Exploring the unique attributes of managing an acutely deteriorating research participant

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Background:

The Children's Clinical Research Facility (CRF) at Leeds Children's Hospital has a portfolio that includes an increasing number of early phase trials involving Investigational Medicinal Products (IMPs). These IMPs have the potential for unexpected or severe side-effects and may result in sudden clinical deterioration, such as an anaphylactoid reaction.

Intervention:

As part of a range of patient safety interventions, the Clinical Research Fellows at Leeds Children's Hospital explored concerns around treating acutely deteriorating study participants. We set up an Emergency Scenario Training Program, consisting of simulation sessions involving the CRF staff, Principal Investigators, research staff conducting study visits, as well as the paediatric resuscitation team. During post-scenario learning conversations, we explored the perceived differences in the management of children receiving IMPs as part of a research trial, and asked staff if they had any questions or concerns.

Who should we contact?

Main themes that emerged

Do we need to consider unblinding?

Are there any specific treatments?

If a patient dies, what are the requirements?

Outcomes:

Stakeholders from within the Children's Research Team and the Children's Hospital, including Intensive Care Consultants and members of the resuscitation team discussed appropriate responses.

Questions were collated into themes

A Standard Operating Procedure (SOP) was developed

Each theme was addressed, and an SOP produced that supplements the hospital's deteriorating patient guidance. Aimed at supporting delegated study staff, on-call teams reviewing study participants admitted from home with symptoms, and members of the hospital paediatric 'crash' team who might form part of the response to an acute deterioration.

Elements were built into our Emergency Scenario Training Program that encouraged exploration of these themes and included scenarios designed around specific trials to ensure staff felt equipped.

Feedback from these sessions was widely positive, stating that the training helped increase familiarity with the CRF environment and equipment, improve collaboration between CRF staff and other teams, and deepen knowledge of how to manage clinical deteriorations involving trial participants.

Our Emergency Scenario Training Programme was modified

Conclusions:

Early phase trials in children involving high-risk IMPs are an emerging element of hospital care. This care is often provided in relatively isolated CRF units, of which the wider hospital teams may have limited knowledge. To ensure study participant safety, robust measures must be in place to train and equip not only research staff, but also the wider acute paediatric teams, to promote appropriate management of deteriorations in these patients.

In-situ simulations and research-related SOPs are integral to meeting the training needs of staff who may potentially work in the research environment, both on a regular and ad-hoc basis.