help from a junior nurse who has been monitoring Ali on a treadmill. They find Ali in a chair and struggling for breath
Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	• Ali is suffering an exercise-induced asthma attack • They are short of breath, has an audible wheeze and is unable to speak in full sentences • Their asthma is usually well controlled • Their condition will continue to deteriorate until appropriate assessment and treatment has been undertaken

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	1. To run the scenario 2. To role play as Alison 3. To role play as the nurse handing over 4. To observe and document scenario events
Learner (Options according to availability)	• Clinical roles (maximum 6 learners) • Learners should assume their own clinical role during the scenario
Area setup for scenario	**Environment** • The Exercise Suite in the CRF **Specific setup** • Ali, sitting in a chair
Equipment setup and possible props needed for scenario	**Equipment immediately available** • O_2, stethoscope, spirometer, Salbutamol inhaler,monitoring equipment **Equipment available on request** • Nebuliser equipment, respiratory drugs, emergency trolley
Participant/ manikin preparations for scenario	**Gender** • Female/male, usually well-controlled asthmatic, no other significant past medical history **Participant's position** • Sitting in a chair **Appearance** • No monitoring, anxious, speaking in short sentences, using accessory muscles **Concomitant medications** • Salbutamol

Medical documentation needed for scenario	**Available** • Study file, medical notes, prescription chart with prescribed Salbutamol inhaler (100 mcg/ metered dose inhalation) and Salbutamol nebuliser (2.5 mg) to be given • Atrovent/ ipratropium bromide 500mcg • Oral prednisolone (40-50mg) • IV hydrocortisone 100mg

Scenario Clinical Course

Observations on initial assessment	**(If applicable) Verbal handover to first responder as they enter scenario:** A. Patent, air gasping, no stridor or additional sounds B. RR 40bpm, reduced bilateral air entry, expiratory wheeze, using accessory muscles, SpO_2 91% on room air (if requested) C. HR 115bpm regular, BP 120/72mmHg, clammy. D. Alert, anxious E. Nil
Initial clinical interventions required in response to the above	• Call for appropriate medical help • Immediate ABCDE assessment • O_2 therapy (15L/min via a non-rebreathe mask) • Consider Salbutamol nebuliser • Is the participant in the optimum position? • Reassure participant throughout • Consider an Arterial Blood Gas, Chest X-ray and cannulation • Consider FBC, U&E, LFTs, CRP, clotting screen • Consider ECG

Clinical course progression	Alison deteriorates further: A. Patent B. Air entry further reduced, RR 40bpm, SpO_2 89% on 15L/min O_2, unable to speak, unable to obtain peak flow, unable to self-administer salbutamol inhaler C. HR 140bpm regular, BP 90/52mmHg, clammy, peripherally cool D. Extremely distressed, very anxious, appears to be tiring, unable to speak. E. Nil
Further clinical interventions required in response to above progression	• Summon the medical emergency team • Summon the emergency trolley (if not already requested) • Further nebulised Salbutamol/Atrovent/Oral prednisolone/IV hydrocortisone • Reassess: ABCDE throughout
Further clinical course progressions (as required)	Participant improving: A. Patent B. RR 25bpm, improved bilateral air entry, wheeze improved, SpO_2 98% on 15L/min O_2, able to speak in sentences, reduced use of accessory muscles C. HR 115bpm, BP120/78mmHg, remains clammy D. Alert, calmer E. Nil
Further clinical interventions (as required)	• Continue to monitor • Reduce O_2 therapy as able • Prepare for transfer to high care area • Continue to reassess using ABCDE approach
Post-emergency care (Time dependent)	• Reassess using ABCDE • Request ECG, ABG, Chest X-ray • Handover of participant – Situation, Background, Assessment, Recommendation (SBAR) • Transfer of minimum records required to accompany participant to ICU or other department as defined in local SOPs

Post-Scenario Discussion

Possible discussion points	• What are the hallmarks and treatment for a severe asthma attack? • What is the local policy on salbutamol administration in an emergency • What is the local process of arranging a transfer to the High Dependency Unit or equivalent? • What equipment is required for transfer? • Possibility of sudden deterioration • Possible causes (infections, allergens, irritants, weather change, physical activity, emotions, medications, occupational exposures, hormonal, non-compliance/running out of medication) • Differential Diagnosis (including Pulmonary Embolism)

Appendices

Attach any background information and supporting documents for the scenario as required, e.g. Clinical records, x-rays, observation chart, drug chart, ECG, fluid balance chart, peak flow chart, blood results, ABGs results etc.

Core Adult Scenario 5: Recognition and Treatment of Adult Sepsis

Case scenario	70-year-old with community acquired pneumonia leading to sepsis
Intended clinical (technical) learning objectives	• ABCDE approach to assessment • Calculation of NEWS2 score to indicate severity of sepsis • Call for help at appropriate time • Appropriate use of interventions/emergency equipment • Recognition and treatment of sepsis
Intended non-technical learning objectives	• To demonstrate good leadership and communication within the team and with the participant • Clear handover to medical team using SBAR approach or equivalent • Appropriate and timely delegation of tasks

Participant's name and age/ DOB	Jamie Harper 70 years old
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced**
	Jamie has been on a trial of a new oral medication for type 2 diabetes and has been taking this new medicine for the last 4 months. On attending a follow up clinic visit today Jamie has reported feeling unwell for the last two day Jamie has been let into the clinic room by a new clinical trials assistant who has called you as a study team member as Jamie says they have not been feeling well with a bad cough for the last two days. As you enter you notice that Jamie is breathing fast.

Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	**Situation**: Jamie has sepsis, from a respiratory tract infection **Background**: Jamie has been on a trial of a new medicine for his type 2 diabetes. Diabetes may make people more susceptible to infections. **Assessment**: Sepsis, high-risk. Jamie will continue to deteriorate unless sepsis is recognised and treated. A NEWS2 score above 7 with a confirmed infection indicates a high risk of severe illness or death from sepsis. A person is also at high risk of severe illness or death from sepsis if they have a: • suspected or confirmed infection • NEWS2 score below 7 And: • a single parameter contributes 3 points to their NEWS2 score • a medical review has confirmed that they are at high risk or there are any other clinical reasons for concern **Recommendations**: Use NICE guidelines (2025) and UKST Adult Inpatient 2024 guidelines and tools to: • Promptly recognise this is sepsis using NEWS2 and local management of deteriorating patient guidelines • Initial treatment within 1-hour • Immediate Senior Doctor review • Oxygen • IV access and bloods & blood cultures • IV antibiotics (check for allergies) • IV Fluids • Monitor

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	1. To run the scenario clinically 2. To record the events chronologically 3. Optional facilitator to role-play as patient
Learner (Options according to availability)	Clinical roles (maximum 6 learners) Learners should assume their own clinical role during the scenario
Area setup for scenario	**Environment** • Clinic room **Specific setup** • Jamie (role player or manikin) sitting on chair in the clinic room
Equipment setup and possible props needed for scenario	**Equipment immediately available** • Wall O_2 and adult O_2 face mask and vital sign equipment **Equipment available on request** • Emergency trolley and contents, ECG, NEWS2 charts and access to local management of deteriorating patient guidelines
Participant/ manikin preparations for scenario	**Gender** • Male/Female **Participant's position** • On clinic room chair **Appearance** • Looks pale and is showing signs of increased respiratory effort. Coughing occasionally **Concomitant medications** • Diabetes oral medicine (IMP) – has been taking for last four months
Medical documentation needed for scenario	**What is available** • NEWS2 chart and management of deteriorating patient/sepsis guides

Scenario Clinical Course

Observations on initial assessment	**(If applicable) Verbal handover to first responder as they enter scenario:** A. Clear B. RR 30bpm, SpO_2 90% on air, using accessory muscles, productive cough C. HR 130bpm, BP 85/45mmHg, clammy, capillary refill time 4 seconds centrally D. Alert E. Temp 38.5°C, no rash
Initial clinical interventions required in response to the above	• Call for appropriate medical help • Immediate ABCDE assessment and treat problems as found • Administer O_2 • Call for emergency trolley and monitoring • Move patient to bed • Explain to patient what's happening • Recognise sepsis and need for early treatment as per guidelines • Early IV access for blood tests, blood cultures, blood gas (including lactate) and IV fluids and antibiotics
Clinical course progression	A. Clear B. SpO_2 98% on 15L/min O_2 (non-rebreather), RR 36bpm, crackles left lower zone on auscultation, no wheeze C. HR 140bpm, BP 80/40mmHg, Capillary Refill Time is 4 seconds centrally D. Alert E. No rash, temp is 38.5°C
Further clinical interventions required in response to above progression	• Early IV access for blood tests, blood cultures, blood gas • Administer IV fluids in bolus or rapidly otherwise • Sample collection to test for source of infection e.g. sputum sample • Fluid balance chart and monitoring of urine output • ECG • Administer IV antibiotics according to local guidelines

	• Reassess: ABCDE and NEWS2 score • Reassure patient
Further clinical course progressions (as required)	Blood gas results (venous or arterial) Lactate 3.5mmol/L Glucose 6.0mmol/L (can be via finger prick glucose) If fail to administer IV fluids and antibiotics: A. Clear B. RR 40bpm, SpO_2 95% on 15L/min O_2, persistent crackles left lower zone on auscultation C. HR 150bpm, BP 70/35mmHg and capillary refill time 4 seconds D. Responds to Voice E. Temp 38.5°C, ECG (if done: sinus tachycardia only) Failure to persistently perform the above may lead to cardiac arrest if planned by facilitators. If IV Fluids and antibiotics are administered, then: A. Clear B. RR 30bpm, SpO_2 90% on air or 99% on 15L/min O_2, persistent crackles left lower zone on auscultation C. HR 100bpm, BP 110/65mmHg, capillary refill centrally 3 seconds D. Alert E. Temp 38.5°C, no rash
Further clinical interventions (as required)	• Handover to resuscitation team as they arrive using SBAR • Consider repeat IV bolus and administration of antipyretics • Call ahead to emergency department and/or intensive care • Explain and reassure patient, explaining what has happened and the plan
Post-emergency care Time dependent)	• Prepare for transfer to Emergency Department or intensive care unit – commence documentation • Consideration of urine output measurement

	• Chest radiograph (X-ray) needed to confirm diagnosis • Involve the critical care outreach team if not already present

Post-Scenario Discussion

Possible discussion points	**Include technical and non-technical points:** • Recognition of sepsis – high HR, fever, low BP (late sign), potential for chest infection source (coughing and respiratory signs) • Discuss an early call for help and who to contact first • Importance of early treatment with fluids and antibiotics • Discuss benefit of treatment for sepsis outweighs the risks for patients with type 2 respiratory failure (15L O_2) and fluids in overloaded patients • NICE (2025) and UKST Adult Inpatient 2024 guidelines in sepsis • Importance of ABCDE and calculating NEWS2 scores (in enabling standardised assessment and prioritising interventions) • Discuss use of equipment • Discuss leadership including delegation, situational awareness, decision making and communication • Discuss team-working: communication, planning and sharing out of interventions • Discuss use of SBAR tool for handover

Appendices

Attach any background information and supporting documents for the scenario as required, e.g. Clinical records, x-rays, observation chart, drug chart, ECG, fluid balance chart, peak flow chart, blood results, ABGs results etc.

Core Adult Scenario 6: Recognition and Treatment of Hypoglycaemia in an Alzheimer's Patient

Case scenario	Recognition and Treatment of Hypoglycaemia in an Alzheimer's Patient
Intended clinical (technical) learning objectives	• Staff can assess patient using ABCDE approach • Staff can recognise signs of hypoglycaemia in a confused patient • Staff can initiate appropriate treatment in a timely manner
Intended non-technical learning objectives	**Communication:** • Staff communicate effectively within the team • Clear SBAR handovers given **Leadership and teamwork:** • Staff have clearly defined roles within the team • An appropriate leader takes charge of the team and delegates appropriately **Decision Making:** • Quick decision made regarding diagnosis and status as an emergency • Appropriate and timely initiation of treatment • Appropriate and timely escalation and involvement of medical emergency team

Participant's name and age/ DOB	Edna Marples Age 78
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced** Mrs Marples is a 78-year-old lady participating in a phase 1 study for patients with Alzheimer's Disease. She has a past medical history of hypertension and type 2 diabetes mellitus.
Facilitator information pre-scenario (Narrative case description)	Around 4 hours post dose, Mrs Marples' son comes to the nurses' station reporting that his mother seems to be behaving peculiar and asks if a nurse can come to see his mother.

Use SBAR (Situation, background, assessment, recommendations)	When the nurse approaches Mrs Marples she angrily shouts at them to leave her alone. She appears sweaty and is holding her head in her hands

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	1. To run scenario 2. To play Mrs Marples 3. To observe and document activity
Learner (Options according to availability)	• Clinical roles (maximum 6 learners) • Learners should assume their own clinical role during the scenario
Area setup for scenario	**Environment:** • CRF ward area **Specific setup** • Mrs Marples (role player or manikin) sitting on chair in the ward room
Equipment setup and possible props needed for scenario	**Equipment immediately available** • Vital signs equipment • Blood glucose machine • Oxygen (if required), • IV access **Equipment available on request** • Hypoglycaemia box • Emergency trolley
Participant/ manikin preparations for scenario	**Gender:** • Female **Participant's position** • Sat out in chair at bedside **Appearance** • Appears sweaty and holding her head in hands **Concomitant medications** • Metformin

	• Gliclazide
Medical documentation needed for scenario	Patient study workbook and clinical notes

Scenario Clinical Course

Observations on initial assessment	**(If applicable) Verbal handover to first responder as they enter scenario:** A. Intact B. RR 12bpm, SpO_2 98% on air C. HR 84bpm BP 105/58mmHg D. Alert but confused, Blood Glucose 2.1mmol/L E. Pale and sweaty
Initial clinical interventions required in response to the above	Check blood sugar, initiate treatment for hypoglycaemia **as per hospital local protocol.** **For example**: NICE CG: Hypoglycaemia CKS summary **-** conscious and able to swallow patient: • Administer fast acting carbohydrate by mouth e.g. glucose liquid, glucose tablets, glucose 40% gels, pure fruit juice, sugar (sucrose) dissolved in an appropriate volume of water. Oral glucose formulations are preferred due to quicker absorption. • Re-assess response and if necessary, repeat treatment after 10-15 minutes up to a maximum of 3 treatments in total, once blood sugar concentration is above 4 mmol/L and patient has recovered long-acting carbohydrate should be given. **Other resource for more specific guidance** - JBDS-IP - The Hospital Management of Hypoglycaemia in Adults with Diabetes Mellitus. JBDS-IP Care
Clinical course progression	If appropriate treatment given: A. Intact B. RR 14bpm, O_2 Sats 98% on air C. HR 82bpm, BP 106/61mmHg D. Alert, appears less confused. Blood Glucose 3.9mmol/L E. Nil of note

Further clinical interventions required in response to above progression	If hypoglycaemia fails to respond, follow **hospital local protocol**. • Urgent medical review • Consider IV glucose. • Close monitoring
Further clinical course progressions (as required)	
Further clinical interventions (as required)	
Post-emergency care **(**Time dependent)	• Consider referral for review by diabetes specialist team • Should this be reported as AE.

Post-Scenario Discussion

Possible discussion points	**Include technical and non-technical points:** • Recognising hypoglycaemia in patients who are already confused. • If appropriate treatment not given, patient may become unresponsive.

Appendices

Attach any background information and supporting documents for the scenario as required, e.g. Clinical records, x-rays, observation chart, drug chart, ECG, fluid balance chart, peak flow chart, blood results, ABGs results etc.

Core Adult Scenario 7: Recognition and Initial Treatment of an Adult Experiencing Cytokine Release Syndrome (CRS) with ICU Transfer

Case scenario	Recognition and initial treatment of an adult experiencing cytokine release syndrome (CRS) with ICU transfer
Intended clinical (technical) learning objectives	• ABCDE approach to assessing the patient • Recognition of signs, symptoms and risk factors of cytokine release syndrome • Prompt initiation of appropriate treatment • Call for help immediately • Appropriate use of interventions/ emergency equipment including emergency trolley
Intended non-technical learning objectives	**Communication:** • Effective communication within the team • Clear handover using SBAR approach **Leadership:** • Identification of a team leader who takes charge of the situation • Staff have clearly defined roles • Appropriate and timely delegation of tasks **Decision-making:** • Quick decision made regarding diagnosis and status as an emergency • Appropriate and timely initiation of treatment • Immediate call for help • Appropriate and timely escalation and involvement of ICU and Critical Care Outreach Team

Participant's name and age/ DOB	Susan Roberts Age 45 years old
	Use only if scenario is announced

Learner information pre-scenario (Narrative case description)	Susan is attending the CRF for a dosing visit for a Phase I, First In Human oncology clinical trial called T-cells Immunotherapy Study. The IMP is an autologous cell product administered intravenously (IV) over 30 minutes. Fifteen minutes after the IMP infusion, Susan starts to complain of feeling generally unwell. She complains of severe headache, nausea and muscle aches. Susan is visibly shaking.
Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	**S**ituation: The visit has been arranged in the Clinical Research Facility for the IV administration of a cell product for a Phase I, First in Human oncology clinical trial called Tcells Immunotherapy Study. Susan has already received the IMP. She is sitting upright on a bed for the protocol-mandated observation and monitoring period when she started to complain of feeling unwell. **B**ackground: Susan has recurrent metastatic cervical cancer. No other significant medical history, apart from multiple lines of chemotherapy. She has no known drug allergies. **A**ssessment: A. Clear and open airway, no stridor. B. SpO_2 93%, normal chest movement, normal air entry. RR 28bpm C. HR 120bpm, BP 90/58mmHg. Pale. CRT 5 seconds. Sweaty. No chest pain. D. Alert but clearly distressed. Blood Glucose: 6.0 mmol/L E. Temp 38.8^{o}C. Widespread skin rash. Rigors **R**ecommendations - learner expected to: • ABCDE Approach. • Call for help immediately • Commence O_2 therapy immediately • Instigate IV fluids (if prescribed) • Consider Sepsis versus other differential diagnosis • Blood cultures and other routine biochemistry • Chest X-ray (as requested by doctor) • ECG • Escalate to medical emergency team • Use SBAR on handover • Facilitate transfer of patient to ICU

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	1. To run the scenario 2. To observe and document scenario events
Learner (Options according to availability)	Clinical roles (maximum 6 learners) Learners should assume their own clinical role during the scenario
Area setup for scenario	**Environment** • CRF **Specific set-up** • Manikin sitting upright on a bed
Equipment setup and possible props needed for scenario	**Equipment immediately available** • O_2, equipment to measure vital signs **Equipment available on request** • Emergency trolley
Participant/ manikin preparations for scenario	**Gender** • 45-year-old female **Patient's position** • Sitting upright on a chair/ bed **Appearance** • Pale, sweaty
Medical documentation needed for scenario	**Available** • Local study data file containing research study consent form, PIS, brief past medical history and current medications. Written entry by PI stating the consent process and brief medical history. • Hospital chart/medical records • Drug chart • NEWS2 chart • Emergency transfer documents and equipment

Scenario Clinical Course

Observations on initial assessment	Susan is sitting upright on bed after having cell therapy infusion. She is complaining of feeling generally unwell, severe headache, nausea and muscle aches. Susan is visibly shaking. Learner expected to obtain following using ABCDE approach: A. Able to speak in short sentences. Clear and open airway, no stridor. B. SpO_2 93%, normal chest movement, normal air entry. Respiration (RR) 28bpm C. HR 120/min. BP 90/58mmHg. Pale. CRT 5 seconds. Sweaty. No chest pain. D. Alert but clearly distressed. Glucose: 6.0 mmol/L E. Temp 38.8°C. Widespread skin rash. Rigors
Initial clinical interventions required in response to the above	• Shout for help, emergency buzzer • Assess participant using ABCDE approach: A. Maintain airway B. O_2 therapy – non-rebreathe with 15L/min O_2 or similar, RR C. Monitor BP, HR D. Temperature, Blood Glucose, AVPU, PEARL E. Reassure participant • Request relevant blood tests • Communicate findings to attending colleagues • Escalate to emergency medical response team- 2222 call needed to be placed. • Assessing and recording of CRS grading as per ASTCT consensus grading of CRS criteria (lee et al., 2019) (or local guidelines)
Clinical course progression	Susan is becoming more anxious A. Airway clear at present but patient is vomiting B. Struggling to catch breath. Patient is wheezy C. BP 78/49mmHg, HR 130bpm, temp 40°C D. Conscious levels diminishing – responsive to voice E. Sweaty, oedematous

Further clinical interventions required in response to above progression	• Reassess using ABCDE approach • Support breathing and airway as appropriate. • Transfer patient to ICU.
Further clinical course progressions (as required)	Insert / Delete as required
Further clinical interventions (as required)	Insert / Delete as required

Post-Scenario Discussion

Possible discussion points	• Recognition and initial treatment of cytokine release syndrome • Local algorithm for management of suspected CRS (e.g. use of Toclizumab, IV fluids, corticosteroids for targeted management) • Early referral and escalation in all cases of suspected cytokine release syndrome • Process/pathway for emergency transfer to ICU • Assessment using ABCDE approach • Draw out attributes of a good team leader – roles planned in advance; identification of team leader; non-technical skills (task management, team working, situational awareness, decision making, structured communication) • Hand over to emergency medical response team using SBAR • Risk of Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) following CRS.

Appendices

Attach any background information and supporting documents for the scenario as required, e.g. Clinical records, x-rays, observation chart, drug chart, ECG, fluid balance chart, peak flow chart, blood results, ABGs results etc

Core Adult Scenario 8: Recognition and Initial Treatment of Major Haemorrhage

Case scenario	Recognition and initial treatment of major haemorrhage
Intended clinical (technical) learning objectives	• ABCDE approach to assessing and treating participants at risk of major haemorrhage • Identify the increased risk of major haemorrhage secondary to trauma
Intended non-technical learning objectives	**Communication** • Structured and effective team communication **Leadership and teamwork** • Managing major haemorrhage • Appropriate and timely allocation of personnel • Managing the needs of relatives **Decision making** • Appropriate call for help

Participant's name and age/ DOB	Barry Wilson 58-year-old male
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced** Barry has just finished a dispensing visit for the TRIGGER: Transfusion in Gastrointestinal Bleeding study (a randomised control trial). He suffers from gastric reflux and has a past medical history of gastric ulcers, type 2 diabetes and hypertension.
Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	**S**ituation: You are a researcher looking after Barry Wilson at visit 3 dispensing visit for the TRIGGER study at the CRF. **B**ackground: He is a 58-year-old man with a history of gastric ulcers, gastric reflux, type 2 diabetes and hypertension. Barry is passing dark tarry offensive smelling stools past 3 days (melaena) **A**ssessment: He has become drowsy (13/15 GCS or V on AVPCU) and dropped his BP (from 145/65mmHg to 121/60mmHg BP compensating), has become tachycardic (HR 105bpm). **R**ecommendations: Can you please come and urgently assess and treat this patient as I think he is deteriorating rapidly. **Medication list with participant** • Metformin, Amlodipine, Furosemide, Lansoprazole.

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	1. To run the scenario 2. To role play as the relative (optional) 3. To role play as the participant (optional) 4. To observe and document scenario events
Learner (Options according to availability)	Clinical roles (maximum 6 learners) Learners should assume their own clinical role during the scenario
Area setup for scenario	**Environment** • Participant sitting in a chair in an examination room in the CRF **Specific set-up** • Can use a facilitator or a manikin as the participant
Equipment setup and possible props needed for scenario	**Equipment immediately available** • Whatever is normally available in the examination room where the scenario is taking place **Equipment available on request** • Emergency trolley, AED, cardiac monitor, O_2 and masks, suction, emergency drugs etc.
Participant/ manikin preparations for scenario	**Gender** • Male participant **Participant's position** • Sitting on a chair in the examination room **Appearance** • No monitoring, no IV lines • Medications: in bag (if asked) • Pallor and Clammy **Concomitant medications** • Metformin • Amlodipine • Furosemide • Lansoprazole.

Medical documentation needed for scenario	**Available** • Concomitant medications list in the participant's pocket • Case Report Forms currently being completed **Not available** • Clinical records not immediately available

Scenario Clinical Course

Observations on initial assessment	**Verbal handover to first responder as they enter:** Participant is complaining of epigastric pain and appears pale and sweaty. A. Clear. Talking with no added sounds but short of breath and struggling to speak in full sentences B. SOB, RR 24bpm, SpO_2 91% on air, symmetrical chest movement, normal breath sounds (bilateral air entry), trachea central, no accessory muscle use, normal resonance on percussion. C. Capillary refill 2 seconds, HR 105bpm, BP 121/60mmHg, Temp 36.2 °C, fingers feel cool to touch, No raised JVP, 12 lead ECG (shows sinus tachycardia if requested), Heart sounds normal, Urine output – patient states that he is passing much less than normal in the past few days. D. Verbal response, BM (if asked) 6.3 mmol/L, Pupils equal and reacting to light, no seizures present or history of seizures. E. Has tender abdomen. Epigastric region, swollen and firm on palpation. No rebound tenderness.
Initial clinical interventions required in response to the above	• Recognition of need for urgent medical help (calls appropriately- would need to call medical senior on log of staff (PI) or the Reg and surgical reg) • Ring 2222 for resuscitation team if participant becomes peri-arrest • Shout for help (staff in Reception; emergency buzzer) • Immediate ABCDE assessment • Ask for resuscitation trolley, O_2 15L/min non rebreathe mask (checks for COPD history) • Ask for ECG 12 lead and three lead cardiac monitoring if available (due to high rate). • Consider taking blood (U&E, Clotting, FBC, cross match 6 units)

	• IV access as skills appropriate (wide bore in both arms) • Once prescribed start fluids, at least 500ml of saline over 15 minutes. • Initial treatment: • O_2 due to low SpO_2 (target 95-98%) • After fluid give O negative blood (1 unit) • Initiate major or massive haemorrhage protocol • Withhold oral tablets especially Furosemide and Amlodipine
Clinical course progression	If initial interventions given as above, then participant's breathing and cardiovascular status remains the same until help arrives – Doctor or Resuscitation Officer If initial interventions are not given, then the participant deteriorates but remains conscious – allow for further assessment below
Further clinical interventions required in response to above progression	**Reassess:** A. Clear B. SOB, RR 25bpm, SpO_2 95% (if on O_2), symmetrical chest movement, and normal breath sounds C. HR 100bpm, Regular (if fluid or blood given) ECG: shows sinus tachycardia, BP 130/85 mmHg, temp 36°C, capillary refill time (peripheral) 2 secs D. Request 12 lead ECG (in pt's notes if requested) E. Verbal response, Blood glucose (if asked) 6.3 mmol/L F. Persistent epigastric pain, pale and clammy to the touch • Check if help has been requested • Doctor/ Resuscitation Officer arrive • Hand over using Situation, Background, Assessment, Response (SBAR)
Further clinical course progressions (as required)	Insert / Delete as required
Further clinical interventions (as required)	Insert / Delete as required

Post-emergency care (Time dependent)	• Reassess using ABCDE • Request ECG, ABG, Chest X-ray, repeat bloods • Handover of participant • Situation Background Assessment Recommendation (SBAR) • Transfer of minimum records required to accompany participant to theatre or ICU or other department as defined in local SOPs prior to theatre.

Post-Scenario Discussion

Possible discussion points	• Using a systematic approach (ABCDE assessment) • Recognise presentation of haemorrhage. Be aware of initial treatment options in major /massive haemorrhage • The importance of a good team leader in the management of haemorrhage • Emphasises importance of effective feedback as a learning tool • Use of SBAR tool • Transfer of patient with the appropriate equipment and notes to the right clinical destination. Knowledge of emergency theatre transfer, obtaining blood, HDU/ICU/ Admissions/ward location locally

Appendices

Attach any background information and supporting documents for the scenario as required, e.g. Clinical records, x-rays, observation chart, drug chart, ECG, fluid balance chart, peak flow chart, blood results, ABGs results etc.

Core Adult Scenario 9: Recognition and Treatment of a Seizure in an Adult

Case scenario	Recognition and treatment of a seizure in an adult
Intended clinical (technical) learning objectives	• ABCDE approach to assessing and treating a participant having a seizure • Call for help at appropriate time • Appropriate use of interventions/ emergency equipment (positioning of participant, O_2, monitoring equipment, emergency drugs) • Appropriately diagnose a seizure
Intended non-technical learning objectives	**Communication** • Structured and effective team communication. • Clear handover to medical/emergency team using SBAR approach **Leadership** • Effective management of an adult having a seizure • Identification of team leader for the situation • Appropriate and timely delegation of tasks **Decision-making** • Appropriate and timely call for help • Allocation of roles within the team **Other** • Know where to locate antiepileptic drugs

Participant's name and age/ DOB	Robin Jackson 51 years old
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced** Robin is attending the CRF for a phase II clinical trial. Robin is known epileptic attending a screening visit for the phase II trial. Sitting at the bedside awaiting the study team to commence the screening procedures.

Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	**S**ituation – a 51-year-old with a history of well-controlled epilepsy. Attending a screening visit for a phase II clinical trial on the CRF. During the conversation, Robin begins to exhibit signs of a seizure including staring blankly into distance, muscle stiffening and then involuntary movements. Consciousness level will reduce. **B**ackground – History of well controlled epilepsy, maintained on Sodium Valproate, BD. **A**ssessment – Study nurse to notice changes in the behaviour of the participant. Participant displays muscle stiffening progressing to muscle twitching. **R**ecommendations – • Early call for appropriate help • Protect from further injury as necessary • Assess using ABCDE approach • Ensure emergency equipment is available • Continual assessment of the participant • Recognise signs of seizure an implement best practice guideline

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	1. To run the scenario 2. To role play as the participant 3. To observe and document scenario events
Learner (Options according to availability)	• Clinical roles (maximum 6 learners) • Learners should assume their own clinical role during the scenario
Area setup for scenario	**Environment** • CRF **Specific setup** • Participant sitting upright on a chair
Equipment setup and possible props needed for scenario	**Equipment immediately available** • O_2, equipment to measure vital signs **Equipment available on request** • Emergency trolley, suction machine

Participant/ manikin preparations for scenario	**Gender** • 51-year-old male/female **Participant's position** • Sitting upright on a chair/ bed **Appearance** • No monitoring, A little uneasy, gradually displays muscle stiffness, involuntary muscle twitching and staring blankly as scenario progresses. **Concomitant medications** • Sodium Valproate, BD
Medical documentation needed for scenario	**Available** • Local study data file containing research study consent form, PIS, brief past medical history and current medications. Written entry by PI stating the consent process and brief medical history • Set of baseline medical observations • Medical Records (at request)

Scenario Clinical Course

Observations on initial assessment	The participant has increased muscular rigidity accompanied by heightened, involuntary myoclonic-type jerks A. Patent B. RR 8bpm, apnoeic episodes, SpO_2 92% on room air C. Pale and clammy. HR 112bpm, BP 148/88mmHg, ECG: Sinus Tachycardia D. Reduced conscious level – staring, unresponsive to verbal commands, BM 5.6mmol/L E. No signs of injury.

Initial clinical interventions required in response to the above	• Shout for help (staff in Reception; emergency buzzer) • Contact study doctor • Assess area, safe to approach • Assess participant using ABCDE approach: A. Maintain airway B. Check RR, O_2 therapy – non-rebreathe mask with 15L/min O_2 C. Vital signs – BP/HR/temp, monitor BP, check capillary refill time. Prepare equipment for IV access, ECG monitoring D. Blood Glucose AVCPU, PEARL E. Reassure participant • Optimum positioning • Communicate findings to attending colleagues • Recognise seizure activity • Preparation of medications for administration
Clinical course progression	• Generalised tonic-clonic seizure activity continues for approximately 2 minutes before gradual cessation. • Participant remains unresponsive for several minutes postictal, with shallow breathing and persistent low oxygen saturations despite high-flow O_2. SpO_2 93% on NRB 15L O_2 • BP low at 94/60mmHg, pulse 112 bpm. • Gradual return of spontaneous movement, but confusion and drowsiness persist. • No evidence of trauma or head injury during event. • Seizure activity does not recur during immediate observation period.
Further clinical course progressions (as required)	Continued assessment of ABCDE
Further clinical interventions (as required)	Insert / Delete as required

Further clinical interventions required in response to above progression	• Continue airway support and high-flow oxygen until saturations consistently >94%. • Maintain participant in lateral recovery position to protect airway during post-ictal phase. • Continuous ECG, SpO_2, and BP monitoring. • Obtain IV access once seizure has ceased; collect blood samples if indicated (Blood Glucose, U&E, antiepileptic drug levels if appropriate). • Consider IV glucose if hypoglycaemia confirmed. • Prepare and administer rescue medication as per protocol if seizure >5 minutes or if recurrent seizures occur (e.g., IV lorazepam 4 mg slow push or buccal midazolam if no IV access — per Resuscitation Council (UK) / Trust policy). • Ongoing neurological observation (GCS or ACVPU) every 5–10 minutes until stable.
Post-emergency care (Time dependent)	• Assessment of the critically ill participant using ABCDE approach • Draw out attributes of a good team leader – roles planned; identification of team leader; non-technical skills (task management, team working, situational awareness, decision making, structured communication) • Continue close observation for at least 1–2 hours post-event to detect recurrent seizure or delayed complications. • Reassess vital signs and neurological status regularly until back to baseline. • Review medication adherence and precipitating factors with participant once alert. • Inform Principal Investigator and complete trial-specific safety reporting requirements (e.g., SAE form, regulatory notification). • Update participant's GP and/or neurologist regarding the event. • Provide written and verbal post-seizure advice to participant (and carer if present). • Arrange safe transport home or hospital admission if ongoing

Post-Scenario Discussion

Possible discussion points	**Recognition & escalation** • What early signs indicated that the participant was having a seizure? • How quickly was help summoned, and was the escalation pathway followed[i] correctly? **Airway safety** • How did you ensure the airway remained patent during the seizure and post-ictal phase? • Were there any risks of airway compromise that could have been managed differently? **Oxygen therapy** • Was oxygen started at the right time, using the correct device and flow rate? • How did you monitor its effectiveness? **ABCDE assessment** • How did you prioritise the ABCDE assessment during a rapidly evolving emergency? • Were any parts skipped or delayed, and why? **Use of emergency equipment & medications** • Was all necessary equipment prepared in advance? • Did you consider when to give rescue medication, and was the choice appropriate according to guidelines? • Discuss the use of the NICE Guidelines **Team communication** • How was information shared between team members during the event? • Were roles allocated clearly and effectively? • Communication with participant and family (if any) **Documentation & reporting** • Was everything recorded accurately, including observations, timings, and interventions? • Did you follow both clinical and trial-specific adverse event reporting requirements?

	Post-event care • How did you decide whether the participant was safe to remain on site or needed transfer?

Appendices

Attach any background information and supporting documents for the scenario as required, e.g. Clinical records, x-rays, observation chart, drug chart, ECG, fluid balance chart, blood results, ABGs results etc.

Core Paediatric Scenarios

Core Paediatric Scenario 1: Recognition and Treatment of Anaphylaxis in a Child

Case scenario	Recognition and treatment of anaphylaxis in a child
Intended clinical (technical) learning objectives	• To systematically utilise ABCDE approach to assess and treat a child with anaphylaxis. • Appropriate use of emergency equipment, drugs and monitoring • Recognise deterioration in a child and the initial treatment/management required.
Intended non-technical learning objectives	**Communication** • Structured and effective team communication • Effective communication with child's parent • Utilise/support learner to provide support for dad • Clear handover to medical/emergency team using SBAR approach. **Leadership** • Effective management of a child with anaphylaxis • Identification of team leader for the situation • Appropriate and timely delegation of tasks • Managing the needs of relatives. **Decision-making** • Appropriate and timely call for help • Initiation of initial treatment.

Participant's name and age/ DOB	Jack Wiggins 6-year-old
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced** Jack suffers from a metabolic condition and has been enrolled into a Phase 3 trial. He has attended the CRF with his dad for a 2nd dose visit of an IV IMP. Jack has a central line which is accessed without any complications. He has also had baseline observations of temp, pulse, BP and respiration rate recorded and all are within normal ranges.
Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	**S**ituation – The investigational medicinal product of enzyme replacement therapy is commenced. Five minutes into the infusion, Jack begins to feel unwell. **B**ackground – Jack has a pre-existing metabolic condition but has been well prior to the study visit. **A**ssessment - Jack has a visible rash on his face and chest and his lips appear swollen. He is also holding his throat, complaining that it is 'scratchy' **R**ecommendations – learner expected to: • Stop the infusion • Monitor and protect airway • Apply O_2 therapy • Call for appropriate help • Maintain continual assessment • Ensure algorithm available for management of condition • Recognition and treatment should be based on Resuscitation Council (UK) Guidelines • Ensure emergency equipment available • Recognise the needs of the parents/carer

Scenario Preparation

Facilitators - at least 3 (You can use additional facilitators as role players)	1. To run scenario and provide observations and changes in Jack's condition e.g. RR, pulse, O_2 Sats, consciousness level. 2. To observe technical and non-technical skills; and document scenario events. 3. To play role of dad. 4. Child manikin to play Jack.
Learner (Options according to availability)	Clinical roles (maximum 6 learners) Lead learner to identify themselves. Learners should assume their own clinical role during the scenario.
Area setup for scenario	**Environment** • The CRF ward area. **Specific setup** • Jack is sitting up in bed with the IMP infusion running. He has observations taken every 30 minutes and IV infusion rate increased every 15 minutes.
Equipment setup and possible props needed for scenario	**Equipment immediately available** • O_2, suction, cardio/ respiratory monitoring for BP, SpO_2%, pulse, respirations, temp. **Equipment available on request** • Resuscitation trolley, defibrillator, airway adjuncts, anaphylaxis kit.
Participant/ manikin preparations for scenario	**Gender** • Male **Participant's position** • Sitting up in bed **Appearance** • Anxious, rash, lips swelling, holding throat, feeling sick **Concomitant medications** • Hydrocortisone orally three times a day

Medical documentation needed for scenario	What is available: • Medical health records • Observation charts • Case Report Form What is available on request: • Study Site File • Investigator brochure • Un-blinding documentation

Scenario Clinical Course

Observations on initial assessment	**Verbal handover to first responder as they enter the scenario:** Jack has a pre-existing metabolic condition. Five minutes into the infusion of study drug via his central line Jack begins to feel unwell. This is the second dose visit for Jack. A. Tongue swollen, stridor audible from end of bed B. RR 40 per minute, increased work of breathing and visible use of accessory muscles, SpO_2 87% on room air (if requested) C. HR 140bpm, BP 80/55 mmHg, CRT 3 seconds, clammy D. Alert, distressed E. Urticarial rash.
Initial clinical interventions required in response to the above	• Stop the infusion • O_2 therapy (15L via a non-rebreathe mask) • Call for help (Resuscitation Team should be called as soon as anaphylaxis recognised) • Immediate ABCDE assessment with treatments given in order of priority. • Administer intramuscular adrenaline (300 mcg 1:1000) • Follow local policy/guidelines for withdrawing from central lines. • Continue to follow algorithm for treatment of anaphylaxis as per Resuscitation Council (UK) Guidelines • Reassure child constantly and keep dad informed of the events and actions • Contact study doctor and PI if not already present.

Clinical course progression	Five minutes into the scenario the child improves if appropriate action taken
Further clinical interventions required in response to above progression	A. Airway swelling resolves, stridor no longer audible following one dose of adrenaline B. RR now 28bpm, note how he is breathing – rate and rhythm, SpO_2 100% with O_2 therapy (discuss reducing O_2 therapy to maintain normal saturations) C. HR 130bpm, BP 105/70mmHg D. Alert but distressed E. Rash resolving
Further clinical course progressions (as required)	Anaphylaxis resolves with appropriate treatment
Further clinical interventions (as required)	Observe for at least 2 hours and up to 24 hours as per Resuscitation Council (UK) Guidelines
Post-emergency care (Time dependent)	• Verbal handover to resuscitation team using SBAR • Arrange appropriate transfer of participant for further observation – Critical Care/ HDU as directed by resuscitation team • Transfer of documentation required to accompany participant to ICU or other department as defined in local policies. • Potential un-blinding and contact PI • Mast cell tryptase should be measured in all patients with suspected anaphylaxis where the diagnosis is uncertain • Initial sample as soon as feasible after initial treatment • Second sample 1-2 hrs (but no later than 4hrs) post symptom onset • Third sample at least 24 hrs after complete resolution • Consider the requirements of un-blinding • Contact the Principal Investigator/Sponsor • Safety reporting

Post-Scenario Discussion

Possible discussion points	• General management of anaphylaxis using Resuscitation Council (UK) Guidelines • What are the first signs and symptoms of anaphylaxis – did you recognise them? • Refractory anaphylaxis treatment. • Do you know where to access the guidelines? • Psychological support for child and dad? • How did you decide who would act as 'lead' in scenario? • Would child need to be un-blinded – what are the steps for this? • Should monitoring equipment be attached at start of infusion? • What should you report to study sponsor? (e.g. AE/AR/SAE)

Appendices

Attach any background information and supporting documents for the scenario as required, e.g. Clinical records, x-rays, observation chart, drug chart, ECG, fluid balance chart, peak flow chart, blood results, ABGs results etc.

Core Paediatric Scenario 2: Recognition and Treatment of a Seizure in a Child

Case scenario	Recognition and treatment of a seizure in a child
Intended clinical (technical) learning objectives	• To systematically utilise the ABCDE approach to assess and treat a child having a seizure • Call for appropriate help in a timely manner • To appropriately identify seizure • To have an awareness and understanding of the seizure algorithm • Appropriate use of emergency equipment, drugs and monitoring
Intended non-technical learning objectives	**Communication** • Structured and effective team communication. • Effective communication with child's parent. • Utilise/support learner to provide support for parent. • Clear handover to medical/emergency team using SBAR approach **Leadership** • Effective management of a child having a seizure • Identification of team leader for the situation • Appropriate and timely delegation of tasks • Managing the needs of relatives **Decision-making** • Appropriate and timely call for help • Allocation of roles within the team **Other** • Know where to locate antiepileptic drugs • Allocation of a 'scribe' to time the seizure and document interventions
Participant's name and age/ DOB	Archie 2-year-old

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	1. To observe technical and non-technical skills; and document scenario events 2. To play role of mum and hold manikin
Learner (Options according to availability)	• Clinical roles (maximum of 6) • Lead learner to identify themselves • Learners should assume their own clinical role • One learner assigned to support family (if possible) • One learner assigned the role of scribe (if possible)
Area setup for scenario	**Environment** • Paediatric room **Specific setup** • Mum is holding the manikin who is seizing
Equipment setup and possible props needed for scenario	**Equipment immediately available** • Bed, O_2 and suction **Equipment available on request** • Stethoscope, monitoring equipment, glucometer and paediatric emergency trolley
Participant/ manikin preparations for scenario	**Gender** • Male **Participant's position** • In Mum's arms **Appearance** • Right arm and leg are twitching (if asked by the learner – is pale and mottled) **Concomitant medications** • None known

Medical documentation needed for scenario	**What is available** • PI contact details (PI not present in the CRF) **What is not available** • Study nurse not present - has gone to get the patient's study folder **What is available on request** • Investigator Site File

Scenario Clinical Course

Observations on initial assessment	**Verbal handover to first responder as they enter scenario:** Archie is a 2-year-old who started twitching in his Mum's arms and is producing gurgling sounds and eye rolling. Mum states that the whole family have had a cold, but Archie has been well.- Archie is in the CRF as he is participating as a control for a study looking at growth and nutrition. He is normally fit and well. **Learner expected to obtain following using ABCDE technique:** A. Gurgling B. RR 50bpm, SpO_2 88% in air C. HR 170bpm regular, BP – unobtainable, mottled and clammy, capillary refill 3 seconds D. Unresponsive (AVCPU), pupils - difficult to assess, seizing, glucose 5.1mmol/L E. Temp 39.0° C
Initial clinical interventions required in response to the above	Call for help: initiate emergency call on 2222. • Airway repositioned • Clear airway with suctioning • O_2 therapy (15 litres via a high concentration paediatric non-rebreathe O_2 mask) • Request paediatric emergency trolley. • Contact PI. • Time seizure. Consider possible causes for seizure and treat these appropriately. • ABCDE assessment continued.

	• Locate Buccal Midazolam and administer as per local/ Resuscitation Council (UK) Guidelines
Further clinical course progressions (as required)	If Buccal Midazolam administered: A. Patent following airway manoeuvres B. RR 35bpm, SpO_2 96% on 15 litres O_2 C. HR 140bpm, BP 90/55mmHg, capillary refill 2-3 seconds D. Seizure has resolved, responding to parent's voice E. Obtain past medical history from mum If learners fail to administer Buccal Midazolam seizure does not self-resolve A. Gurgling returns B. Erratic shallow breathing pattern, SpO_2 92% on 15L O_2 C. HR 180bpm regular, BP – unobtainable, mottled and clammy, capillary refill 4 seconds D. Unresponsive, convulsing continues E. Clothing removed
Further clinical interventions required in response to above progression	• Confirm the Resuscitation Team are on route – Emergency call initiated • Reassess ABCDE throughout • Consider IV access • Maintain / reduce O_2 therapy as per local policy • Request bloods (Blood culture, blood gas, full blood count, electrolytes and urea) • Consider and identify underlying cause of seizure
Post-emergency care **(Time dependent)**	• Reassess using ABCDE • Verbal handover of child to Resuscitation Team using SBAR • Contact relevant senior staff to discuss transfer and admission to HDU • Complete appropriate documentation (local policy and protocol)

Post-Scenario Discussion

Possible discussion points	• Assessment of the seizing child using an ABCDE approach • Discuss the recognition and management of seizures in children using Resuscitation Council (UK) Guidelines • Do you know where to find Advanced Paediatric Life Support guidelines? • What is the local escalation process for admitting to other departments within the Trust? • How would you recognise postictal state? • What is your reference guide for weight/drug dosage? - • The role of supporting parent(s) • The role of the scribe to highlight start time of seizure and administration time(s) of antiepileptic drug(s) • How were roles within the team allocated? • What should you report to the sponsor? (AE/SAE)

Appendices

Attach any background information and supporting documents for the scenario as required, e.g. Clinical records, x-rays, observation chart, drug chart, ECG, fluid balance chart, peak flow chart, blood results, ABGs results etc.

Core Paediatric Scenario 2a: Recognition and Treatment of Status Epilepticus in a Child and Transfer to PICU

Case scenario	Recognition and treatment of status epilepticus
Intended clinical (technical) learning objectives	• To systematically use the ABCDE approach to assessing and treating a child with status epilepticus • Call for help at appropriate time • Appropriate use of interventions/ emergency equipment • To demonstrate correct procedure and equipment needed to move sick children from the CRF to the PICU • To familiarise staff with documentation required for a transfer and knowledge of the relevant SOP
Intended non-technical learning objectives	**Communication** • To demonstrate good communication within and between the CRF and the MDT • Effective communication with the child and their parent(s) • Clear handover to the medical team using SBAR approach or equivalent **Leadership** • Identification of team leader for the situation • Appropriate and timely delegation of tasks • Managing the needs of relatives

Participant's name and age/ DOB	Archie 7 years old
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced**
	Archie has autism, sleep difficulties and epilepsy. He is a new participant in the Phase 3 Double Blinded trial. He is attending the CRF today with his Mum. This is his first study visit. The study nurse has completed his clerking in his study notes, and he has had some baseline observations of temp, pulse, BP and respiration rate recorded - all are within normal ranges.

Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	**S**ituation – whilst the study nurse and Mum are completing study questionnaires, Archie is getting noticeably irritable. When they turn to him, they see he is rigid with generalised tonic-clonic movements. **B**ackground –He is a known epileptic and is well controlled with BD Sodium Valproate. **A**ssessment – On examination Archie is seizing, he appears pale with visible secretions in his mouth. **R**ecommendations – learner(s) are expected to: • Call for appropriate help • Commence O_2 therapy (15 litres via a high concentration paediatric non-rebreathe O_2 mask) • Assess Archie using the ABCDE approach • Time seizure activity • Ensure emergency equipment available • Maintain continual assessment • Recognition and treatment should be based on Resuscitation Council (UK) Guidelines • Recognise and respond to the needs of the parents/carer

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	1. To manage the paediatric manikin, controlling its responses as the scenario progresses 2. To provide any additional information verbally 3. To observe technical and non-technical skills and to document scenario events including timings 4. To time the transfer from CRF to PICU 5. To play role of parent - if asked emergency drugs have been left at home.
Learner (Options according to availability)	Clinical roles (maximum 6 learners) Learners should assume their own clinical role during the scenario
Area setup for scenario	**Environment** • CRF – children's area **Specific setup** • Archie has been moved onto a bed

Equipment setup and possible props needed for scenario	**Equipment immediately available** • CRF patient notes • O_2 with paediatric face mask • Suction **Equipment available on request** • Paediatric emergency trolley, airway adjuncts, defibrillator • Archie's seizure treatment plan • Transfer bag
Participant/ manikin preparations for scenario	**Manikin** • Paediatric manikin **Participant's position** • On bed **Appearance** • Rigid, visible seizure activity **Concomitant medications** • Sodium valproate • Buccal Midazolam (PRN)
Medical/ documentation needed for scenario	**What is available:** • Medical health records • Clerking from the current visit including observations, height and weight • Initial blood gas **What is available on request:** • Study site file and folder • Investigator brochure • Transfer SOP and documentation

Scenario Clinical Course

Observations on initial assessment	Verbal handover to first responder as they enter the scenario: Archie is seizing with generalized tonicclonic movements. Mum shares details of Archie' s emergency plan - if seizure lasts longer than 5 minutes to administer Buccal Midazolam.

Observations on initial assessment	A. At risk- secretions visible- clear with suctioning B. RR 18 bpm shallow, SpO_2 88% in room air, bilateral air entry on auscultation C. HR 145bpm, BP unrecordable, CRT < 2 seconds. D. AVCPU- Unresponsive, Glucose 5.0mmol/L E. E- Clear
Initial clinical interventions required in response to the above	• Call for appropriate help- Resuscitation Team. Initiate emergency call. Contact PI to inform. • Commence 15L of oxygen via non-rebreathe mask. SpO_2 increased to 92% • ABCDE assessment • Time seizure • Suction if required • Administer 1st dose of Benzodiazepine as per local/ Resuscitation Council (UK) Guidelines • Locate paediatric emergency trolley • Prepare to establish IV access • Check Glucose • If IV access established take bloods and gas
Clinical course progression	• Resuscitation Team arrive • Role allocation • ABCDE assessment • Seizure continues 5 minutes after initial dose of Benzodiazepine • SpO_2 remain at 92% in 15L of oxygen, HR 140bpm. • 2nd dose of Benzodiazepine administered - Shallow breathing, still seizing. • Reposition airway - if apnoeic bag valve mask • Start to consider 2nd line agents as per APLS guidelines • Call Anaesthetist and Intensive Care Team

Further clinical interventions required in response to above progression	• Assist Resuscitation Team to further manage seizure as per APLS Status Epilepticus guidelines. • CRF staff to support stabilisation and transfer pathway and complete relevant documentation • Get transfer documents (transfer checklist, handover sheet, observation chart, medical history sheet, prescription chart, ID band, study information) • Collect equipment required for transfer
Further clinical interventions (as required)	• Following administration of 2nd line agents seizing stops. Patient is intubated by Anaesthetist and prepared for transfer to PICU • Discuss unblinding procedure with PI
Post-emergency care (Time dependent)	• Emergency documentation must be completed as per local procedures • Ensure the CRF Nurse Manager has been provided with a copy of the completed Paediatric CRF Handover Sheet • Inform sponsor (AE, SAE, SUSAR).

Post-Scenario Discussion

Possible discussion points	**Include technical and non-technical points:** • Assessment of the critically ill participant using ABCDE approach • Recognition and treatment of status epilepticus • Escalation to Resuscitation Team • Team working – roles planned; identification of team leader; task management; situational awareness; decision making; structured communication • Basic management of airway. – Suction, Airway reposition, non-rebreathe versus Bag Valve Mask (BVM) • Points specific to the scenario topic – include timings • Any issues with equipment/Importance of handovers, including the use of specific tools (SBAR)

Appendices

Attach any background information and supporting documents for the scenario as required, e.g. Clinical records, x-rays, observation chart, drug chart, ECG, fluid balance chart, peak flow chart, blood results, ABGs results etc.

If considering running this type of scenario you may wish to consider which medications are routinely available in your unit and if not, where are rescue medications for seizures available within your hospital.

Core Paediatric Scenario 3: Recognition and Treatment of Childhood Asthma

Case scenario	Recognition and treatment of childhood asthma
Intended clinical (technical) learning objectives	The scenario is to test the ability to identify a deteriorating child and respond appropriately. • To systematically utilise the ABCDE approach to assess and treat a child with worsening symptoms of asthma • Call for help at the appropriate time • Appropriate use of interventions/ emergency equipment including O_2 and drug therapies • Awareness and identification of potential for child with respiratory compromise to quickly de-compensate
Intended non-technical learning objes	**Communication** • Effective communication with the child and family • Effective communication with multi-disciplinary team • Clear handover to medical team using SBAR • Provide support for family. **Leadership** • Effective management of child with asthma • Identification of team leader for the situation • Appropriate and timely delegation of tasks • Managing the needs of relatives **Decision-making** • Appropriate and timely call for help • Initiation of primary treatment.

Participant's name and age/ DOB	Thomas 8-year-old
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced** Thomas is attending the unit for a scheduled study visit for a study looking at the characteristics and progression of childhood asthma. He was diagnosed at 4 years old and is managed with daily Beclomethasone and Salbutamol inhalers. He has never attended hospital with an exacerbation and is normally well managed. During the visit he will undergo several respiratory tests including peak flow, lung function testing and plethysmography. He has had a cough and cold for 10 days but his mum reports that he has become significantly worse overnight and wanted him to see a doctor. Nil other significant history, nil known drug allergies.
Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	**S**ituation: Thomas is attending for a study visit on the progression of childhood asthma. He has had several previous study visits. **B**ackground: Thomas was diagnosed at 4 years old and is managed with daily Beclomethasone and Salbutamol inhalers. He has never attended hospital with an exacerbation of asthma and is normally well managed. He has had a cough and cold for 10 days but his mother reports that he has become significantly worse overnight and wanted him to see a doctor. Nil other significant history, nil known drug allergies. **A**ssessment: wheeze present with obvious signs of increased work of breathing, speaking in short sentences, anxious and pale. **R**ecommendations - learner expected to: • Call for appropriate help in a timely manner • Complete ABCDE assessment and identify exacerbation of asthma • Assess the classification of severity to determine treatment path as per resuscitation council guidelines • Recognise the needs of mum • Recognise the psychological support for Thomas

Scenario Preparation

Facilitators - at least 3 (You can use additional facilitators as role players)	1. To run the scenario and provide observations of Thomas's condition 2. To role play as the mum (optional) 3. Observing and documenting scenario events (technical and non-technical skills).
Learner (Options according to availability)	Clinical roles (maximum 6 learners) Lead learner to identify themselves Learners should assume their own clinical role during the scenario.
Area setup for scenario	**Environment** • A CRF or designated research area **Specific setup** • Child manikin sitting upright on a chair
Equipment setup and possible props needed for scenario	**Equipment immediately available** • O_2, stethoscope. **Equipment available on request** • Equipment to measure vital signs, emergency trolley, nebuliser mask and acorn, Salbutamol nebules, paediatric BNF.
Participant/manikin preparations for scenario	**Gender** • Male **Participant's position** • Sitting upright on a chair. **Appearance** • Saturation monitor in situ. Thomas is sat very upright, is pale, has increased respiratory effort and looks scared. **Concomitant medications** • Beclomethasone 50 mcg, 2 puffs (twice daily) • Salbutamol MDI (as required)
Medical documentation needed for scenario	**What is available** • Observation chart with set of baseline observations, study site file, case report form, medical health records. **What is not available** • No medication chart completed at this time, no information in clinical records.

Scenario Clinical Course

Observations on initial assessment	**(If applicable) Verbal handover to first responder as they enter scenario:** Thomas has had a cough and cold for 10 days and has become significantly worse overnight Learner expected to obtain following using ABCDE technique: A. Audible wheeze, able to speak in short sentences B. RR 37bpm per minute, SpO_2 90% on room air, widespread wheeze on auscultation, slightly reduced air entry C. Pulse 128bpm, central capillary refill (if requested) 2 seconds, BP 100/70mmHg D. Glucose 5.6 mmoml/L, appears anxious E. Temp 37.4^{o}C
Initial clinical interventions required in response to the above	• Call for help- Initiate emergency call for Resuscitation Team • Contact PI • Enable the child to maintain a 'comfortable' position i.e. sat propped up • Assess patient using ABCDE approach: A. Anxious, has audible wheeze and is unable to speak in full sentences. Wants to remain in an upright position. B. Commence O_2 therapy 15L via non-rebreathe face mask; SpO_2 increases to 92%, RR-38bpm, moderate work of breathing, widespread wheeze on auscultation. Requires urgent prescription of nebulised Salbutamol and Ipratropium C. Attach ECG and assess rhythm, HR-128bpm, BP-101/74mmHg, CRT- 2 seconds D. AVCPU, Glucose 5.6mmol/L, PEARL size 4. E. No rashes, Temperature 37.1^{o}C • Reassure Thomas and mum constantly.

Clinical course progression	Thomas has just been seen by a medic who prescribed nebulised Salbutamol and Ipratropium bromide. This has been started on Thomas. Thomas is becoming tired and more anxious. A. Patent B. RR 33bpm, moderate work of breathing, SpO_2 92% on 6L of O_2 (driving nebuliser), widespread wheeze on auscultation C. HR130bpm, BP-100/71mmHg, CRT 2seconds, sinus tachycardia D. AVCPU- V, Anxious E. Nil
Further clinical interventions required in response to above progression	It has been 20 mins since the first nebulisers and there is no change to ABCDE: • Repeat nebulisers as prescribed • Administration of oral dexamethasone • Ongoing ABCDE assessment A. Patent, no audible wheeze from end of bed B. Minimal wheeze audible on auscultation 20 minutes post repeated nebuliser, increased air entry, SpO_2 96% on 2L O_2, Mild work of breathing C. HR –120bpm, BP 100/70mmHg, CRT 2 seconds D. Less anxious and brighter in self E. Nil • Provide mum with support and information • Keep Thomas informed of actions providing constant reassurance.
Post-emergency care (Time dependent)	• Arrange transfer to acute clinical area including transport monitoring and portable O_2 • Full documentation of all assessments and care given • Handover of participant - Situation Background Assessment Recommendation (SBAR) • Keep mum informed of progress and planned actions, providing relevant support.

Post-Scenario Discussion

Possible discussion points	**Include technical and non-technical points:** • How would you classify severity of acute Asthma exacerbation according to APLS • Assessment of the critically ill child using ABCDEapproach • Clinical management of exacerbation of asthma according to APLS • What is the local process for obtaining urgent medical help fast bleep, crash call? • What transfer equipment is required? • Potential treatments if child had not responded to course of Salbutamol nebulisers (back-to-back) and what are the next steps? • Discuss psychological management of child and mum? • How was the team leader identified? • Discussion on the role and attributes of a team leader • Importance of handovers, including the use of specific tools (SBAR)

Appendices

Attach any background information and supporting documents for the scenario as required, e.g. Clinical records, x-rays, observation chart, drug chart, ECG, fluid balance chart, peak flow chart, blood results, ABGs results etc.

Core Paediatric Scenario 4: Recognition and Treatment of Paediatric Sepsis

Case scenario	10-month-old infant with bronchiolitis and sepsis.
Intended clinical (technical) learning objectives	• Early recognition of sepsis • To systematically utilise the ABCDE approach to assess and treat a child with sepsis • Call for help at appropriate time • Appropriate use of interventions/emergency equipment including O_2 and drug therapies
Intended non-technical learning objectives	• To demonstrate good leadership and communication within the team and with the participant • Clear handover to medical team using SBAR approach or equivalent • Managing the needs of the family • Appropriate and timely delegation of tasks

Participant's name and age/ DOB	Millie 10 months old
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced**
	Millie is a 10-month-old girl with an inherited metabolic disease, she is participating in a Phase 3, Open label, Single-dose Gene Therapy Study. She has been brought into the CRF by her Dad to complete the final part of her screening visit.
Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	Millie has just been called into the height and weight room by her Research Nurse to measure her weight. Dad undresses Millie for weighing. The nurse notices her increased WOB, lethargy and mottled appearance, and calls to her colleague for help.

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	1. To run the scenario 2. To play dad 3. Observing and documenting scenario events 4. If unannounced, to play first study nurse

Learner (Options according to availability)	Clinical roles (maximum 6 learners) Learners should assume their own clinical role during the scenario
Area setup for scenario	**Environment** • Clinic outpatient room **Specific setup** • Millie is laying on the couch undressed ready for weighing, with Dad and the study nurse next to the couch.
Equipment setup and possible props needed for scenario	**Equipment immediately available** • Wall O_2 and appropriately sized O_2 face mask **Equipment available on request** • Monitoring, Resus trolley and contents
Participant/ manikin preparations for scenario	**Gender** • Female **Participant's position** • On patient couch **Appearance** • Looks pale, mottled, is showing signs of increased respiratory effort. Lethargic. **Concomitant medications** • None.
Medical documentation needed for scenario	**What is available** • Medical notes.

Scenario Clinical Course

Observations on initial assessment	**(If applicable) Verbal handover to first responder as they enter scenario:** **Initial assessment using the ABCDE approach** A. Patent, weak cry B. RR - 70bpm with obvious use of accessory muscles marked intercostal recession. SpO_2 87% in air C. Pale and mottled, HR 177bpm sinus tachycardia, CRT 4 seconds, BP- 60/38mmHg D. AVCPU – V, Glucose 3.0 mmol/L E. Temp 39.7°C, mottled

Initial clinical interventions required in response to the above	• Call for appropriate medical help - Initiate emergency call to Resuscitation Team • Immediate ABCDE assessment • Administer 15 litres of oxygen via non- rebreathe face mask • Call for emergency trolley and monitoring including ECG • Obtain IV access, bloods and blood gas • Prepare for 10ml/kg IV fluid bolus and 2ml/kg of 10% dextrose • Explain to Millie's Dad and obtain some verbal history of current illness
Clinical course progression	A. Remains patent, weak cry, does not fight O_2 mask B. Moderate WOB, SpO_2 Sats 93% in 15L/min O_2, RR 70bpm, crepitations on auscultation C. HR 175bpm, BP 60/38mmHg, CRT is 4seconds centrally D. AVCPU - V E. No rash, temp is 39.7°C
Further clinical interventions required in response to above progression	• Recognition of sepsis • Establish IV access if not yet done so send bloods - FBC, U&E's, Culture, Lactate, Blood glucose Level and obtain a blood gas • Administer IV fluid bolus 10mls/kg 0.9% sodium chloride - reassess after each bolus. • Administer 2mls/kg of 10% Dextrose. • Administer IV antibiotics early according to local guidelines • Administer antipyretic • Reassess: ABCDE • Plan for transfer to appropriate area • Reassure Dad, updating him on interventions
Further clinical course progressions (as required)	A. Remains Patent, B. RR 68bpm, SpO_2 95% in 15L/min C. HR 160bpm, CRT 3 seconds centrally, BP is 70/42mmHg D. AVCPU- V, Glucose 6.0mmol/L E. Temp 38.7°C

Further clinical interventions (as required)	• Handover to Resuscitation team as they arrive • Repeat IV fluid bolus • Request chest x-ray • Request admission to HDU/ PICU for initiation of Airvo/CPAP, NIV, IV fluids and IVABs • Explain the plan of care to the father, providing reassurance and support.
Post-emergency care (Time dependent)	• Prepare for transfer – commence documentation • Inform PI if not already aware • Documentation as per local policy and protocol • What should you report to study sponsor (AE, SAE, SUSAR)? • Involve the outreach team if not already present

Post-Scenario Discussion

Possible discussion points	**Include technical and non-technical points:** • Importance of ABCDE (in enabling standardised assessment, early recognition and management of sepsis) • Importance of prompt administration of antibiotics • Importance of checking blood glucose levels • Discuss leadership including delegation, situational awareness, decision making and communication • Discuss team-working: communication and planning discuss use of SBAR tool for handover • Discuss coordinator/leader role

Appendices

Attach any background information and supporting documents for the scenario as required, e.g. Clinical records, x-rays, observation chart, drug chart, ECG, fluid balance chart, peak flow chart, blood results, ABGs results etc.

Core Paediatric Scenario 5: Recognition and Treatment of Paediatric Hypoglycaemia

Case scenario	Recognition and treatment of a child with hypoglycaemia
Intended clinical (technical) learning objectives	• To utilise the ABCDE approach to assess child • Recognition of hypoglycaemia • Initiation of treatment with appropriate equipment and drug therapy. • Appropriate escalation to medical team.
Intended non-technical learning objectives	**Effective communication:** • With Child and Family • With staff on ward and wider MDT • Utilising SBAR to escalate to medical team. **Leadership**: • Managing needs of family • Escalation in a timely manner using SBAR • Delegation to staff on ward to support situation

Participant's name and age/ DOB	Sarah 4 years old
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced**
	Sarah is taking part in a research study offering risk screening for type 1 diabetes. Sarah has completed an initial blood test which has identified she has antibodies which may suggest she has an increased risk of developing type 1 diabetes within her lifetime. She has returned to the CRF today accompanied by her dad to complete an oral glucose tolerance test as part of the study. Sarah has been fasted overnight in preparation for her visit. Sarah has her blood glucose checked at 08.30am and it is 4.0mmol/L. At 10.00am following placement of cannula, the Nurse notices Sarah appears to be pale and clammy whilst sitting on the bed.

Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	**S**ituation: Sarah is attending for a study visit to complete an Oral Glucose Tolerance Test. In preparation for the test, she has fasted overnight. Cannula in situ for blood draws. Dad in attendance as mum at home with new baby and older sibling **B**ackground: Sarah has a family history of type 1 diabetes, her venous blood sample confirmed that she has 3 autoantibodies **A**ssessment: Tired, clammy, pale. Father unsure of symptoms **R**ecommendations: learners expected to • Complete an ABCDE assessment of patient • Recognition of signs and symptoms of hypoglycaemia • Escalate appropriately • Appropriate management and treatment • Supports and communicates with Sarah and father

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	1. To run the scenario 2. To role-play dad 3. Technician to provide observations on Sarah's condition vital signs/blood glucose
Learner (Options according to availability)	Clinical roles (maximum 6 learners) 2 Nurses: Study nurse and back up. All other learners to observe via video link
Area setup for scenario	**Environment:** • 6 bedded bay area **Specific setup** • Child manikin sitting upright in bed. Peripheral cannula in situ.
Equipment setup and possible props needed for scenario	**Equipment immediately available** • Wall O_2 and paediatric O_2 face mask. Glucometer **Equipment available on request** • Monitoring, emergency trolley, Rescue medication

Participant/ manikin preparations for scenario	**Gender** • Female child **Participant's position** • Playing on bed. **Appearance** • Pale, clammy, and unsettled **Concomitant medications** • None
Medical documentation needed for scenario	**What is available** • Medical notes. • Observation charts prescription chart with rescue medication prescribed.

Scenario Clinical Course

Observations on initial assessment	**(If applicable) Verbal handover to first responder as they enter scenario:** A. Patent B. RR 20bpm, SpO_2 97% in air, comfortable WOB C. HR-100, CRT less than 2 seconds, BP 98/60mmHg D. Tired unsettled, clammy, pallor E. Temp 37°C.
Initial clinical interventions required in response to the above	• Immediate ABCDE assessment • Call for monitoring/glucometer • Contact PI, request medical review • Discuss with Millie's Dad plan of care
Clinical course progression	A. Remains patent B. RR 20bpm, O_2 Sats 98% in air, comfortable WOB C. HR120bpm, CRT less than 2 seconds, BP 98/60mmHg D. Remains tired. Peripheral blood glucose 2.8mmol/L E. Temp 37°C

Further clinical interventions required in response to above progression	• Recognise patient is hypoglycaemic
	• Take blood sample for lab glucose
	• Treat hypoglycaemia as per trust guidelines:
	  ○ If conscious and able to swallow administer oral glucose solution/oral glucose gel
	  ○ If unable to tolerate orally, administer 2mls/kg of 10% glucose intravenously over 3-5 minutes
	• Reassess ABCDE
	• Repeat blood glucose level 15 minutes post treatment
	• Reassure Millie and Dad, updating Dad on interventions

Further clinical course progressions (as required)	A. Remains patent B. RR 20bpm, SpO_2 98% in air, comfortable WOB C. HR100bpm, CRT less than 2 seconds, BP 98/60mmHg D. Blood Glucose 5.0mmol/L, Sarah more alert and settled E. Nil
Further clinical interventions (as required)	• Handover to medic using SBAR • Discontinue fast • Repeat blood glucose level at 30 minutes and 1 hour • Sarah to be observed for two hours post fast on ward prior to discharge • Further review by medic prior to discharge • Explain and reassure father, explaining what has happened and the plan
Post-emergency care **(**Time dependent)	Documentation of all assessments and interventions

Post-Scenario Discussion

Possible discussion points	**Include technical and non-technical points:** • What are the signs of Hypoglycaemia? • What is the treatment of Hypoglycaemia? • Importance of ABCDE to assess unwell child • Discuss preparation of space for caring for fasting child, what equipment /documentation should be prepared? • Discuss communication with team, patient and family • Discuss teamwork • Discuss use of SBAR tool for handover • Escalation/calling for help • Anticipation and planning

Appendices

Attach any background information and supporting documents for the scenario as required, e.g. Clinical records, x-rays, observation chart, drug chart, ECG, fluid balance chart, peak flow chart, blood results, ABGs results etc

Core Paediatric Scenario 5a: Recognition and Treatment of Paediatric patient in Diabetic Ketoacidosis

Case scenario	Recognition and treatment of a paediatric patient in DKA
Intended clinical (technical) learning objectives	• To systematically use the ABCDE approach to assess and treat an adolescent in DKA • To recognise and manage a patient in DKA • Initiation of treatment with appropriate equipment and drug therapy • Appropriate escalation to medical team
Intended non-technical learning objectives	**Effective communication:** • With Child and Family • With staff on ward and wider MDT • Utilising SBAR to escalate to medical team. **Leadership**: • Managing needs of family • Escalation in a timely manner using SBAR • Delegation to staff on ward to support situation
Participant's name and age/ DOB	Alex 13 years old
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced** Alex is a 13-year-old, taking part in a type 1 diabetes research study. Alex is a known diabetic and has been admitted to the CRF to provide a blood sample and complete questionnaires as part of a research study. Over the past few days, Alex has been feeling increasingly unwell but attributed it to a mild flu. Upon arrival, Alex appears visibly unwell. The research Nurse immediately notices signs of distress. Alex is pale, breathing rapidly (Kussmaul breathing) and has a fruity odour on their breath. Alex complains of severe abdominal pain, nausea and fatigue.

Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	**S**ituation: Alex is attending for a final study visit. Mum in attendance. Upon arrival to the CRF the Research Nurse notes that Alex appears unwell. **B**ackground: Known Type 1 Insulin Dependent Diabetic diagnosed 5 months ago. **A**ssessment: Pale, tachypnoeic, Kussmaul breathing, fruity odour to breath, severe abdominal pain, nausea, fatigue. Mother has attributed symptoms to a mild flu. **R**ecommendations: • Call for help - Contact Medical team for immediate review • Learner uses ABCDE approach to assess patient • Instigates treatment • Escalates appropriately • Supports and communicates with Alex and mother

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	1. To run the scenario 2. To role play mum 3. Technician to provide observations on Alex's condition Vital signs/blood glucose/ketones
Learner (Options according to availability)	Clinical roles (maximum 6 learners) 2 Nurses: Study nurse and back up.
Area setup for scenario	**Environment:** • CRF ward area **Specific setup** • Child manikin sitting upright in chair
Equipment setup and possible props needed for scenario	**Equipment immediately available** • Wall O_2 and paediatric O_2 face mask. Glucometer and Ketone meter **Equipment available on request** • Monitoring, Emergency trolley

Participant/ manikin preparations for scenario	**Gender** • Male or Female adolescent **Participant's position** • Sat on chair. **Appearance** • Unwell, pale, tachypnoeic **Concomitant medications** • On usual insulin regime
Medical documentation needed for scenario	**What is available** • Medical notes.

Scenario Clinical Course

Observations on initial assessment	**(If applicable) Verbal handover to first responder as they enter scenario:** A. Patent B. RR 30, Kussmaul breathing, fruity breath smell, SpO_2 96% C. HR- 120bpm; CRT 3 Seconds, BP 85/50mmHg, pale D. Tired and unsettled, GCS 14 E. Temp 37.8^{o}C
Initial clinical interventions required in response to the above	• Call for help – Immediate medical review • Recognition of DKA symptoms • Immediate ABCDE assessment • Administer 15L Oxygen via non-rebreathe mask • Call for monitoring - including ECG • Obtain IV access. Take bloods: Blood glucose, Ketones and blood gas, HbA1c, FBC, U&E's, CRP, lab glucose • Explain care to Alex and mum, obtain history

Clinical course progression	A. Remains patent B. RR 30bpm, SpO_2 98% in 15L of Oxygen, Kussmaul breathing, fruity breath smell C. HR 120bpm; CRT 3 Seconds, BP 85/50mmHg, pale D. Remains tired. Peripheral blood glucose check 30mmol/L, Ketones 3.2 mmol/L, pH on blood gas 7.2 E. Temp 37.8^{o}C
Further clinical interventions required in response to above progression	Medical assistance arrives • Reassess ABCDE • Administer 10ml/kg bolus (0.9% sodium chloride) • Start fluids and insulin infusion as per DKA protocol • Reassure mum and Alex, updating on interventions • Contact study doctor and PI if not already present • Arrange appropriate transfer of patient to Critical Care/HDU as directed by medical team
Further clinical course progressions (as required)	A. Remains patent B. RR 30bpm, SpO_2 98% in 15L of Oxygen C. HR 110bpm, CRT 2 seconds, BP 100/60mmHg D. Blood glucose 30mmol/L, PEARL size 4, GCS 15 E. No rashes, no bruising
Further clinical interventions (as required)	• Continue to reassess using the ABCDE approach • Review blood results from labs • Follow DKA protocol • Explain and reassure to both Mum and Alex what has happened and the plan • The medical team investigates potential triggers for DKA. Alex reveals they had been feeling unwell with flu-like symptoms and had missed several insulin doses due to nausea and loss of appetite. This, combined with the stress of illness, likely precipitated the DKA episode.
Post-emergency care (Time dependent)	• Documentation of all assessments and interventions • Contact PI/Sponsor • Safety reporting (SAE)

Post-Scenario Discussion

Possible discussion points	**Include technical and non-technical points:** • What are the signs and symptoms of DKA? • What is the treatment pathway in DKA? • When should you start insulin in the patient with DKA? • What are the signs a patient is in shock? • What is the importance of neurological assessment and pupil response in a patient in DKA? • Importance of ABCDE to assess unwell patient • Discuss communication with team, patient and family • Discuss teamwork • Discuss use of SBAR tool for handover • Escalation/calling for help

Appendices

Attach any background information and supporting documents for the scenario as required, e.g. Clinical records, observation chart, drug chart, ECG, fluid balance chart, blood results, VBG results etc.

Core Paediatric Scenario 6: Recognition and Initial Treatment of a Paediatric Patient Experiencing Cytokine Release Syndrome (CRS)

Case scenario	Recognition and initial treatment of a paediatric patient experiencing Cytokine Release Syndrome (CRS)
Intended clinical (technical) learning objectives	• To systematically use the ABCDE approach when assessing and treating a child experiencing Cytokine Release Syndrome (CRS) • Awareness and recognition of the signs and symptoms of CRS • Appropriate escalation • Initiation of appropriate management of CRS
Intended non-technical learning objectives	**Communication** • Effective communication with the child and family • Effective communication with multi-disciplinary team • Clear handover to medical team using SBAR • Provide support for family. **Leadership** • Effective management of child experiencing CRS • Identification of team leader for the situation • Appropriate and timely delegation of tasks • Managing the needs of relatives **Decision-making** • Appropriate and timely call for help • Quick decision regarding diagnosis and status as an emergency • Appropriate and timely initiation of treatment • Immediate call for help • Timely escalation

Participant's name and age/ DOB	Daniel 15 years old

Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced** Daniel is attending the CRF for a dosing visit for a Phase 2 Haematology Clinical Research Gene Therapy trial. The ATIMP is administered intravenously (IV) over 30 minutes. Daniel arrives with his mother, appearing well, afebrile, baseline vitals within range. Daniel has a peripheral canula sited and infusion commences as per protocol. 20 minutes into the infusion, Daniel starts to report feeling hot, with a severe headache, nausea and myalgia.
Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	**Situation**: Daniel attends the CRF for a dosing visit as part of a Phase 2 Haematology Clinical Research Gene Therapy trial. 20 minutes into the ATIMP infusion Daniel is complaining of feeling hot, with severe headache, nausea and myalgia. **Background**: Daniel has a diagnosis of Homozygous Sickle Cell Disease. Daniel has experienced multiple prior vaso-occlusive crises, with history of acute chest syndrome at age of 12 years. No known drug allergies. **Assessment:** A. Patent B. RR-25bpm, SpO2 96% in air C. HR-110bpm, BP- 110/65 mmHg, CRT 2 seconds D. AVPU- A, PEARL size 4, Glucose 6.0mmol/L, severe headache E. Temp- 39.1, myalgia, nausea **Recommendations** - learner expected to: • Stop infusion • ABCDE assessment • Call for help • Continuous monitoring • Consider CRS (including differential diagnosis) • Commence 02 therapy immediately • Administer fluids • Commence management of CRS as per local policy • Blood cultures and other routine biochemistry • Appropriate escalation • Recognise the psychological support for Daniel and Mother

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	1. To run the scenario and provide observations of Daniel's condition 2. To role play as the mum (optional) 3. Observing and documenting scenario events (technical and non- technical skills).
Learner (Options according to availability)	Clinical roles (maximum 6 learners) Lead learner to identify themselves Learners should assume their own clinical role during the scenario.
Area setup for scenario	**Environment:** • CRF ward area **Specific setup** • Paediatric Manikin sitting upright on a bed
Equipment setup and possible props needed for scenario	**Equipment immediately available** • O2, equipment to measure vital signs **Equipment available on request** • Emergency trolley, paediatric BNF
Participant/ manikin preparations for scenario	**Gender** • Male **Participant's position** • Sitting upright on a bed **Appearance** • Monitoring in situ. Daniel is sat upright appears flushed.
Medical documentation needed for scenario	**What is available** Observation chart with set of baseline observations. Study site file, Case report form, medical health records.

Scenario Clinical Course

Observations on initial assessment	**(If applicable) Verbal handover to first responder as they enter scenario:** Learner expected to obtain the following, using ABCDE assessment: A. Patent B. RR-25bpm, SpO2 96% in air C. HR-110bpm, BP- 110/65 mmHg, CRT 2 seconds D. AVPU – A, PEARL size 4, Glucose 6.0mmol/L, severe headache E. Temp- 39.1, myalgia, nausea.
Initial clinical interventions required in response to the above	• Consider CRS - stop infusion • Call for appropriate medical help - Initiate emergency call to Resuscitation Team on 2222 • Commence O2 therapy – non-rebreathe mask with 15L/min • Assess patient using ABCDE approach • Commence continuous monitoring • Consider antipyretic
Clinical course progression	Daniel now appears flushed and has mild shortness of breath. Learner expected to obtain following using ABCDE technique: A. Patent B. RR - 28bpm, SpO2 93% in air, shortness of breath C. HR - 118bpm, BP - 95/55 mmHg, CRT 3 seconds, flushed and sweaty D. AVPU - A but clearly distressed, PEARL size 4, Glucose 6.0mmol/L, severe headache E. Temp- 39.1, myalgia
Further clinical interventions required in response to above progression	• Initiate emergency call for help • Assess patient using ABCDE approach • Administer IV fluid bolus • Commence clinical management of Cytokine Release Syndrome as per local policy • Assessing and recording of CRS grading as per ASTCT consensus grading of CRS criteria • Obtain blood culture and relevant blood tests

	• Communicate clearly with Daniel and family
Further clinical course progressions (as required)	• Reassess using ABCDE approach • Verbal handover to resuscitation team using SBAR • Prepare patient for transfer • Complete appropriate documentation • Contact PI/Sponsor

Post-Scenario Discussion

Possible discussion points	**Include technical and non-technical points:** • Recognition and grading of Cytokine Release Syndrome (CRS) • Local treatment and management of CRS– (e.g. Use of Tocilizumab, corticosteroids, IV fluids) • CRS V's clinical differentials • Early referral and escalation in all cases of suspected cytokine release syndrome • Communication and decision making under stress • Protocol adherence • Handover to emergency team using SBAR

Appendices

Attach any background information and supporting documents for the scenario as required, e.g. Clinical records, observation chart, drug chart, ECG, fluid balance chart, blood results, VBG results etc.

Debriefing Delivery Tool

Health care simulation has evolved over time and has become a routine aspect of clinical education. Duff et al., (2024) believes that debriefing is a critical component of simulation scenarios, with an evolving number of debriefing tools being used to guide the format. According to International Nursing Association for Clinical Simulation and Learning (INACSL) Standards Committee et al (2021) debriefing in simulation is defined as a guided conversation among participants, which includes a range of activities, feedback and guided reflection.

Purpose and Timing of Debriefing

Most debriefing approaches are conducted soon after the experience, however some allow more time for formal reflection. Also, if skills or behaviours are seriously flawed, debriefing may need to occur during the scenario (Fanning & Gaba 2007). Learners' emotions can run high immediately after a simulated experience as they begin to analyse their performance and the critical aspects of the scenario (Arafeh et al 2010). These emotions can be re-organised and focused in a productive manner by debriefing immediately after the scenario.

Facilitator Role and Environment

Fanning and Gaba (2007) suggest debriefing should be facilitated and coordinated by suitably qualified and experienced facilitators to ensure a safe environment. The Resuscitation Council (UK) Generic Instructor Course includes training in debriefing skills (Resuscitation Council (UK) 2021). However, it may also be possible to negotiate in-house training with local resuscitation officers.

During a structured debriefing session, good ethical practice should ensure that the facilitator sets a safe, confidential and supportive environment where learners feel valued and respected. The facilitator's role is to lead a safe discussion and encourage deep thinking by asking meaningful pre-planned questions. Many topics can be discussed during a debrief. However, it is important to initially focus on what the learners want to discuss. Once discussion is underway, key learning objectives and other issues (strengths and weaknesses) that arise can also be discussed

It is important to remember and understand that the expected learners are adults and come with their own personal experiences, knowledge and feelings which may influence and drive their actions (Fanning & Gaba 2007). There are various approaches to debriefing. Generally, debriefings move without facilitation via their own power through three phases of description, analysis and application (Steinwachs 1992). Further guidance on facilitating these phases is provided below.

Useful Facilitation Techniques

Technique Category	Examples / Prompts
Open-ended Questions	• How well did you feel the team performed? • What caused you frustration or discomfort? • What surprised you about how you operated? • Why did you feel that affected your ability to make decisions? • How did you feel when that happened? • What did you understand of that instruction? • What was happening at the time? • What did you learn? • How will you do it differently next time? • Why did you say or do that? • What do you think can be improved?
Probing Questions	• What would have made you more comfortable? • What would you prefer to have happened? • Tell me more about how you felt when that was said? • Explain your thoughts at the time… • How could that be improved? • What were you doing when this occurred? • Why do you think they did that?
Closed Questions	• Is that what you meant when you said that you wanted (someone) to do that? • Did anyone notice what he said to the surgeon? • Did you understand the instructions / was the instruction clear? • Have you identified the cause of tachycardia at this stage? • Was that a reasonable request? • Was that action expected? • Did you not like that? • Was that a good decision at that point? • Does anyone have anything further to add?
Reflection & Summarising	• So, you have said that we should do this in the future… • What you have agreed is that this is what happened… • Is what you are saying…? • You have agreed that you will… • So, is that a fair summary of how you handled that problem? • And you are willing to use the learning…
Other Techniques	Allow silences as they naturally occur – it will promote further discussion.

Debrief Stages

Stage 1: Opening the discussion or conversation

The discussion is to be conducted in a non-threatening/ non-judgmental manner. Start by communicating the session's expectations, using phrases such as:

- Debriefing is a time to discover together what happened and what it all means…
- We now have time to reflect…
- To make this discussion as rich as possible, please contribute ideas, and leave time for others to do the same…
- Listen and learn from each other…

Explain the ground rules:

- Honour confidentiality
- Give unconditional respect to self and others
- Participate as much as possible
- Speak only for myself, not others
- Be open and honest with group members
- Be silent if it feels right

Explain the debrief structure that will be followed:

- Factual description of the scenario
- As learners begin to discuss events, encourage them to continually analyse the events, thoughts, feeling and reactions
- Summarise the learning the group has discussed
- Explore what happened (6 minutes)

Stage 2: Descriptive phase

Ask learners to describe what has happened in the scenario:

- Keep learners to the factual events as they occurred during the scenario
- Take notes of key phrases that are said by the group to use during the analysis
- phase
- Keep the focus on the group and not individual learners – no blame
- Try to encourage all learners to contribute

Summarise the clinical (technical) queries and issues by discussing clinical signs / symptoms and treatment that the scenario was designed to show.

Stage 3: Analysis phase

Explore jointly any issues that emerge (12 minutes)

Ask learners, “How did you feel?”

- Use key phrases/ quotes from notes taken in the descriptive phase to start discussions and explorations
- Acknowledge and facilitate discussion – remember to ask Why? Why? Why? Why? Why?
- Try to promote the “oh yes” moments
- Try to focus on one or two non-technical skills and how it influenced the course of the scenario; there will not be enough time to discuss all non-technical skills (decision making, planning, situation awareness, team-working, leadership, communication)
- Listen to what learners are saying, pick up on key issues from them.
- May need to ask additional questions for deeper thinking; may need to give your opinion
- Include and encourage impressions from all learners within the group

What have you (the learners) learnt from this experience?

- Support learners to share their observations and their perceptions, including strengths and areas for change
- Consider all of the group’s learning; do not overload one learner
- Keep the learning objectives in mind and take opportunities to reinforce any technical or non-technical elements

Ask learners if there is anything that they would have done differently?

- Include impressions/ suggestions from the entire group – what ideas or suggestions have the group got for how to deal with that situation?

Do any events during this scenario reflect reality?

- Ask learners to share if they have been involved in situations like this during clinical practice
- Real clinical examples are powerful learning tools; seek experience from the ‘real world’ to emphasise points and help relate experience to the real world

Ask to learners if there are any further issues, question or comments that they would like to offer.

Stage 4: Key learning points
Ask the learners to summarise the learning the group has discussed (4 minutes) Using examples from the learners, give your summary - keep it brief! Finish on a positive note! Consider providing theory sessions on the topic at the debriefing session after the feedback.

Examples of UK-Based Debriefing Tools for Clinical and Emergency Scenarios

🧰 SHARE Debrief Tool (NHS England)

- Steps: Scene → Hear → Articulate → Response → Embed.

📎 Download the SHARE Debrief Tool (PDF)

⏱️ STOP5 Hot Debrief Model (Edinburgh Emergency Medicine)

- Rapid debrief (within 5 minutes) after emergency cases like trauma or cardiac arrest.

- Focuses on reflection, team learning, and emotional processing.

📎 STOP5 Hot Debrief Model Overview

References

Arafeh J M, Hansen S S, Nichols A (2010). Debriefing in simulated-based learning facilitating a reflective discussion. Continuing Education 24: 302.

Association of the British Pharmaceutical Industry (2007). Guidelines for Phase I Clinical Trials. London.

Association of the British Pharmaceutical Industry (2012). Guidelines for Phase I Clinical Trials 2012 edition, London (last updated: 12th November 2014)

Association of the British Pharmaceutical Industry (2018). Guidelines for Phase I Clinical Trials 2018 edition.

Duff, J.P., Morse, K.J., Seelandt, J., Gross, I.T., Lydston, M., Sargeant, J., Dieckmann, P., Allen, J.A., Rudolph, J.W. and Kolbe, M. (2024) Debriefing methods for simulation in healthcare: A systematic review, *Simulation in Healthcare*, 19(Supplement 1), pp. S112–S121.

Fanning R M, Gaba M D (2007). The role of debriefing in simulation-based learning. Simulation in Healthcare 2: 115.

INACSL Standards Committee, Decker, S., Alinier, G., Crawford, S.B., Gordon, R.M., Jenkins, D.J., & Wilson, C. (2021) 'Healthcare Simulation Standards of Best Practice: The Debriefing Process', *Clinical Simulation in Nursing*, 58, pp. 27–32.

Lee, D.W., Santomasso, B.D., Locke, F.L., Ghobadi, A., Turtle, C.J., Brudno, J.N., Maus, M.V., Park, J.H., Mead, E., Pavletic, S., Go, W.Y., Eldjerou, L., Gardner, R.A., Frey, N., Curran, K.J., Peggs, K., Pasquini, M., DiPersio, J.F., van den Brink, M.R.M. and Komanduri, K.V. (2019). ASTCT Consensus Grading for Cytokine Release Syndrome and Neurologic Toxicity Associated with Immune Effector Cells. *Biology of Blood and Marrow Transplantation*, 25(4), pp.625–638. [Online] Available from https://doi.org/10.1016/j.bbmt.2018.12.758. [Last accessed 21 Oct 2025]

Medicines and Healthcare products Regulatory Agency (2012) Good Clinical Practice Guide. London.

Medicines and Healthcare products Regulatory Agency. Phase I accreditation scheme requirements. Version 3 2015. [Online] Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/473579/Phase_I_Accreditation_Scheme.pdf [Last accessed 23 May 2019]

MHRA PHASE I ACCREDITATION SCHEME REQUIREMENTS. Version 5. (2025). Available at: https://assets.publishing.service.gov.uk/media/67f51ec432b0da5c2a09e152/1._MHRA_Phase_I_Accreditation_Scheme_Requirements.pdf [Last accessed 08 December 2025]

National Institute for Health and Care Excellence (2023) Clinical Knowledge Summary: Blackouts and Syncope. [Online] Available at:https://cks.nice.org.uk/topics/blackouts-syncope/ [Last accessed 21 July 2025]

National Institute for Health and Care Excellence (2020) *Acute coronary syndromes. NICE guideline [NG185].* London: NICE; published 18 November 2020.

National Institute for Health and Care Excellence (2023) Clinical Knowledge Summaries:Hypoglycaemia.

National Institute for Health and Care Excellence (2025) Overview | Suspected sepsis in people aged 16 or over: recognition, assessment and early management | Guidance | NICE Published 19 November 2025

Nursing and Midwifery Council (NMC) (2018). The Code: Professional standards of practice and behaviour for nurses, midwives and nursing associates. [Online] Available from: https://www.nmc.org.uk/globalassets/sitedocuments/nmc-publications/nmc-code.pdf [Last Accessed: 23 December 2025]

Perkins G D (2007). Simulation in resuscitation training. Resuscitation 73: 202. Resuscitation Council (UK) (2015) Resuscitation Guidelines London

Perkins G and Clark AB (27 November 2025) Resuscitation Council Executive summary of the main changes since the 2021 Guidelines. [Online] Available at:https://www.resus.org.uk/professional-library/2025-resuscitation-guidelines/executive-summary-main-changes-2021-guidelines [Last accessed 21 January 2026]

Resuscitation Council UK. (2025). *Instructor Courses*. [Online] Available at: https://www.resus.org.uk/training-courses/instructor-courses [Last accessed 8 Dec 2025].

Resuscitation Council Emergency Treatment of Anaphylactic Reactions: Guidelines for Healthcare Providers (UK) (2021). Resuscitation Council UK, London

Soar, J., Deakin, C., Nolan, J. et al (2021) Adult Advanced life support Guidelines. Resuscitation Council UK, London

Steinwachs B (1992). How to facilitate a debriefing. Simulation and Gaming 23: 186.

The UK Sepsis Trust Edited by Daniels R and Nutbeam T (2024) The Sepsis Manual 7th Edition. [Online] Available at:

Sepsis-Manual-7th-Edition-2024-V1.0.pdf [Last accessed 25 January 2026]

The UK Sepsis Trust (2024) Sepsis Screening Tool Acute Assessment Aged 16+. [Online] Available at:

https://sepsistrust.org/wp-content/uploads/2024/08/Acute-Hosp-16-2025-ACUTE-16-001.pdf [Last accessed 25 January 2026]

Tole J W, Lieberman P (2007). Biphasic anaphylaxis: review of incidence, clinical predictors, and observation recommendations. Immunology Allergy Clinics of North America 27(2):309-26, viii.

Appendix 1: Template for Clinical Emergency Scenario Guidance and Reporting Details (blank copy)

Title of scenario	
Date of scenario	
Type of scenario (announced or unannounced)	
Was scenario training video recorded and if so, where is this stored?	
Intended clinical (technical) learning objectives	
Intended non-technical learning objectives	
Participant's name and age/ DOB	

Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced**
Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	
Learner (Options according to availability)	
Area setup for scenario	
Equipment setup and possible props needed for scenario	
Participant/ manikin preparations for scenario	
Medical documentation needed for scenario	

Scenario Clinical Course

Observations on initial assessment	
Initial clinical interventions required in response to the above	
Clinical course progression	
Further clinical interventions required in response to above progression	
Further clinical course progressions (as required)	
Further clinical interventions (as required)	
Post-emergency care (Time dependent)	

Post-Scenario Discussion

Possible discussion points	

Supporting documents for scenario

Attach any background information and supporting documents for the scenario as required,

e.g. Clinical Records, X-rays, Observation Chart, Drug Chart, ECG, Fluid Balance Chart, Peak Flow Chart, Blood Results, ABGs results etc.

Appendix 2: Template for Clinical Emergency Scenario (with guidance notes) and Reporting Details

Title of scenario	
Date of scenario	
Type of scenario **(Announced or unannounced)**	
Was scenario training video recorded and if so, where is this stored?	
Intended clinical (technical) learning objectives	The clinical skills (objectives) that are intended by the scenario: • Understand the approach to the participant with…? • Recognise the signs and symptoms of…? • Know how to manage the participant with…?)
Intended non-technical learning objectives	The human factors which are vital to the scenario: • Cognitive or mental skills - decision making, planning, situation awareness. • Social skills - team-working, leadership, communication
Participant's name and age/ DOB	
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced** Brief outline
Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	Brief outline

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	1. To run the scenario 2. To role play as the relative (optional) 3. To role play as the participant (optional) 4. Observing and documenting scenario events
Learner (Options according to availability)	Clinical roles (maximum 6 learners) Learners should assume their own clinical role during the scenario
Area setup for scenario	**Environment** • Where will the scenario take place? **Specific setup** • The set-up of the manikin (where, with what etc.) and/or brief notes for the facilitator role-playing as the participant
Equipment setup and possible props needed for scenario	**Equipment immediately available** • What is normally available in the area where the scenario is to take place **Equipment available on request** • e.g. O_2, suction, ECG
Participant/ manikin preparations for scenario	**Gender** • Male / Female **Participant's position** • Where is the participant? Are they sitting/ lying on floor/ in bed? **Appearance** • Does the participant have any monitoring equipment on or is there an infusion running? **Concomitant medications** • If applicable
Medical documentation needed for scenario	**What is available** • e.g. Clinical records, observation charts, medication chart **What is not available** • e.g. Clinical records, observation charts, medication chart

Scenario Clinical Course

Observations on initial assessment	**(If applicable) Verbal handover to first responder as they enter scenario:** A. B. C. D.
Initial clinical interventions required in response to the above	List interventions
Clinical course progression	How does the participant respond to initial interventions above?
Further clinical interventions required in response to above progression	Description of how the participant responds to initial clinical interventions in A-E format
Further clinical course progressions (as required)	What happens next because of intervention
Further clinical interventions (as required)	As required

Post-emergency care (Time dependent)	**Where should the participant go and what should be done first?**

Post-Scenario Discussion

Possible discussion points	**Include technical and non-technical points:** • Assessment of the critically ill participant using ABCDE approach • Draw out attributes of a good team leader – roles planned in advance; identification of team leader; non-technical skills (task management, team working, situational awareness, decision making, structured communication) • Points specific to the scenario topic • Importance of handovers, including the use of specific tools (SBAR)

Supporting documents for scenario

Attach any background information and supporting documents for the scenario as required,

e.g. Clinical Records, X-rays, Observation Chart, Drug Chart, ECG, Fluid Balance Chart, Peak Flow Chart, Blood Results, ABGs results etc.

Observed Learning Notes: Technical (Clinical/ Medical)		
	Time	**Comments**
Summon help (Shout or use phone to get help)		
Pull/ push emergency alarm button		
Response time from awareness of emergency to initial call for help		
ABCDE assessment		
Call for resuscitation team		
Appropriate equipment arrives		
Appropriate interventions such as O2 therapy		
Appropriate monitoring attached		
Cardiac rhythm recognition		
Airway management		
Quality of chest compressions		
Drug administration		
Transfer to hospital/ critical care		
Unblinding procedure		

Observed learning notes : Non – technical (human factor-related)	
	Comments
Decision making	
Planning	
Situation awareness	
Team working	
Leadership	
Communication	

Summary of Debrief
Additional information (if required) including: • Discussion points from facilitator • Feedback

Confirmation of Scenario Completion		
Name of Facilitators	**Role in scenario**	**Signature**

The trainer should retain this document for proof of training

Learner Attendance Log				
#	**Name**	**Job Title**	**Place of Work**	**Signature**
1				
2				
3				
4				
5				
6				

Appendix 3: Template for Clinical Emergency Scenario Guidance and Reporting Details (copy completed with example observations

Title of scenario	Recognition and treatment of anaphylaxis with recognition to un- blind
Date of scenario	20th January 2026
Type of scenario **(Announced or unannounced)**	*This can be copied and pasted from relevant scenario outline* Unannounced
Was scenario training video recorded and if so, where is this stored?	*This can be copied and pasted from relevant scenario outline* No
Intended clinical (technical) learning objectives	*This can be copied and pasted from relevant scenario outline* • Performance of the patient assessment using systematic ABCDE approach • Staff can recognise and initiate treatment of anaphylaxis in line with resus council UK 2021 guidelines • Staff recognise the need to call for help early and the requirement for follow up care and reasons why • Staff demonstrate that they understand and can safely follow the process for un-blinding

Intended non-technical learning objectives	*This can be copied and pasted from relevant scenario outline* **Communication:** • Staff communicate effectively within the team • Clear SBAR handovers given **Leadership and teamwork:** • Staff have clearly defined roles within the team • Staff consider the needs of family – contact the next of kin • Clear leadership by a team member • Appropriate and timely delegation of tasks **Clinical Outcomes:** • Safe management of Anaphylaxis • Recognise the signs and symptoms of anaphylaxis and life-threatening problems • Know how to manage the patient with anaphylaxis • Understand the appropriate treatment of anaphylaxis • Understand what refractory anaphylaxis is and how this is managed **Decision Making:** • Quick decision made regarding diagnosis and status as an emergency • Appropriate and timely initiation of treatment • Appropriate and timely escalation and involvement of medical emergency team • Appropriate decision making to perform un-blinding

Participant's name and age/ DOB	*This can be copied and pasted from relevant scenario outline* Sam Claus Age 21
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced** *This can be copied and pasted from relevant scenario outline* Sam is taking part in a phase 1 study – This is Sam's first infusion of the trial's investigational medicinal product (IMP). Sam is not taking any regular medications and has no known drug allergies. After 5 minutes Sam starts to complain of feeling generally unwell; faint, abdominal pain and pins and needles in their fingers – on initial assessment there is nothing to note other than a slightly increased respiratory rate.
Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	*This can be copied and pasted from relevant scenario outline* Sam is experiencing an anaphylaxis reaction relating to the IMP intravenous infusion. Sam is usually well with no known allergies and has no past medical history. Sam will continue to deteriorate, until the first dose of adrenaline administration. Recognition and treatment should be based on Resuscitation Council (UK) (2021) Emergency Treatment of Anaphylactic Reactions Guidelines: • Staff use ABCDE approach • Discontinue the intravenous infusion • Initiate treatment • Call made to CRF Physician, medical emergency team and request for an anaesthetist • Handover using SBAR or similar communication tool • Consider transfer to ICU • Complete adverse event report

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	*This can be copied and pasted from relevant scenario outline* 1. To run the scenario AM 2. To role play as the relative (optional) not required 3. To role play as the participant (optional) PM 4. To observe and document scenario events PC
Learner (Options according to availability)	This can be copied and pasted from relevant scenario outline Clinical roles (maximum 6 learners) Learners should assume their own clinical role during the scenario
Area setup for scenario	*This can be copied and pasted from relevant scenario outline* **Environment** • The CRF ward area **Specific setup** • Sam is sitting up in bed with the IMP infusion running • Vitals signs and ECGs are scheduled to be recorded every hour
Equipment setup and possible props needed for scenario	*This can be copied and pasted from relevant scenario outline* **Equipment immediately available** • Oxygen • Cardio / respiratory monitoring for blood pressure, SpO_2, pulse, respirations, temperature **Equipment available on request** • Emergency trolley, defibrillator • Anaphylaxis kit containing adrenaline and algorithm • Intravenous fluids and IV administration sets • Blood glucose monitoring equipment

Participant/ manikin preparations for scenario	*This can be copied and pasted from relevant scenario outline* **Gender** • Male/Female **Participant's position** • Sitting up in bed **Appearance** • Anxious, pale, clammy • Concomitant medications nil
Medical documentation needed for scenario	*This can be copied and pasted from relevant scenario outline* **Available** • Case report form or patient workbook containing relevant medical notes • IMP Prescription chart • NEWS2 observation chart • Anaphylaxis algorithm

Scenario Clinical Course

Observations on initial assessment	*This can be copied and pasted from relevant scenario outline* **(If applicable) Verbal handover to first responder as they enter the scenario:** A. Clear B. RR 18bpm C. HR 90bpm, BP 110/60mmHg D. Alert, anxious E. Normal

Initial clinical interventions required in response to the above	*This can be copied and pasted from relevant scenario outline* Over the next 10 minutes, Sam becomes very short of breath, has a widespread wheeze, develops an urticarial rash, and feels lightheaded.
Clinical course progression	*This can be copied and pasted from relevant scenario outline* A. Complains of tightness in throat B. RR 28 min, widespread wheeze C. HR120 min, BP 80/60mmHg D. Alert, although very anxious E. Widespread urticarial rash
Further clinical interventions required in response to above progression	*This can be copied and pasted from relevant scenario outline* • Discontinue the intravenous infusion • Contact the medical emergency team • Repeat ABCDE use deteriorating patient guidelines • Oxygen via non-rebreather • Treat anaphylaxis in accordance with Resus council guidelines • Monitoring (pulse oximetry, non-invasive blood pressure, 3-lead ECG) • Lay flat, with legs raised or semi recumbent position if breathing problematic • Recognise potential need for IV fluids and not using the same cannula as the drug • Handover using SBAR • Consider the requirements of un-blinding • Contact the Principal Investigator/Sponsor • Consider transfer to ICU • SAE report
Further clinical course progressions (as required)	*This can be copied and pasted from relevant scenario outline* Anaphylaxis resolves with appropriate treatment

Further clinical interventions (as required)	*This can be copied and pasted from relevant scenario outline* • Review by a senior clinician • Mast cell tryptase should be measured in all patients with suspected anaphylaxis where the diagnosis is uncertain • initial sample as soon as feasible after initial treatment • second sample 1 – 2 hr (but no later than 4 hr) symptom onset • third sample at least 24 hr after complete resolution • Observed in a clinical area with facilities for treating life-threatening ABC problems for following lengths of time • 2 hrs – single dose, good response, complete resolution, has auto injector and trained previously, adequate supervision on discharge • At least 6 hours – 2 doses needed or prior biphasic reaction • At least 12 hrs - > 2 doses, severe asthma or respiratory reaction, continued allergy absorption, late night admission, access to emergency care difficult if discharged • All patients should be referred to a specialist clinic for allergy assessment. • Offer patients an appropriate adrenaline injector as an interim measure before the specialist allergy assessment (unless the reaction was drug induced). • Patients prescribed adrenaline auto-injectors must receive training in their use and have an emergency management or action plan. • Anaphylaxis reactions should be reported to the UK Anaphylaxis Registry at www.anaphylaxie.net (to register, email anaphylaxis.registry@ic.ac.uk) • Refractory anaphylaxis (no improvement after 2 doses of IM adrenaline) refer to algorithm
Post-emergency care **(**Time dependent)	*This can be copied and pasted from relevant scenario outline* Arrange appropriate transfer of participant for further observation – ICU/ HDU Handover of participant to an appropriate area using Situation Background Assessment Recommendation (SBAR) Transfer of minimum records required to accompany participant to ICU or other department as defined in local SOPs

Post-Scenario Discussion

Possible discussion points	*This can be copied and pasted from relevant scenario outline* Anaphylaxis is a severe, life- threatening, generalised or systemic hypersensitivity reaction. This is characterised by rapidly developing life-threatening airway and/or breathing and/or circulation problems usually associated with skin and mucosal changes. • Discuss the importance of an ABCDE approach and why interventions should occur as you find problems. • Discuss the approach to management: O_2, IM adrenaline, lying flat, legs raised or semi recumbent (if breathing issues) - 2021 Resuscitation Anaphylaxis Algorithm • Discuss reason other drugs have been removed from the initial treatment of anaphylaxis • Reason to call for help early and who should be contacted first in this scenario • Refractory anaphylaxis – what this is and how treated • What airway problems you would anticipate with the patient • Tools available to help make decisions • Equipment locations • Discuss the merits of intramuscular compared with intravenous adrenaline • What are the dangers of excessive doses of IV adrenaline in the patient with spontaneous circulation?

Supporting documents for scenario

Attach any background information and supporting documents for the scenario as required, e.g. Clinical records, x-rays, observation chart, drug chart, ECG, fluid balance chart, peak flow chart, blood results, ABGs results etc.

Observed Learning Notes: Technical (Clinical/ Medical)		
	Time	**Comments**
Time of Incident	09:46:45	Sam starts to feel very short of breath, has a widespread wheeze, develops an urticarial rash, and feels lightheaded.
Summon help (Shout or use phone to get help)	09:48:42 (+2 mins)	Called for study doctor
Pull/ push emergency alarm button	09:48:45 (+2 mins)	Activated as unable to contact study doctor
Response time from awareness of emergency to initial call for help	09:48:45 (+2 mins)	After ABC assessment and treated problems systematically
ABCDE assessment	09:47:45 (+1 min)	ABC assessed, D and E not completed
Call for resuscitation team	09:51 (+4:15 mins)	Initial decision to call study doctor and for extra help and emergency trolley when unable to contact study doctor. Staff who arrived later decided to call resuscitation team after recognising anaphylaxis and stopping study drug
Appropriate equipment arrives	09:49 (+ 2.15	Emergency trolley, anaphylaxis kit and oxygen
Appropriate interventions such as O2 therapy	09:48 (+ 1.45 mins)	Oxygen via non-rebreathe mask 15L Legs raised
Appropriate monitoring attached	09:48:45 (+2 mins)	Oxygen saturations and heart rate continuously and blood pressure on 2 min repeat cycle

Cardiac rhythm recognition		No monitoring
Airway management	09:51 (+4:15 mins)	Monitored, 2nd person recognised potential for deterioration and called for emergency medical team
Quality of chest compressions		N/A
Drug administration	09:52	0.5 mg IM adrenaline
Transfer to hospital/ critical care		Planned not completed
Unblinding procedure		Procedure followed as per protocol instructions

Observed learning notes : Non – technical (human factor-related)	
	Comments
Decision making	Good rapid assessment of ABC and systematic treatment
Planning	Call for help Send for crash trolley
Situation awareness	First responder not aware potential anaphylaxis caused be study drug until second responder communicated this
Team working	Effective communication noted between all responders
Leadership	Good clear leadership displayed by second responder
Communication	Effective communication noted between all responders

Summary of Debrief

First responder recognised need to call for help but prioritised calling the study doctor over emergency team.

ABCDE initiated and systematic approach good, did not proceed to disability and exposure or recognise anaphylaxis and need to stop the study drug initially.

Second responder recognised anaphylaxis, need for emergency team, stopped study drug and gave adrenaline, acted as team leader.

Third responder acted as runner, ensuring emergency call had been activated, documenting observations and preparing adrenaline.

There was good effective communication between all responders

- Adapt to the environment that you are faced with, bring the equipment needed to the situation and remove anything that can be moved.
- Don’t be afraid to call for emergency help early and prioritise who is required, the study doctor does need to be involved, but only an anaesthetist can manage an airway, and the emergency team brings an anaesthetist

- Utilise the tools and guidelines available to manage emergencies, e.g. NEWS2 charts, management of deteriorating patient guidelines, anaphylaxis algorithms
- By documenting the vital signs on NEWS2 charts, the score directs you to call for emergency help immediately
- By completing a systematic ABCDE approach, life threatening problems are identified and treated before progressing to less life-threatening problems.
- Reassessment of ABCDE allows evaluation of treatment and monitoring of condition
- What would D and E have shown that would have helped you recognise/confirm anaphylaxis?
- Use the equipment available e.g. defibrillation machines have ECG monitors
- What is Anaphylaxis - severe and life-threatening, generalised or systematic hypersensitivity reaction - Sudden onset of Airway and/or Breathing and/or Circulation problems and usually skin changes (e.g. itchy rash)
- Recognising life-threatening problems
  - **A**irway - Hoarse voice, stridor
  - **B**reathing - ↑work of breathing, wheeze, fatigue, cyanosis, SpO2 <94%
  - **C**irculation - Low blood pressure, signs of shock, confusion, reduced consciousness
- Treatment:
  - Use ABCDE approach
  - Call for HELP - Call resuscitation team or ambulance
  - Remove trigger if possible (e.g. stop any infusion)
  - Lie patient flat (with or without legs elevated)
  - A sitting position may make breathing easier – If pregnant, lie on left side
  - Give intramuscular (IM) adrenaline
  - Establish airway
  - Give high flow oxygen
  - Apply monitoring: pulse oximetry, ECG, blood pressure
- If no response:
  - Repeat IM adrenaline after 5 minutes
  - IV fluid bolus
- If no improvement in Breathing or Circulation problems despite TWO doses of IM adrenaline:
  - Confirm resuscitation team or ambulance has been called
  - Follow REFRACTORY ANAPHYLAXIS ALGORITHM
  - Review refractory anaphylaxis algorithm
- Why have other drugs been removed? They were being given in priority over adrenaline and there is limited evidence for their use

- Why is IM adrenaline given rather than IV?
- How much adrenaline can be given in an emergency by a nurse?
- Why would you unblind this person and how?
- What other clinical skills do you have that could be utilised in this situation? Cannulation, venepuncture, ECGs
- Use of SBAR
- Where should be patient be moved to and why?
- Is there any follow up required?
- Can you give IV fluids without a prescription in an emergency?

Confirmation of Scenario Completion		
Name of Facilitators	**Role in scenario**	**Signature**
AM	Run scenario	*A Mooδψ*
PD	Play Participant	*P Dummy*
PC	Observe and document scenario events	*P Concise*

The trainer should retain this document for proof of training

Learner Attendance Log				
#	**Name**	**Job Title**	**Place of Work**	**Signature**
1	TK	CRN	CRF	*T Kirk*
2	JS	CRN	CRF	J Shady
3	JD	CRN	CRF	*J Darton*
4				
5				
6				

Appendix 4: Template Corrective & Preventive Action Plan (CAPA) Following Feedback / Debrief Session (blank copy)

Complete one sheet for each CAPA

Title of emergency scenario training			
Date of emergency scenario training			
Date of feedback/debrief session			
Person responsible for distribution of scenario learning outcomes/ CA/PA to all staff			
Description of learning outcome	**Corrective and/or preventative action (CA/PA)**	**Time frame for action completion**	**Name of person responsible for delivery of CA/PA**
CA/PA circulation to all staff			
Method of circulation: (e.g. email, team meeting, unit meeting) **Date:** **Name:** **Signature:**			
CA/PA completion			
Date: **Name:** **Signature:**			

Appendix 5: Template Corrective & Preventive Action Plan (CAPA) Following Feedback / Debrief Session (copy completed with example actions)

Title of emergency scenario training	Recognition & treatment of anaphylaxis
Date of emergency scenario training	15th April 2015
Date of feedback/debrief session	15th April 2015
Person responsible for distribution of scenario learning outcomes/ CA/PA to all staff	Pauline Hickey

Description of learning outcome	**Corrective and/or preventative action (CA/PA)**	**Time frame for action completion**	**Name of person responsible for delivery of CA/PA**
Nursing staff were unsure of the management of Anaphylaxis in emergency scenario	Appropriate monographs will be printed and put into folder on emergency trolley. Pauline Hickey will be responsible for ensuring these are regularly checked for updates	2 weeks for distributing monographs	Pauline Hickey

Method of circulation:

Senior staff to be notified at next senior team meeting. Email will be sent to all staff.

Date 23.04.15 **Name:** Pauline Hickey **Signature:**

CA/PA completion

Date **Name:** **Signature:**

Appendix 6: Emergency Simulation Training (EST) Annual Report Template

A sample template for annual reporting of EST sessions is provided below. This includes sections for recording attendee roles and EDI characteristics to support CRF annual reporting. The template may be adapted as required to align with local structures and priorities.

Summary of YYYY

Dates	Candidate numbers	Gender	Ethnicity	Bands	Did not attend	Reasons	Venue	Faculty	Other comments
DD/MM/YYY	*5*	*4F, 1M*	*4 BME*	*1 x Band 7* *3 x Band 6* *1 x Band 3*	*1*	*Staff Sickness*	*Clinical Research Facility – Room 1*	*Name of Facilitator*	*Level 5 Team EST*

Specifics:

- Total number of staff ## out of scheduled ## CRF staff attended ## EST sessions in YYYY
- ## sessions were supported by an EST Link nurse; ## session was supported by [Other] (e.g. Resuscitation team)
- All sessions were ‘ward based’
- 0 CAPA plans were generated from ward-based EST; 0 Trust incident forms were completed
- Average scenarios per EST n=2
- Scenario types included:
    - *E.g. Anaphylaxis (Based on study XXX)*

- All scenarios were “tailor made” for the candidate groups with suitable story background to enable the candidate to relate better to the scenario and respond according to their role and skill set
- Additional topics covered in EST (*add as relevant*):
    - *ABCDE assessment*

What’s new in YYYY?

-

What has worked well in YYYY?

-

Main challenges YYYY

-

What’s coming up?

-

Appendix 7: UKCRF Network Emergency Scenario Delivery Team

The members of the Emergency Scenario Training Guidance Sub-Group responsible for developing and reviewing this document are listed below.

Original development by

- Terese Morley – CRF Nurse Manager, Cardiff
- Sujamole Subin – Trainee Advanced Nurse Practitioner, Manchester
- Ailsa McLean – Clinical Research Nurse, Guys & St Thomas, London
- Janet Johnson – Education and Training Officer, Glasgow
- Richard Hellyar – Clinical Research Nurse, Cardiff
- Lisa Berry – Senior Research Sister, Southampton
- Judith Rucklidge – Quality Lead, Manchester

Original review by

- Katie Rees – Children's Research Sister, Great Ormond Street, London
- Michelle Casey – Paediatric Senior Sister, Southampton
- Anne Elmer – Senior Research Sister, Cambridge
- Shona McDermott – Assistant Director, Glasgow
- Susan Caddy – Education Lead, Southampton
- Kay Riding – Lead Paediatric Research Nurse, Edinburgh
- Beverley Kilner – Education & Training Lead, Sheffield
- Farah Latif – Clinical Research Fellow, Cardiff

Further review by

- Norma Diaper – Lead Clinical Research Educator, Southampton
- Elizabeth Moore – Lead Children's Clinical Research Educator
- Beverley Kilner – Education & Training lead, Sheffield

Further review and development of new scenarios (version 5)

- Gail Mills – Lead Nurse R & D, Sheffield
- Branwen Ellison- Handley – Experimental Medicine Research Sister, Sheffield
- Zalina Rashid - CRU Clinical Manager, Liverpool

- Sally Batham - Research Space Clinical Manager, Leicester
- Jane Martin - Children's Senior Research Sister, Southampton
- Gerry Trillana - Clinical Research Facilities Matron, London
- Sarah Kent - Senior Sister LCRF/CRUK Nurse, Leeds
- Sally Pearson - Lead Nurse Research, Leeds
- Lucy Cooper - Advanced Nurse Practitioner, Birmingham
- Nick Fosh - Senior Early Phase Specialist Research Nurse, Cambridge
- Norma Diaper - Lead Clinical Educator, Southampton
- Paula Darroch - CRF Education Lead, London
- Stewart Fuller - CCRC Head Nurse, Cambridge
- Omabe Obasi - Research Nurse Manager, Cardiff

Further review and development of new scenarios (version 6)

- Hayley Clark - Clinical Research Practice Educator, Birmingham
- Emma Sang – Simulation Lead, Birmingham
- Dr Janapriya Sugumar – Clinical Fellow in Paediatric ICU ,Birmingham
- Helen Wollff – Research Training and Education Lead and Senior Sister, Sheffield
- Megan Webb – Research Practice Development Nurse, Cambridge
- Rebecca Nicol – CRF Training and Education Lead, Nottingham
- Marivic Ricamara – CRF Lead Nurse and Research Directorate Head of Research Delivery, London
- Nicola Thomson – Education and Training Facilitator, Glasgow

Further Acknowledgements

The Education Theme Group would like to acknowledge the contributions and assistance of:

- All those individuals who responded to the questions in the scoping surveys
- UKCRF Network Education Theme Group Members
- UKCRF Quality Assurance Theme Group Members
- UKCRF Research Nurses & Practitioners Theme Group Members
- UKCRF Network Senior Management Team
- Matthew Norridge - Education Lead, London

- Dr. Nathan Brendish – Research Fellow, Southampton
- Dr. Diane Gbesemete – Research Fellow, Southampton
- Ruth Ensom – Senior Children's Research Nurse, Southampton
- Dr Hasan Qayyum – A&E Consultant, Sheffield
- Zubeir Essat – Clinical Skills Facilitator, Leicester
- Dr. Richard FitzGerald – CRF Director, Liverpool
- Christopher Jenkins – Resuscitation Officer, Cardiff
- Dr. Daniel Owens – Research Fellow, Southampton
- D. Alasdair Munro – Research Fellow, Southampton
- Dr. Kim Sykes – Paediatric Consultant, Southampton
- Ruth Ensom - Senior Children's Research Nurse, Southampton
- Christie Mellish – Senior Children's Research Nurse, Southampton
- Joanne Richardson – Resus Officer, Sheffield