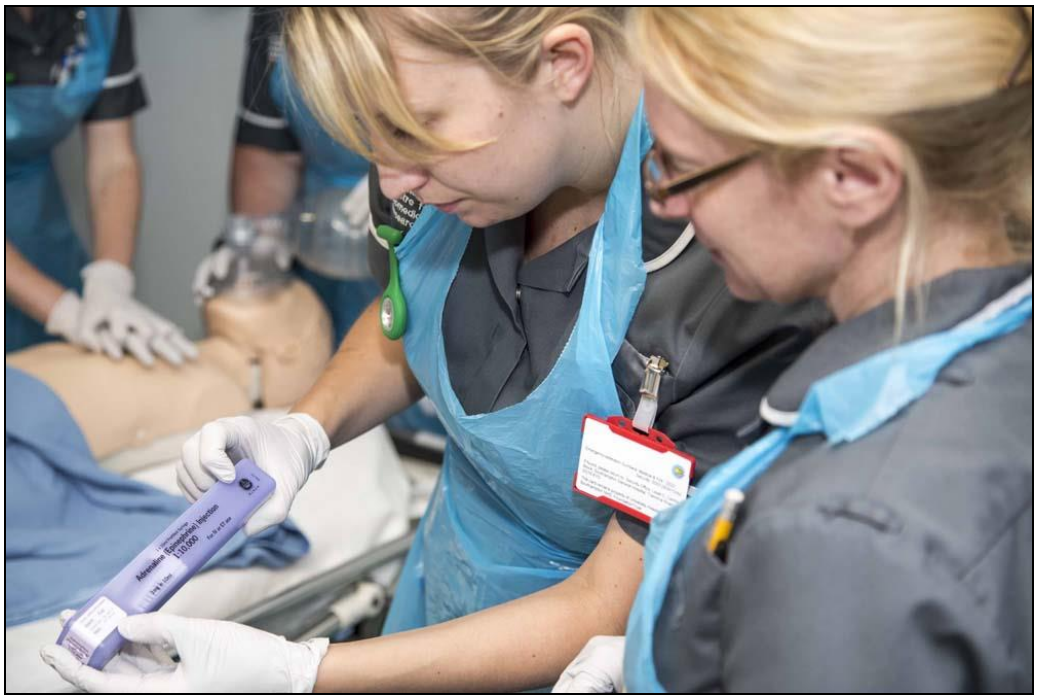
UKCRF NETWORK

Emergency Scenario Training Guidance Document

Version 5.0 – June 2019



FUNDED BY NIHR | National Institute for Health Research

CHIEF SCIENTIST OFFICE

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Version 5.0 – July 2019

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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).

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
AVPU	Alert voice pain unresponsive
BBB	Bundle branch block
BM	Blood glucose measurement
BNF	British National Formulary
BP	Blood pressure
CAPA	Corrective action & preventative action
CCU	Coronary care unit
CPR	Cardio-pulmonary resuscitation
CRF	Clinical Research Facility
CRP	C-reactive protein
ECG	Electro-cardio gram
EPLS	European Paediatric Life Support
ET	Endotracheal tube
GCS	Glasgow Coma Scale
HDU	High dependency unit
HR	Heart rate
ICU	Intensive care unit
IHD	Ischaemic heart disease
ILS	Immediate Life Support
IMP	Investigational medicinal product
IV	Intravenous
IVAB's	Intravenous antibiotics
kg	Kilogram
mcg	Microgram
MDI	Metered dose inhaler
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
O2 Sats	Oxygen saturation
O2	Oxygen
OD	Once daily
PEA	Pulseless electrical activity
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
Sats	Saturations
SOB	Shortness of breath
SOP	Standard operating procedure
STAT	Immediately
TYPE1 DM	Type1 diabetes mellitus
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 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 in order 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 and 2015).

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 and 2015).

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 and 2015), 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.

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

Frequency of Training

The MHRA (2007, 2012, and 2015) 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 the majority of 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 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 and debrief/ feedback. However, if this support is limited or 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.

Feedback Mechanisms

A feedback/ 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 structured feedback, a debriefing delivery tool is included at the end of this guidance document (page 107). A template for recording details of the training session that can then be used to support the debriefing session is also included in Appendix 2. The Generic Instructor course run by the Resuscitation Council (UK) includes training in providing feedback (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 CA/PA 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 - 4 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 that qualified nursing staff should 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 lab staff are all appropriate to be involved in the delivery of emergency scenario training.
- A feedback-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 within acute and ambulance settings. The National Early Warning Score 'NEWS' was developed by the Royal College of Physicians. In 2007 a revised version of the Early Warning score was published: NEWS2 and is being 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 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 resuscitation trolley?

A. All clinical staff (including medical staff) should be involved in the checking of the resuscitation 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. Are there any logistical preparations that need to be undertaken prior to emergency scenario training?

A. There should be a pre-plan with the relevant CRF Manager to ensure appropriateness of any announced sessions and 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 in advance. 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) in order 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 1 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 putting together the props needed for the scenario (e.g. O2 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.

Stage 1: Pre-Scenario Preparation (continued)

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, cardiac arrest trolley, drug/ observation charts, ECGs, medical notes, blood results).
- Make copies of the template for recording activities during the scenario (Appendix 2) and identify a facilitator to time and document relevant events during the scenario as they occur.

3. Briefings

Brief the facilitators on:

- The scenario narrative (read it out), and intended learning objectives.
- Specific instructions for each facilitator involved in the scenario (e.g. observer, note- taker, participant).
- Learners' experience levels.

If the scenario is announced, brief the learners on:

- The scenario in the context of the training and the process (brief, scenario, debrief).
- The scenario narrative (read it out), and intended learning objectives (e.g. improve technical and non-technical skills).
- 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 feedback.
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 feedback via facilitated debrief: this is the time to reflect on and discover in a group 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 with 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.93).

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: M one year ago with recurrent angina, hypertension and type 1 DM • NKDA, Ex-smoker 30/day until 6/12 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** Resuscitation 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, Resp 24, O_2 Sats 91% on air, symmetrical chest movement, normal breath sounds, trachea central, percussion normal resonance • C: HR 110 min, regular (ECG: shows sinus tachycardia), BP 140/80 mmHg, temp 37.0°C, capillary refill time (perip and/or central) 2 secs, 12 lead ECG (attached) if requested • D: Verbal response, BM (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, U&E, FBC, Clotting Initial treatment: • O2 with appropriate delivery device if indicated as result of low O2 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, Resp 25, O_2 Sats 98% (if on O_2), symmetrical chest movement, and normal breath sounds • C: HR 120 min, Regular (ECG: shows sinus tachycardia with ST segment changes ST elevation on certain views eg ST elevation on inferior leads – whatever the ECG shows), BP 150/105 mmHg (BP would drop with GTN 130/70), temp 37.0oC, capillary refill time (peripheral) 2 secs – this would not be delayed • Request 12 lead ECG (in patient's notes if requested) • D: Verbal response, BM (if asked) 6.3 mmol/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) • Reason, Story, Vitals, Plan (RSVP)
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 • 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	• Using a systematic approach (ABCDE assessment) • Recognise presentation of ACS. Females may present with atypical features, prompting a higher index of suspicion being required • Be aware of initial treatment options in ACS • The importance of a good team leader in the management of ACS • 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 CCU/ HDU/ITU/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 and a Participant in Cardiac Arrest

Case scenario	Assessment and initial treatment of a critically ill participant and a 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 **Leadership and teamwork** • Management of cardiac arrest • Appropriate and timely allocation of personnel • 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 6/12 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
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** Resuscitation trolley, AED, cardiac monitor, O2 and masks, suction, emergency drugs etc
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, Resp 28 , O2 Sats 96% on O2, 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 140/68 mmHg, temp 37.0^{o}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 Initial treatment: • O2 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 chestcompressions • Pause CPR to confirm rhythm - VF on monitor • Restart CPR whilst defibrillator is charging • 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

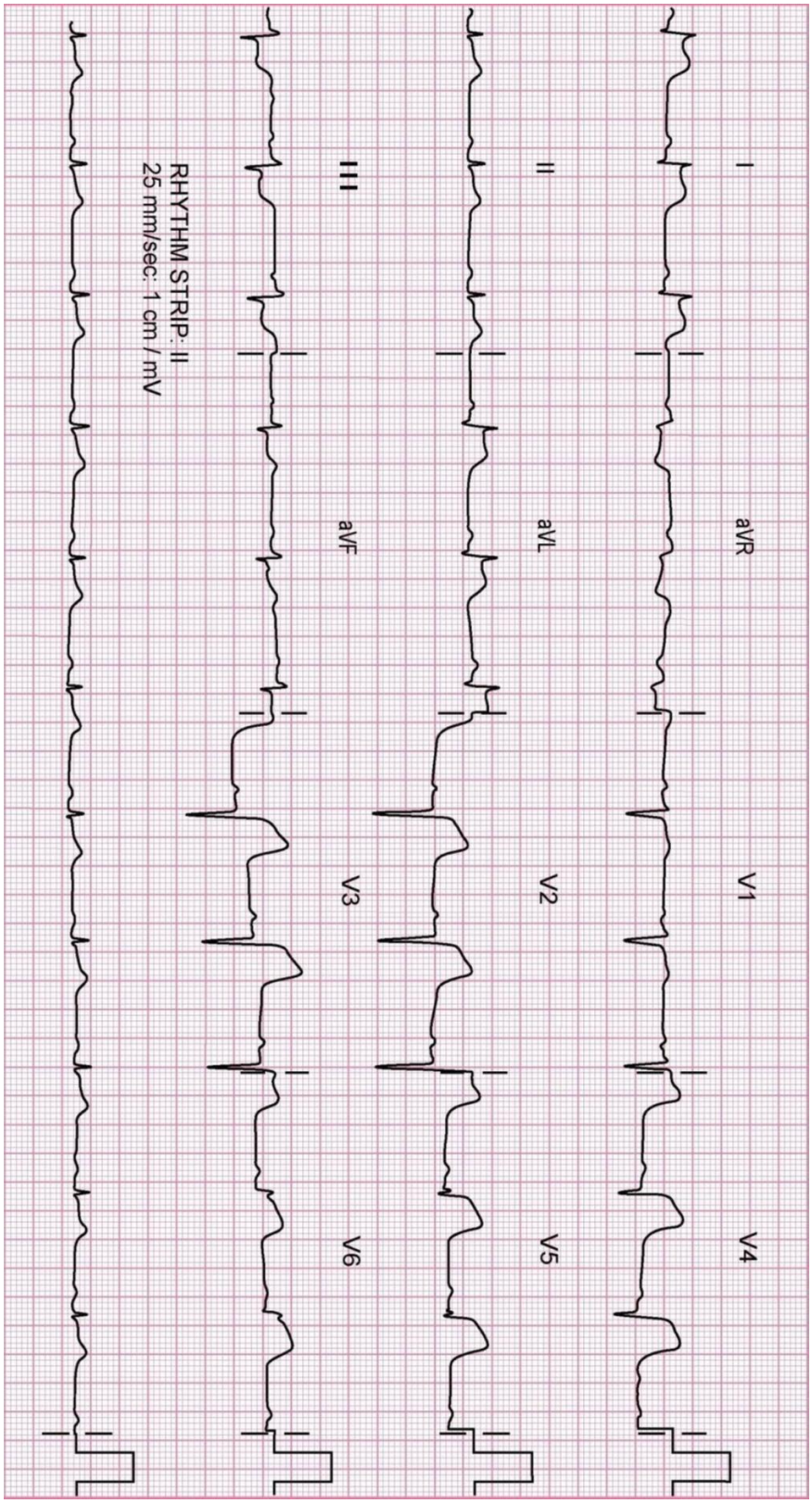
Post-Scenario Discussion

Possible discussion points	• Using a systematic approach (ABCDE assessment) for the assessment of a participant at risk of cardiac arrest • Resuscitation Council (UK) 2015 Resuscitation Guidelines (Resuscitation Council (UK) 2015 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 and 1b



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, O2, 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 and on 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 sitting upright on a chair/ bed
Equipment setup and possible props needed for scenario	**Equipment immediately available** O2, equipment to measure vital signs **Equipment available on request** Resuscitation 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 16 • C: Pale and clammy. HR 112, regular BP 80/52 • 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: O2 therapy – non-rebreathe with 15L/min O2 or similar • C: Raise participant's legs, monitor BP • D: Vital signs - BP, HR, RR, temps, BM • E: Reassure participant • Optimum positioning • Communicate findings to attending colleagues
Clinical course progression	Participant improving; examination findings: • A: Patent • B: RR 14, O2 Sats 98% on room air • C: HR 90, BP 109/70 • D: AVPU - 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 2a: Recognition and Treatment of Syncope with BBB

Case scenario	Recognition and treatment of syncope
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, O2, monitoring equipment, emergency drugs) • Understand the causes of syncope • Recognition of abnormal ECG
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	Gabriel Smith Age 51 years old
Learner information pre-scenario **(**Narrative case description)	**Use only if scenario is announced** Gabriel is attending the CRF for a phase II clinical trial. He is now awaiting a blood test and is anxious. Gabriel will complain to the first responders that he feels dizzy and then collapse in the chair. Past medical history of hypertension and hypercholesterolemia, on medication. 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 scenario is to test response to attending collapsed participant - syncope with BBB. Left sided BBB is more traditionally associated with MI, and therefore it is important to establish whether or not the BBB is old or new. In the acute setting with an unwell patient assume it is new until proven otherwise.

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 setup** Manikin sitting upright on a chair/ bed
Equipment setup and possible props needed for scenario	**Equipment immediately available** O2, equipment to measure vital signs **Equipment available on request** Resuscitation trolley, suction machine
Participant/ manikin preparations for scenario	**Gender** 51 year old male **Participant's position** Sitting upright on a chair/ bed **Appearance** Pale, sweaty and clammy **Concomitant medications** Irbesartan 150 mg OD Simvastatin 20mg OD
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	Participant has collapsed and looks pale, sweaty and clammy. • A: Patent • B: RR 12, Sats 95% on room air • C: Pale and clammy. Pulse 50 BP 78/52 • D: Unconscious • E: Nil • ECG
Initial clinical interventions required in response to the above	• Shout for help, emergency buzzer • Contact study doctor • Assess participant using ABCDE approach • A: Maintain airway • B: O_2 therapy – non-rebreathe mask with 15L/min O2 or similar • C: Vital signs – BP/HR/RR/temp, elevate participant's legs, IV Access and IV fluids, monitor BP, check capillary refill time • D: BM , ECG monitoring, blood tests (not a priority but consider FBC, U&E, CRP, Troponin, , group and cross match) • E: Reassure participant • Optimum positioning • Communicate findings to attending colleagues
Clinical course progression	Participant improving; examination findings: • A: Patent • B: RR 14, Sats 98% on 15l/m O2 • C: HR 52, BP 90/62, clammy, peripherally cold • D: Responding to voice, ECG-abnormal • E: Nil
Further clinical interventions required in response to above progression	• Medical help arrives - hand over to medic • ECG - bundle branch block • Check medical notes for evidence of previous ECG to see if BBB is new or old • Continue monitoring. Reassess: ABCDE • Transfer participant to appropriate unit for further monitoring and investigations • Report as an SAE • Reassess participant and response to interventions
Further clinical course progressions (as required)	Insert / Delete as required
Further clinical interventions (as required)	Insert / Delete as required

Post-emergency care (Time dependent)	• 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) • Cause of syncope - BBB and high risk group involved • Other causes of syncope • Importance of handovers, including the use of specific tool (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 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 ABCDE approach • Staff are able to recognise and initiate treatment of Anaphylaxis • Staff demonstrate that they understand and are able to 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 clear defined roles within the team • Considering 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 • Know how to manage the patient with anaphylaxis • Understand the appropriate treatment of anaphylaxis **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	Mr 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 and he requires a further 7 if there are no problems reported. He has no significant past medical history but has previously been dosed with an investigational product via intravenous infusion for study 5344. He is not taking any regular medications and has no known drug allergies. After 5 minutes he starts to complain of feeling generally unwell; faint, abdominal pain and pins and needles in his 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 a severe anaphylaxis reaction relating to the IMP intravenous infusion. Sam is usually well with no known allergies and has no past medical history. He will continue to worsen up until the point of adrenaline administration. Recognition and treatment should be based on Resuscitation Council (UK) (2015) Emergency Treatment of Anaphylactic Reactions Guidelines: • Staff use ABCDE approach • Discontinues the intravenous infusion • Initiate treatment • Call made to CRF Physician, medical emergency team and request for an Anaesthetist • Consider transfer to ITU • 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 Sam 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** 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** O2, cardio / respiratory monitoring for blood pressure, O2 Sats , pulse, respirations, temperature **Equipment available on request** Resuscitation trolley, defibrillator, anaphylaxis kit containing pre-filled adrenaline syringe, Hydrocortisone, Salbutamol, Chlorphenamine, intravenous fluids and IV administration sets
Participant/ manikin preparations for scenario	**Gender** Male **Participant's position** Sitting up in bed **Appearance** Anxious, pale, clammy, Concomitant medications None
Medical documentation needed for scenario	**Available** Case report form or patient workbook containing relevant medical notes IMP Prescription chart NEWs observation chart **Available on request** Study site file Investigator brochure Study Protocol Study contact detail form Emergency transfer pack

Scenario Clinical Course

Observations on initial assessment	**(If applicable) Verbal handover to first responder as they enter the scenario:** • A: Clear • B: RR 18 min • C: P90 min, BP 110/60 mmHg • 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 light headed.
Clinical progression	• A: Complains of tightness in throat • B: RR 28 min, widespread wheeze • C: P120 min, BP 80/60 mmHg • 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 • Consider the requirements of un-blinding • Contact the Principal Investigator/Sponsor • Consider transfer to ITU • SAE report
Further clinical course progressions (as required)	Anaphylaxis resolves with appropriate treatment
Further clinical interventions (as required)	• Observe for at least 6 hours and up to 24 hours as per Resuscitation Council (UK) Emergency Treatment of Anaphylactic Reactions Guidelines (2008) • Blood samples for Mast cell tryptase (3 samples) as soon as possible after onset but do not delay resuscitation • 1-2 hours after initial reaction • 24 hours or in follow-up allergy clinic • Review by a senior clinician • Consider anti-histamine/ oral steroid therapy for up to 3 days post-incident

Post-emergency care (Time dependent)	Arrange appropriate transfer of participant for further observation – Critical Care/ 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 approach to management: O2, IM adrenaline, antihistamines, steroids, fluids and bronchodilators. • Discuss the merits of intramuscular compared with intravenous adrenaline. Most ALS providers do not use IV adrenaline in their routine practice so should not use it for treatment of an anaphylactic reaction. • What are the dangers of excessive doses of IV adrenaline in the patient with spontaneous circulation? • What airway problems would you anticipate with the patient? • Resuscitation Anaphylaxis Algorithm

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
Intended non-technical learning objectives	• Communication • Leadership • Decision-making • Timing

Participant's name and age/ DOB	Alison Mitchell 25 year old female
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced**
	Alison has agreed to participate in a 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 Alison on a treadmill. They find Alison in a chair and struggling for breath
Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	Alison is suffering an exercise-induced asthma attack She is short of breath, has an audible wheeze and is unable to speak in full sentences Her asthma is usually well controlled Her 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** Alison, sitting in a chair
Equipment setup and possible props needed for scenario	**Equipment immediately available** O2, stethoscope, spirometer, Salbutamol inhaler,monitoring equipment **Equipment available on request** Nebuliser equipment, respiratory drugs, resuscitation trolley
Participant/ manikin preparations for scenario	**Gender** Female, 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

Scenario Clinical Course

Observations on initial assessment	**(If applicable) Verbal handover to first responder as they enter scenario:** • A: Patent • B: RR 40, reduced bilateral air entry, expiratory wheeze, using accessory muscles, O2 Sats 91% on room air (if requested) • C: HR 115 regular, BP 120/72 mmHg, clammy. • D: Alert, anxious • E: Nil
Initial clinical interventions required in response to the above	• Call for appropriate medical help • Immediate ABCDE assessment • O2 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
Clinical course progression	Alison deteriorates further: • A: Patent • B: Air entry further reduced, RR 40, O2 Sats 89% on 15L/min O2, unable to speak, unable to obtain peak flow • C: HR 140 regular, BP 90/52, 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 resuscitation trolley (if not already requested) • Further nebulised Salbutamol • Reassess: ABCDE throughout
Further clinical course progressions (as required)	Participant improving: • A: Patent • B: RR 25, improved bilateral air entry, wheeze improved, O_2 Sats 98% on 15L/min O_2, able to speak in sentences, reduced use of accessory muscles • C: HR 115, BP120/78, 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) • Reason, Story, Vitals, Plan (RSVP) • 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 process of arranging a transfer to the High Dependency Unit or equivalent? • What equipment is required for 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.

Core Adult Scenario 5: Recognition and Treatment of Adult Sepsis

Case scenario	70 year old male with community acquired pneumonia leading to sepsis
Intended clinical (technical) learning objectives	• ABCDE approach to assessment • 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	Jeff Harper 70 years old
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced** Jeff has been on a trial of a new oral medication for type 2 diabetes. He has been taking this new medicine for the last 4 months, and today has come for a follow up clinic visit. He has reported feeling unwell for the last two days. Jeff has been let into the clinic room by a new clinical trials assistant who has called you as a study team member as Jeff says he has not been feeling well with a bad cough for the last two days. As you enter you notice that Jeff is breathing fast.
Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	Situation: Jeff has sepsis, from a respiratory tract infection Background: Jeff 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. He will continue to deteriorate unless his sepsis is recognised and treated. Recommendations: Prompt treatment required with IV fluid and antibiotics (the NICE guidelines are useful here)

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** Jeff (role player or manikin) sitting on chair in the clinic room
Equipment setup and possible props needed for scenario	**Equipment immediately available** Wall O2 and adult O2 face mask **Equipment available on request** Monitoring, Resus trolley and contents
Participant/ manikin preparations for scenario	**Gender** Male **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** Medical notes.

Scenario Clinical Course

Observations on initial assessment	**(If applicable) Verbal handover to first responder as they enter scenario:** • A: Clear • B: RR 30, O2 Sats 90% on air, using accessory muscles, productive cough • C: HR 130, BP 85/45, 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 • Administer O2 • Call for resus trolley and monitoring • Move patient to bed • Explain to patient what's happening • Early IV access for blood tests, blood cultures, blood gas and IV fluids and antibiotics
Clinical course progression	• A: Clear • B: O2 Sats 98% in 15L/min O2, RR 36, crackles left lower zone on auscultation, no wheeze • C: HR 140, BP 80/40, 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 • Administer IV antibiotics according to local guidelines • Reassess: ABCDE • Reassure patient

Further clinical course progressions (as required)	Blood gas results (venous or arterial) Lactate 3.5 Glucose 6.0 (can be via fingerprick glucose too) If fail to administer IV fluids and antibiotics: • A: Clear • B: RR40, O2 Sats 95% on 15L/min O2, persistent crackles left lower zone on auscultation • C: HR 150, BP 70/35 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 facilitators wish. If do administer IV fluids and antibiotics then: • A: Clear • B: RR 30, O2 Sats 90% on air or 99% on 15L/min O2, persistent crackles left lower zone on auscultation • C: HR 100, BP 110/65, capillary refill centrally 3 seconds • D: Alert • E: Temp 38.5°C, no rash
Further clinical interventions (as required)	• Handover to resus team as they arrive • 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) • Importance of fluids and antibiotics • NICE guidelines in sepsis • Importance of ABCDE (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 are able to assess patient using ABCDE approach • Patients are able to recognise signs of hypoglycaemia in a confused patient • Staff are able to 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) **Use SBAR** (Situation, background, assessment, recommendations)	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. 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, O2 (if required), IV access **Equipment available on request** Hypo-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
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 – In tact • B – RR 12, O2 Sats 98% on air • C- HR 84 BP 105/58 • D - Alert but confused, BM 2.1 • E – Pale and sweaty
Initial clinical interventions required in response to the above	Check blood sugar, initiate treatment for hypoglycaemia
Clinical course progression	If appropriate treatment given: • A – In tact • B – RR 14, O2 Sats 98% on air • C- HR 82 BP 106/61 • D – Alert, appears less confused. BM 3.9 • E – Nil of note
Further clinical interventions required in response to above progression	• Consider IV glucose • Close monitoring • Consider referral for review by diabetes specialist team
Further clinical course progressions (as required)	
Further clinical interventions (as required)	
Post-emergency care (Time dependent)	

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 a Cytokine Release Syndrome (CRS) with ITU Transfer

Case scenario	Recognition and initial treatment of an adult experiencing a cytokine release syndrome (CRS) with ITU transfer
Intended clinical (technical) learning objectives	• ABCDE approach to assessing the patient • Recognition of signs and symptoms and risk factors of cytokine release syndrome • Prompt initiation of appropriate treatment • Call for help immediately • Appropriate use of interventions/ emergency equipment including crash 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 ITU

Participant's name and age/ DOB	Susan Roberts Age 45 years old
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced** Susan is attending the CRF for a dosing visit for a Phase I, First In Human oncology clinical trial called Tcells 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 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. **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: O2 Sats 93%, normal chest movement, normal air entry. Respiration (RR) 28/minute • C: HR 120. BP 90/58 mmHg. Pale. Capillary refill 5 seconds. Sweaty. No chest pain. • D: Alert but clearly distressed. Glucose: 6.0 mmol/L • E: Temp 38.8^{o}C. Widespread skin rash. Rigours **R**ecommendations - learner expected to: • ABCDE Approach. • Call for help immediately • Commence O2 therapy immediately • Instigate IV fluids (if prescribed) • Consider Sepsis v 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 ITU

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** O2, equipment to measure vital signs **Equipment available on request** Resuscitation 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: O2 sat 93%, normal chest movement, normal air entry. Respiration (RR) 28/minute • C: HR 120/min. BP 90/58 mmHg. Pale. Capillary refill 5 seconds. Sweaty. No chest pain. • D: Alert but clearly distressed. Glucose: 6.0 mmol/L • E: Temp 38.8^{o}C. Widespread skin rash. Rigours
Initial clinical interventions required in response to the above	• Shout for help, emergency buzzer • Assess participant using ABCDE approach • A: Maintain airway • B: O2 therapy – non-rebreathe with 15L/min O2 or similar • C: Monitor BP • D: Vital signs - BP, PR, RR, temps, Blood Glucose • E: Reassure participant • Request relevant blood tests • Communicate findings to attending colleagues • Escalate to emergency medical response team- 2222 call needed to be placed.
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 78/49, HR 130, temp 40^{0}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 ITU.
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, corticosteroids for targeted management) • Early referral and escalation in all cases of suspected cytokine release syndrome • Process/pathway for emergency transfer to ITU • 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

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, 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 a 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. Eliminating dark tarry offensive smelling stools past 3 days (melaena) **A**ssessment: He has become drowsy (13/15 GCS or V on AVPU) and dropped his BP (from 145/65 to 121/60 BP compensating), has become tachycardic (HR 105). **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** Resuscitation 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: 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 finding it hard to complete sentences in one breath • B: SOB, Resp rate 24, O_2 Sats 91% on air, symmetrical chest movement, normal breath sounds (bi lateral air entry), trachea central, no accessory muscle use, normal resonance on percussion. • C: Capillary refill 2 seconds, HR 105 min, BP 121/60 mmHg, 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	• Shout for help (staff in Reception; emergency buzzer) • Immediate ABCDE assessment • Ask for O2 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) • Starts fluid, at least 500ml of saline over 15 minutes. • 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 cardiac arrest team if subject becomes peri- arrest Initial treatment: • O2 due to low O2 Sats (target 95-98%) • After fluid give O neg 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, Resp 25, O_2 Sats 95% (if on O_2), symmetrical chest movement, and normal breath sounds • C: HR 100 min, Regular (if fluid or blood given) ECG: shows sinus tachycardia, BP 130/85 mmHg, temp 36^{o}C, capillary refill time (peripheral) 2 secs • Request 12 lead ECG (in pt's notes if requested) • D: Verbal response, BM (if asked) 6.3 mmol/L • E: Persistent epi gastric 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 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 • Utilize/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 boy
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 III trial. He has attended the CRF with his dad for a 2nd dose visit of an IV infusion. 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 O2 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, O2 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** O2, suction, cardio/ respiratory monitoring for BP, O2 Sats (SpO2%), 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 began 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, O2 Sats 87% on room air (if requested) • C: HR 125, BP 80/55 mmHg, clammy • D: Alert, distressed • E: Urticarial rash.
Initial clinical interventions required in response to the above	• Stop the infusion • O2 therapy (15 litres 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) every 5 minutes until clinical improvement • 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 28 per minute, note how he is breathing – rate and rhythm, O2 Sats 100% with O2 therapy (discuss reducing O2 therapy to maintain normal saturations) • C: HR 130, BP 105/70 • 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 6 hours and up to 24 hours as per Resuscitation Council (UK) Guidelines 2008
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 Handover of participant to an appropriate area using Situation Background Assessment Recommendation (SBAR) Transfer of minimum documentation required to accompany participant to ICU or other department as defined in local policies. Potential un-blinding and contact PI

Post-Scenario Discussion

Possible discussion points	
	• This was a severe reaction to the study drug but in milder allergic reactions, what other medications could be considered before giving adrenaline? (Hydrocortisone 100mg IV, Chlorphenamine 5mg IV, Salbutamol for wheeze as per Resuscitation Council (UK) Guidelines 2008.) • General management of anaphylaxis using Resuscitation Council (UK) Guidelines? • What are the first signs and symptoms of anaphylaxis – did you recognise them? • 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 • To identify the need for IV access
Intended non-technical learning objectives	**Communication** • Structured and effective team communication. • Effective communication with child's parent. • Utilize/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 1 year old infant

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 baby manikin
Learner (Options according to availability)	• Clinical roles (maximum of 7) • Lead learner to identify themselves • Learners should assume their own clinical role • Learner able to obtain IV access on a child (if possible) • 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 infant manikin who is seizing
Equipment setup and possible props needed for scenario	**Equipment immediately available** Bed, O2 and suction **Equipment available on request** Stethoscope, monitoring equipment, glucometer and paediatric resuscitation trolley
Participant/ manikin preparations for scenario	**Gender** Male baby **Participant's position** In Mum's arms **Appearance** Right arm and leg are twitching (if asked by the learner – the baby 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 notes **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 1 year old baby who started twitching in his Mum's arms and is producing gurgling sounds. Mum states that the whole family have had a cold but Archie has been well.- Archie is in the CRF for a 1 year follow up as he is participating as a control for a study looking a baby's growth and nutrition. He is normally fit and well. **Learner expected to obtain following using ABCDE technique:** • A: Gurgling • B: RR 50, O2 Sats 88% in air • C: HR 170 regular, BP – unobtainable, mottled and clammy, capillary refill 3 seconds • D: Unresponsive (AVPU), seizing, glucose 5.1mmol • E: Temp 37.6° C
Initial clinical interventions required in response to the above	Call for appropriate nursing/medical help • Airway repositioned - neutral position • Clear airway with suctioning • O_2 therapy (15 litres via a high concentration paediatric non-rebreathe O2 mask) • Request paediatric resuscitation trolley + 2222 call. • ABCDE assessment continued. • Locate antiepileptic drugs
Clinical course progression	Reassess: • A: Patent following airway manoeuvres • B: RR 40, SpO2 94% on 15l O2 • C: HR 170, clammy, peripherally cool, capillary refill 3 seconds, consider IV access (if learner able) • D: Unresponsive (AVPU), seizing, PEARL size 3 • E: Remove clothing – no rash or marks to skin

Further clinical course progressions (as required)	(Insert / Delete as required) If IV access attempted and antiepileptic drugs located: • A: Patent • B: RR 35, SpO_2 96% on 15 litres O_2 • C: HR 164, BP 90/55, capillary refill 2-3 seconds • D: Seizure has self-resolved, responding to parent's voice • E: Obtain past medical history from mum If learners fail to consider IV access and/or location of antiepileptic drugs: • A: Gurgling returns • B: Erratic shallow breathing pattern, SpO_2 92% on 15 litres O2 • C: HR 180 regular, BP – unobtainable, mottled and clammy, capillary refill 4 seconds • D: Unresponsive, convulsing continues for > 5 minutes • E: Clothing removed
Further clinical interventions (as required)	(Insert / Delete as required) • Reposition and suction airway, supporting with neck roll as appropriate • Administer 1st line antiepileptic drug (IV Lorazepam/ buccal Midazolam) if seizure lasts > 5 minutes • Administer IV bolus if tachycardia and delayed capillary refill continues
Further clinical interventions required in response to above progression	• Confirm the resuscitation team are on route. • Reassess ABCDE throughout • 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 member using SBAR • Contact relevant senior staff to discuss transfer • Complete appropriate documentation (local policy)

Post-Scenario Discussion

Possible discussion points	• What is the local policy for managing and treating a seizure in a child? • Where is your local policy located? • Do you know where to find resuscitation algorithms? • What is the local process of arranging a transfer to Emergency Department/inpatient ward? • What other areas could a child be transferred to locally? • What equipment is required for transfer? • Consider and discuss PEWS • 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?

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 an Infant 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 leadership and communication within and between the CRF and Resus teams • 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 **MHRA Phase I Accreditation Requirements** • Timing from leaving the CRF to arrival at PICU • Ensuring the procedure outlined in and local SOP (Example: SCBR/Child/V1/072 “Transporting Deteriorating or Unwell Paediatric Research Participants to the ED, PICU or other appropriate clinical environment”) is followed

Participant's name and age/ DOB	Archie Langley DOB: 18.01.2013 2.5 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 some questionnaires, Archie is getting noticeably irritable. When they turn to him they see he is rigid with noticeable twitching localised to his left side. They have lifted him off the floor onto the bed. **B**ackground –He is a known epileptic, and is well controlled with BD Sodium Valporate. **A**ssessment - Study nurse can see left sided twitching and whole body rigidity. **R**ecommendations – learner(s) are expected to: • Call for appropriate help • Assess Archie using the ABCDE approach • Start BLS • 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 infant 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 dad/mum
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** • Tabards for sim faculty • Pushchair or wheelchair with toys, coats, nappy bag • CRF patient notes • O2 with paediatric face-mask, suction **Equipment available on request** • Simulation drug pack (see attached) • Paediatric Resuscitation trolley, airway adjuncts, defibrillator • Archie's seizure treatment plan / drugs from Mum • Transfer bag

Participant/ manikin preparations for scenario	**Manikin** Ideally, if available use a simulator Nursing baby or similar on transfer bed ready to move to PICU (intubated and on transport monitoring) **Participant's position** On bed **Appearance** Rigid, visible seizure activity with left-sided limb jerking **Concomitant medications** Sodium valproate
Medical/ documentation needed for scenario	**What is available:** • Medical health records • Clerking from the current visit including observations, height and weight • Initial gas **What is available on request:** • Study site file and folder • Investigator brochure • Transfer SOP and documentation

Scenario Clinical Course

Observations on initial assessment	The study nurse will give a handover to the first responders and show them the patient notes. He / She could initiate discussion with mum re what she normally does when Archie fits if no-one else does. This will prompt Mum to talk about his emergency plan and to get his buccal midazolam out. Once the scenario has commenced, she should make her excuses and join the faculty to observe.
Initial clinical interventions required in response to the above	ABCD assessment Suction if needed Hi flow O2 applied Crash call Get paediatric resus trolley Prepare to establish IVI access Check BM If IVI established take bloods and gas

Clinical course progression	Crash team arrive Role allocation Establish need for 2nd dose of Benzodiazepine CRF staff to locate Midazolam and other drugs required by crash team Archie continues to fit after 2nd dose of Benzodiazepine and remains tachycardic and desaturated
Further clinical interventions required in response to above progression	Crash team to decide either to continue seizure management in CRF or to get PICU to prepare drugs and to transfer patient (still fitting) to PICU CRF staff to initiate transfer pathway and complete relevant documentation
Clinical course progression	Assist crash team to further manage seizures including intubation or establish a plan to stabilise and move to PICU Do not leave department until clear plan made and checklist completed
Further clinical interventions (as required)	• Get transfer documents (transfer checklist, handover sheet, obs chart, medical history sheet, prescription chart, ID band, study information) • Collect equipment required for transfer • Ensure someone available to time the transfer (from time leaving the CRF to time of arrival at PICU entrance) • Consider use of the PEWS chart • Liaise with PICU re: estimated time to transfer/arrival and give brief handover • Ensure mum/dad informed of transfer
Post-emergency care (Time dependent)	• Ensure all equipment, including CRF bed is returned to the CRF and cleaned • 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
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	**Include technical and non-technical points:** • Assessment of the critically ill participant using ABCDE approach • Recognition and treatment of status epilepticus • Team working – roles planned in advance; identification of team leader; task management; situational awareness; decision making; structured communication • Points specific to the scenario topic – include timings • Any issues with equipment? • Any problems with PICU team? – location, equipment requirements • 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. The list provided below is an example:

Drug box

Paediatric resus trolley:

- Adrenaline 1:10,000 in 10 ml
- Adrenaline 1:1000 in 1 ml
- Amioderone 300mg in 10 ml
- Atropine 600mcg in 1 ml
- Fluids: 0.9% saline and 10% dextrose

Additional drugs on the Adult resus trolley:

- Sodium bicarbonate 8.4%
- Calcium chloride 1000 in 10ml
- Fluids: Hartmans solution

Other IV medications of interest (I haven't listed them all) in the adult treatment room:

- Adrenaline 1:1000 in 10 ml
- Chlophenamine 10mg/ml
- Dexamethasone 4mg/ml
- Furosemide 20mg/2ml
- Glucose 50%
- Hydrocortisone 100mg
- Lidocaine 1% and 2%
- Magnesium sulphate 1g/2ml
- Naloxone 400mcg/ml
- Diazepam 10mg/2ml

In the bronch suite (again, I haven't listed them all):

- IV midazolam
- IV Alfentanil

Initial blood gas
CRF Transfer pack
CRF Transfer out SOP

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 O2 and drug therapies • Awareness and identification of potential for child with respiratory compromise to quickly de-compensate.
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 • Utilise support learner to 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 Lewis 8 year old boy
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 Beclometasone, Dipropionate and Salbutamol inhalers. He has never attended hospital with an exacerbation and is normally well managed. During the visit he will undergo a number of 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 Beclometasone Dipropionate 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, speaking in short sentences, anxious and pale **R**ecommendations - learner expected to: • Observe breathing and identify exacerbation of asthma • Recognise the needs of mum • Recognise the psychological support for Thomas • Call for appropriate help in timely manner.

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** O2, stethoscope. **Equipment available on request** Equipment to measure vital signs, resuscitation 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** Beclometasone Diproprionate 50, 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: Able to speak in short sentences • B: RR 37 per minute, O2 Sats 90% on room air, wheeze audible with stethoscope, slightly reduced air entry • C: Pulse 114,central capillary refill (if requested) 2 seconds • D: Looks scared • E: Temp 37.4 axilla.

Initial clinical interventions required in response to the above	• Ask for appropriate medical assistance
	• Request urgent medical review – using local policy.
	• Contact study doctor
	• Enable the child to maintain a 'comfortable' position i.e. sat propped up
	• Assess participant using ABCDE approach
	• Determine if Thomas or mum have Salbutamol inhaler with them
	• Reassure Thomas and mum constantly.
	• O2 therapy 15 litres via face mask
	  ○ Requires medical assessment and urgent prescription of nebulised Salbutamol or other meds (ie Ipratropium)
	  ○ Ongoing O2 Sats monitoring
	  ○ Assess work of breathing (additional respiratory noises, neck muscle use, inter and sub-costal muscle use)
	  ○ Use of observation charts (as per local policy) and appropriate escalation re SBAR.

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 33 per minute, O2 Sats 92% on 6 litres of O2 (driving nebuliser), wheeze audible with stethoscope • C: Pulse 120 • D: Anxious • E: Nil

Further clinical interventions required in response to above progression	• Ongoing ABCDE assessment. • Repeated nebulisers as prescribed and required • Document observations on observation chart. • Liaise with bed manager to arrange transfer to an in- patient bed • Prescription and administration of oral Prednisolone • Provide mum with support and information • Keep Thomas informed of actions providing constant reassurance. • A: Patent • B: Minimal wheeze audible with stethoscope 20 minutes post nebuliser, increased air entry, O2 Sats 96% on 2 litres O2 via face mask, reduced work of breathing, slightly reduced air entry • C: Pulse 125 • D: Less anxious and brighter in self • E: Nil
Post-emergency care (Time dependent)	• Where should the participant go and what should be done first? • Medic may refer for chest X-ray • Arrange transfer to acute clinical area including transport monitoring and portable O2 • 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.
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	**Include technical and non-technical points:** • What are the signs of deterioration in a child? • Assessment of the critically ill child using ABCDE approach? • Administration of Salbutamol prior to medical review e.g. ask mum to give own inhaler via spacer device? • 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 • What % O2 therapy should be used and why? • 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	• ABCDE approach to assessment • Call for help at appropriate time • Appropriate use of interventions/emergency equipment
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 Watts 10 months old
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced** Millie has been brought to the baby hip clinic in the CRF this morning by her Dad Steve, as she is a potential study participant.
Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	Millie has just been called into the clinic room by the nurse, where her Dad undresses her 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** Baby 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 O2 and appropriate sized O2 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:** • A: Visible chest rise and fall, and a weak cry • B: RR is 74 with obvious use of accessory muscles marked intercostal recession and grunting • C: Pale and mottled • D: Lethargic • E: Mottled
Initial clinical interventions required in response to the above	• Call for appropriate medical help • Immediate ABCDE assessment • Administer O2 • Call for resus trolley and monitoring • Explain to Millie's Dad where possible and obtain some verbal history of current illness
Clinical course progression	• A: Still patent, with weak cry, does not fight O2 mask • B: O2 Sats 98% in 15L/min O2, RR 68, wheeze on auscultation • C: HR 196, BP 78/40, CRT is 4s centrally • D: Remains lethargic • E: No rash, temp is 39.7^{o}C
Further clinical interventions required in response to above progression	• Switch to paediatric non-rebreathe face mask in appropriate size • Establish IV access via IV/IO routes (send bloods and cultures, measure Blood Sugar Level (BSL) and obtain a blood gas • Administer IV fluid bolus • Administer IV antibiotics according to local guidelines • Reassess: ABCDE • Reassure Dad, updating him on interventions
Further clinical course progressions (as required)	• A: Cry is stronger, still maintaining airway • B: RR still 60 with recessions, O2 Sats now 100% in 15L/min • C: CRT now 3 seconds centrally, BP is 88/42, HR 160 • D: BSL is 3.5mmol • E: Temp remains high
Further clinical interventions (as required)	• Handover to resus team as they arrive • Consider reducing O2 L/min and observe O2 Sats • Consider repeat IV bolus and antipyretics • Request admission to paediatric ward for initiation of Optiflow/Airvo/NIV, IV fluids and IVABs • Explain and reassure father, explaining what has happened and the plan
Post-emergency care (Time dependent)	• Prepare for transfer to ward – commence documentation • 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 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 • Discuss coordinator/leader role • Discuss anything else specific to scenario

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	Recognising and treatment of 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 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 Jones 4 years
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced** Sarah has long term metabolic disorder (glycogen storage disease). Blood sugar well managed at home. Gastrostomy feeds overnight. Admitted for dietary supplement trial comparing current starch treatment with new starch supplement. Commenced fasting at 0700. Study visit requires fasting to continue for 12 hours or until blood sugar falls below 3.6. Blood sugars to be checked on the hour. Blood sugar checked at 1100 and is 4.5. At 1130 Sarah complains of tiredness whilst playing on bed. Nurse notices Sarah is clammy.

Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	**S**ituation: Sarah is attending for first study visit. Administered unknown starch/standard treatment starch at 0700, Fast commenced and plan to monitor blood sugars for 12 hours. Cannula in situ for blood draws. Dad in attendance as mum at home with new baby. **B**ackground: Glycogen storage disease diagnosed at 1 month. Managed with overnight gastrostomy feed and 2x daily boluses. **M**edication: starch supplement once a day. Well managed at home, normally only drops blood sugar if acutely unwell. **A**ssessment: Tired, Clammy, unsettled. Father unsure of symptoms Recommendations: • Learner uses ABCDE approach • Instigates treatment • Escalates appropriately • Supports and communicates with Sarah and father

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	To run the scenario To role play dad Technician to provide observations on Sarah's condition Vital signs/blood sugar
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
Equipment setup and possible props needed for scenario	**Equipment immediately available** Wall O2 and paediatric O2 face mask. Gastrostomy connection. Glucometer **Equipment available on request** Monitoring, Resus 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: 20 • C: Pulse 100; CRT less than 2 • D: tired unsettled • E: Temp 37°C. Looks flushed
Initial clinical interventions required in response to the above	• Immediate ABCDE assessment • Administer O2 • Call for monitoring/glucometer • Ask for medical review • Explain to Millie's Dad where possible and obtain some verbal information about condition
Clinical course progression	• A: Still patent • B: O2 Sats 98% in O2 • C: Pulse 120 • D: Remains tired. Peripheral blood sugar check 3.5 • E: Temp 37
Further clinical interventions required in response to above progression	• Administer glucose as per rescue plan, via gastrostomy • Prepare IV glucose bolus in case oral rescue solution not tolerated via gastrostomy. Ensure patency of cannula. • Reassess ABCDE • Repeat blood glucose level • Reassure Dad, updating him on interventions
Further clinical course progressions (as required)	• A: Patent • B: RR 25 • C: 120bpm • D: Blood Glucose 4.0 • E: Sarah more alert and settled
Further clinical interventions (as required)	• Handover to medic using SBAR • Discontinue fast • Repeat Blood glucose level at 30 minutes, 1 hour. • Consider bolus feed • 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 Hypoglycaemia in a known Diabetic

Case scenario	Recognising and treatment of a teenager with hypoglycaemia
Intended clinical (technical) learning objectives	• To utilise the ABCDE approach to assess teenager • 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 • 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	Harry Jones 13 years
Learner information pre-scenario (Narrative case description)	**Use only if scenario is announced** Harry is a 13 year old boy taking part in a research study. He is a known diabetic and has been admitted for a "mixed meal tolerance test" as part of a research study. Soon after arrival Harry complains of tiredness and the nurse notices Harry is clammy.
Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	**S**ituation: Harry is attending for his final study visit. Mum in attendance. **B**ackground: Known Type 1 Insulin Dependent Diabetic **A**ssessment: Tired, Clammy, unsettled. Mother unsure of symptoms **R**ecommendations: Learner uses ABCDE approach Instigates treatment Escalates appropriately Supports and communicates with Harry and mother.

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	To run the scenario To role play mum Technician to provide observations on Harry's condition Vital signs/blood sugar
Learner (Options according to availability)	Clinical roles (maximum 6 learners) 2 Nurses: Study nurse and back up.
Area setup for scenario	**Environment :** Temperature & Humidity Room **Specific setup** Child manikin sitting upright in chair
Equipment setup and possible props needed for scenario	**Equipment immediately available** Wall O2 and paediatric O2 face mask. Glucometer **Equipment available on request** Monitoring, Resus trolley, Rescue medication
Participant/ manikin preparations for scenario	**Gender** Male teenager **Participant's position** Sat on chair. **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 20 • C: Pulse 100; CRT less than 2 • D: tired unsettled • E: Temp 37. Looks flushed
Initial clinical interventions required in response to the above	• Immediate ABCDE assessment • Administer O_2 • Call for monitoring/glucometer • Ask for medical review • Explain to Harry's mum where possible and obtain some verbal information about condition
Clinical course progression	• A: Still patent • B: O2 Sats 98% in O2 • C: Pulse 100 • D: Remains tired. Peripheral blood sugar check 3.5 • E: Temp 37
Further clinical interventions required in response to above progression	• Reassess ABCDE • Repeat BM • Reassure mum, updating him on interventions
Further clinical course progressions (as required)	• A: Patent • B: RR 25 • C: 100bpm • D: BM 4.0 • E: Harry more alert and settled
Further clinical interventions (as required)	• Handover to medic using SBAR • Discontinue fast • Repeat Blood glucose level at 30 minutes, 1 hour. • Consider bolus feed • Harry to be observed for two hours post fast on ward prior to discharge. Further review by medic prior to discharge • Explain and reassure mum, 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/teenager • Discuss preparation of space for caring for fasting child/teenager, 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.

Debriefing Delivery Tool

Debriefing is a critical aspect of simulation. Debriefing is described as "…the process whereby the healthcare team can re-examine the clinical encounter to foster the development of clinical reasoning, critical thinking, judgment skills and communication through reflective learning processes" (Arafeh et al 2010). Debriefing is an important process designed to synergise, strengthen, and transfer learning from the experiential exercise (Warrick et al 1979).

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 manor by debriefing immediately after the scenario.

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) 2015 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, to ensure vital reflection.

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 different 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

Ask open ended questions – for example:

a. How well did you feel the team performed?

b. What caused you frustration or discomfort?

c. What surprised you about how you operated?

d. Why did you feel that affected your ability to make decisions?

e. How did you feel when that happened?

f. What did you understand of that instruction?

g. What was happening at the time?

h. What did you learn?

i. How will you do it differently next time?

j. Why did you say or do that?

k. What do you think can be improved?

Probing questions:

l. What would have made you more comfortable?

m. What would you have preferred to have happened?

n. Tell me more about how you felt when that was said?

o. Explain your thoughts at the time…

p. How could that be improved?

q. What were you doing when this occurred?

r. Why do you think they did that?

Closed questions:

s. Is that what you meant when you said that you wanted …. to do that?

t. Did anyone notice what he said to the surgeon?

u. Did you understand the instruction/ was the instruction clear?

v. Had you identified the cause of the tachycardia at this stage?

w. Was that a reasonable request?

x. Was that action expected?

y. Did you not like that?

z. Was that a good decision at that point?

aa. Does anyone have anything further to add?

Reflection and summarizing – for example:

bb. So you have said that we should do this/ that in the future…

cc. What you have agreed is that this is what happened…

dd. Is what you are saying…?

ee. You have agreed that you will…

ff. So, is that a fair summary of how you handled that problem?

gg. And you are willing to use the learning…

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 particular 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 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.

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Appendices

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.

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

Title of scenario	
Date of scenario	
Type of scenario	
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. O2, 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: • E:
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	Participant improving; examination findings: • A: Patent • B: RR 14, Sats 98% on 15l/m O2 • C: HR 52, BP 90/62, clammy, peripherally cold • D: Responding to voice, ECG-abnormal • E: Nil
Further clinical course progressions (as required)	Anaphylaxis resolves with appropriate treatment
Further clinical interventions (as required)	• Observe for at least 6 hours and up to 24 hours as per Resuscitation Council (UK) Emergency Treatment of Anaphylactic Reactions Guidelines (2008) • Blood samples for Mast cell tryptase (3 samples) as soon as possible after onset but do not delay resuscitation • 1-2 hours after initial reaction • 24 hours or in follow-up allergy clinic • Review by a senior clinician Consider anti-histamine/ oral steroid therapy for up to 3 days post-incident
Post-emergency care (Time dependent)	**Where should the participant go and what should be done first?** • Reassess using ABCDE • Request ECG, Bloods, Chest X-ray • Handover of participant - Situation Background Assessment Recommendation (SBAR) • Arrange transfer to appropriate clinical area • Complete local paperwork

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**
Time of Incident		
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				

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

Title of scenario	Recognition and treatment of anaphylaxis
Date of scenario	9th December 2011
Type of scenario (Announced or unannounced)	Unannounced
Was scenario training video recorded and if so, where is this stored?	No
Intended clinical (technical) learning objectives	*This can be copied and pasted from relevant scenario outline*
Intended non-technical learning objectives	*This can be copied and pasted from relevant scenario outline*

Participant's name and age/ DOB	Mr 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 – he claims he has no known allergies and has been dosed with investigational product via intravenous infusion for study 5344. This is Sam's first infusion and requires a further 7 is there are no problems reported. After 5 minutes he starts to complain of general "un-wellness" – abdominal pain and pins and needles in his fingers – on initial assessment there is nothing to note other than a slightly increased RR.
Facilitator information pre-scenario (Narrative case description) **Use SBAR** (Situation, background, assessment, recommendations)	*This can be copied and pasted from relevant scenario outline*

Scenario Preparation

Facilitators - at least 2 (You can use additional facilitators as role players)	AM -To run the scenario PD- To role play as Sam PC To observe and document scenario events
Learner (Options according to availability)	TK –first responder JS – team member JD- team member KC- team member
Area setup for scenario	The CRF ward area
Equipment setup and possible props needed for scenario	Manikin sitting upright on a chair/ bed
Participant/ manikin preparations for scenario	Male Sitting up in bed Anxious, pale, clammy, Concomitant medications none
Medical documentation needed for scenario	N/A

Scenario Clinical Course

Observations on initial assessment	• A: Clear • B: RR 18 min • C: P90 min, BP 110/60 mmHg • D: Alert, anxious • E: Normal
Initial clinical interventions required in response to the above	Over the next 10 minutes, Sam becomes very short of breath, has a widespread wheeze, develops an urticarial rash, and feels light headed.
Clinical course progression	• A: Complains of tightness in throat • B: RR 28 min, widespread wheeze • C: P120 min, BP 80/60 mmHg • 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 • Consider the requirements of un-blinding • Contact the Principal Investigator/Sponsor • Consider transfer to ITU • SAE report
Further clinical course progressions (as required)	Anaphylaxis resolves with appropriate treatment
Further clinical interventions (as required)	• Observe for at least 6 hours and up to 24 hours as per Resuscitation Council (UK) Emergency Treatment of Anaphylactic Reactions Guidelines (2008) • Blood samples for Mast Cell Tryptase (3 samples) as soon as possible after onset but do not delay resuscitation • 24 hours or arrange appointment in allergy clinic • Review by a senior clinician • Consider anti-histamine/ oral steroid therapy for up to 3 days post-incident

Post-emergency care (Time dependent)	Arrange appropriate transfer of participant for further observation (Critical Care/ HDU) Handover of participant to an appropriate area using Situation Background Assessment Recommendation (SBAR) Transfer of minimum records required to accompanyparticipant 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 approach to management: O2, IM adrenaline, antihistamines, steroids, fluids and bronchodilators. • Discuss the merits of intramuscular compared with intravenous adrenaline. Most ALS providers do not use IV adrenaline in their routine practice so should not use it for treatment of an anaphylactic reaction. • What are the dangers of excessive doses of IV adrenaline in the patient with spontaneous circulation? • What airway problems would you anticipate with the patient? • Resuscitation Anaphylaxis Algorithm

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	Pt collapsed in ward 1 toilet.
Summon help (Shout or use phone to get help)	09:48:42	Called for study doctor
Pull/ push emergency alarm button	09:46:45	Relative pressed call bell
Response time from awareness of emergency to initial call for help	10 Seconds	Good response to call bell
ABCDE assessment	1 minute	A and B, no CDE assessment, monitoring
Call for resuscitation team		Emergency Team not called; team decision to call study doctor
Appropriate equipment arrives	1 minute	O2 cylinder
Appropriate interventions such as O2 therapy	1 minute	O2 therapy
Appropriate monitoring attached		No monitoring
Cardiac rhythm recognition		No monitoring
Airway management		Good airway management displayed. Use of bag valve mask using 2 members of staff
Quality of chest compressions		N/A
Drug administration	09:52	Second doses of Hydrocortisone administered (not prescribed?)
Transfer to hospital/ critical care		N/A
Unblinding procedure		Procedure followed as per protocol instructions

Observed learning notes : Non – technical (human factor-related)	
	Comments
Decision making	Good rapid assessment of ABC
Planning	Call for help Sent to crash trolley Third responder dealt with upset relative
Situation awareness	Identified need for participant notes
Team working	Effective communication noted between all responders
Leadership	Good clear leadership displayed by first responder
Communication	Effective communication noted between all responders

Summary of Debrief

Call bell by relative. Emergency buzzer should have also been initiated

Call for help went to Study doctor, 2222 call also required

ABCDE initiated with airway and breathing assessment. However no further progression to circulation, disability, and exposure

Participant given second dose of Hydrocortisone and Chlorphenamine (not prescribed)

Adrenaline not administered

Priority was given to moving the participant into a chair; moving a sick participant is not a priority

Summary of Debrief (continued)

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. Call for help early to the appropriate expert teams. Do not be afraid to call 2222 if a participant is still conscious and you think there is potential for deterioration ABCDE assessment is vital to identify clinical deterioration
- Work through ABCDE to identify signs and symptoms to guide appropriate care and treatment
- Remember to reassess
- Anaphylaxis – severe life-threatening, generalised or systemic hypersensitivity reaction Signs and symptoms - Any rapidly developing, life-threatening airway, breathing and/or circulatory problem usually with skin and/or mucosal changes
- Recognise and treat – Supportive treatments e.g. O2, fluids etc. However the first line treatment for life-threatening anaphylaxis is intra-muscular adrenaline 0.5mg 1:1000 (500mcg) then repeat after 5 minutes if symptoms do not improve

Refer to local policies as relevant Resuscitation Council UK Guidelines (2015)

Any nurse, teacher, parent etc. can administer adrenaline injection 1 in 1000 (1 mg in 1 ml) if the purpose is to save life, without needing permission from an authorised prescriber. If they do this, they will not commit an unlawful act under the Medicines Act 1968. Note adrenaline dosage is set out – further dosing over 1 mg in 1 ml must be prescribed. The Statutory Instrument is 1997 The Prescription Only Medicines (Human Use) Order no 1830. This legislation can be found at www.hmso.gov.uk

Note: nurses involved must work within the Nursing and Midwifery Council (NMC) standards (NMC 2018), and must therefore be competent in being able to recognise the anaphylactic reaction and administer adrenaline using an auto-injector. Therefore it would be sensible for trusts/ employers to ensure that such a provision is included in their first aid or anaphylaxis guidelines.

Confirmation of Scenario Completion		
Name of Facilitators	**Role in scenario**	**Signature**
AM		
PD		
PC		

The trainer should retain this document for proof of training

Learner Attendance Log				
#	**Name**	**Job Title**	**Place of Work**	**Signature**
1	TK	CRN	CRF	
2	JS	CRN	CRF	
3	JD	CRN	CRF	
4	KC	CRN	CLRN	
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:**			

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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 how to make up Hydrocortisone IV and piriton IV 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
CA/PA circulation to all staff			
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: 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.

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Original review by

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- Michelle Casey – Paediatric Senior Sister, Southampton
- Anne Elmer – Senior Research Sister, Cambridge
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- Beverley Kilner – Education & Training Lead, Sheffield
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Further review by

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Further review and development of new scenarios (version 5)

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- Branwen Ellison- Handley – Experimental Medicine Research Sister, Sheffield
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- Sally Batham - Research Space Clinical Manager, Leicester
- Jane Martin - Children's Senior Research Sister, Southampton
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- Omabe Obasi - Research Nurse Manager, Cardiff

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

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- Dr. Richard FitzGerald – CRF Director, Liverpool
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