**Background**

In the UK, in 2006, a set of extremely serious adverse reactions occurred during the first in human non-therapeutic clinical trials of a monoclonal antibody, TGN1412. The subsequent expert investigation into the events resulted – amongst others – in the stipulation to set up ‘Medicines and Healthcare products Regulatory Agency (MHRA)’ accredited Phase I Trials centres. Staff working at these centres would have to regularly undertake simulation training in dealing effectively with emergency scenario situations that they may encounter with their clinical research participants.

The management of the NIHR/Wellcome Trust Clinical Research Facility in Cambridge regarded such a training requirement as a gold standard that was to be achieved for its own clinical staff. Over the past 3 years the education & training staff of the unit have systematically implemented, evaluated and improved a simulation training programme for their nursing staff.

**Example of Scenarios**

- Sepsis - chest infection in patient with severe traumatic brain injury
- Syncope secondary to hypoglycaemia
- Acute coronary syndrome (non ST elevation MI)
- Massive blood loss following liver biopsy
- Anaphylaxis following administration of IV investigational medicinal product
- Paediatric scenario: febrile convulsion

**Rationale for Emergency Scenario Training**

- To enhance research participant safety
- To provide training complementary to that already covered by the hospital's annual mandatory resuscitation training
- To expose staff to possible peri-arrest situations relevant to the research studies they facilitate
- For staff to gain confidence in dealing with emergency scenarios due to safe and supportive training environment
- For staff to gain competence in dealing with emergency scenarios effectively due to structured up-front training and careful debriefing

**The training programme**

- 09.00 Introduction to concept of simulation training
- 09.15 Anaphylaxis – what it is – how to deal with it
- 10.00 Oxygen therapy in the unwell patient
- 10.15 Break
- 10.45 ABCDE assessment
- 11.30 Systematic communication in an emergency – use of Situation – Background – Assessment – Recommendations (SBAR) approach
- 11.45 Watching a video designed to trigger discussion on what can lead to emergencies not being dealt with effectively
- 12.00 Introduction to the Simulation Centre set-up
- 12.30 Lunch break
- 13.15 Running 3 scenarios in varied combinations of staff. Staff not actively involved in the Simulation room observe live events on screen in adjacent room. Debriefing of staff straight after each scenario. Leader records learning points.
- 15.00 Break
- 15.20 Running 3 further scenarios
- 16.50 Evaluation of the day – Finish at 17.00

**Staff collaboration**

- Course lead who plans and prepares scenarios
- Sim staff who remotely operate the simulation mannequin
- Staff who provides the voice of the mannequin
- Member of the hospital resuscitation trainers team to consult
- Observer to lead the individual/group debriefing after simulation
- Ideally a medical doctor playing the "medical cover" for the study

**Evaluation / Discussion**

- Since January 2010 completed eleven different training days
- Mean average number of staff learners attending per course = 5.7
- Mean average of staff forming faculty - per course = 5
- Each scenario has generated relevant and new learning points the attendees consider as valuable insight

Of the learners who completed the course evaluation forms in 2012:
- 90 -100% report the training has met their expectations and that they have benefited from attending the training
- 100% would recommend the training to a colleague
- 75 – 83 % of the learners report they have not been exposed to a real life emergency in the 12 months prior to training and find it very useful to have simulated clinical emergencies for practice

- The careful planning required for each course is time consuming
- Learners report high pre-course anxiety levels, worried about “losing face” if perhaps appearing to not be fully in control

**Future plans**

- By March 2013, to produce in-house training DVD of a typical simulation scenario to demonstrate use of ABCDE assessment process and to prepare staff better for what to expect
- Faculty to complete specific training of debriefing after scenarios
- Introducing unannounced scenario training in clinical areas

**Contact details**

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