Document E: ECLIPSE protocol for handling suspected errors

Protocol: Action to be taken if a researcher in the ECLIPSE study observes an error, or has other concerns about poor practice

This draft protocol focuses on observing error in context. It is only a small aspect of the broader ethical considerations on ECLIPSE but it is perhaps the most obvious and acute. This document has been informed by our on-going studies on CHI+MED, the ECLIPSE team's extensive experience of using observation to identify medication administration errors, and the WHO's (2013) guidance *Ethical Issues In Patient Safety Research*.

Similar to the WHO (2013) guidance we take a "no blame" approach to our research, which underlies much of patient safety and human factors research, i.e. *Patient safety improvement is based on the understanding that most harmful incidents occur not because of negligent or unprofessional behaviour, but, instead, because of systemic problems with the manner in which health care is delivered* (p.19).

This protocol addresses two possible situations: (1) researchers who become aware of a suspected medication error that has to be dealt with immediately; and (2) the more diffuse observation of a systematic weakness which could be cause for concern for the likelihood of future errors occurring, e.g. poor practice. We address each in turn:

1. Observation of a suspected medication error

There are two stages in the project where errors might be observed or suspected: the point prevalence study (Phase 1 where the observer will be clinicians from the trust / organisation) and the qualitative study (Phase 2 where the observers will be researchers on ECLIPSE).

In both, the first four stages of the protocol for dealing with a suspected error are similar:

1. Identify the responsible clinician (e.g. the nurse assigned to that patient or dealing with that treatment).
2. Convey your concerns and check your understanding – raising questions is often enough for the professional to check and detect the error (WHO, p.28).
3. Observe any remedial action taken as appropriate.
4. If satisfied by the response talk to the clinician about the event at a time that is appropriate, e.g. this might be a while after the event to save embarrassment (this dampens social and psychological risks for the people involved (WHO, p.15)). If unsatisfied with the response and there is still concern for patient safety then raise the issue with the ward manager or equivalent until satisfied. Again, talking about the suspected error for data collection purposes is secondary to error avoidance and recovery. Talking about the suspected error might happen a while after the event for the reasons stated above.

After the acute phase of error avoidance and recovery has passed, the relevant trust's procedures for reporting errors or near misses should be followed. For our study, these processes differ depending on whether the observers are employees of the organisation concerned (i.e. Phase 1) or external researchers (i.e. Phase 2).

Point Prevalence Phase (Phase 1)

The clinical team that will be carrying out the point prevalence study should follow their trust's / organisation's practice for reporting errors and/or near misses. This could include collaboration with the clinicians on the ward or it could mean reporting the errors independently.

All observers will receive training from ECLIPSE so data gathering is effective and follows the correct protocols for ethics and intervention.

Qualitative Phase (Phase 2)

The non-medical researchers will not be employees of the relevant organisation. They will ask an appropriate member of staff to report the error according to local incident reporting procedures.

In addition, phase 2 of the study will include the set-up and programming of infusion pumps. This introduces the possibility of watching errors develop and unfold. In such cases the researcher needs to balance naturalistic data collection to improve safety in the longer term with intervening to reduce potential disturbances and errors that happen as a normal part of the system (WHO, p.28). The researcher should tactfully intervene before the error is committed or becomes significant or embarrassing. The WHO guidance states that the researcher has a duty to intervene when *researchers are qualified to assess risk, and if the risk of harm seems imminent, if the harm would be severe and irreversible, and if interfering could prevent the harm* (p.28). The nature of intervention will depend on the situation but in our experience, this can normally be done tactfully by raising a question with the attending clinician (p.28). Observing error that has the potential to cause serious harm is rare, e.g. during a 10 day study on a haematology ward only one incident of this nature was encountered:

'We previously observed a nurse type the wrong numbers into an infusion pump, but delayed raising this with her to see if she would notice and correct this herself. Before she pressed START to commit to the error we intervened tactfully by asking whether the figures were correct or if they should be X instead. She appreciated that we raised the error with her so she could recover from it, also that we did this tactfully and discreetly. Delaying the raising of the potential error gave her an opportunity to self-correct and satisfied our naturalistic data gathering requirements as we needed to see if this error would have been detected if we were not present.' Example from Haematology Ward.

In terms being '*qualified to assess risk*' the named researchers on the project do not have a medical background and so their ability to assess risk is limited to fairly rudimentary error (e.g. wrong drug, wrong rate, wrong dose, and wrong patient) rather than error requiring more specialist knowledge (e.g. drug incompatibilities and nuances in drug delivery). The named researchers have expertise in human factors, which will enhance their ability to notice sociotechnical system strengths and weaknesses. This is why it is important for them to raise concerns with a medical professional who is qualified to assess risk.

Prof. Bryony Dean-Franklin, who has experience in carrying out detailed studies of error in medical administration, will provide training for the researchers that will cover intervention and ethics.

2. Diffuse Observations of Suspected Vulnerability

Observations of practice might alert the observer to good and poor practices. The WHO guidance states that there is a duty to report aggregated data to improve patient safety practices (p.28). In general, we will be reporting aggregated data to the relevant organisation in order to provide local data, while protecting the identity of individuals who have been observed. Aggregated data is used to help protect participant and institutional confidentiality (p.25-6). However, in the unlikely situation that we have serious concerns about one or more individuals we will inform them that we will be raising these concerns locally so that they can best be supported. Similarly, if our interviews suggest that health care professionals have concerns about safety issues locally, we will seek to support them in raising these concerns. Our participant information leaflets will make these points clear.

3. Ad hoc ethical decision handling for unanticipated ethical issues

Following the WHO (2013, p.29) guidance we will establish and refer unanticipated ethical issues that arise during the study to a 'safety committee'. This committee will be composed of senior members of the research team and the advisory group and relevant external experts. They will advise on the best way to handle the ethical issue.

References

WHO. Ethical issues in patient safety research: interpreting existing guidance. 2013. World Health Organization. WHO press, Switzerland.