Document A: Topic guide for the debrief and focus group sessions

ECLIPSE (Exploring the Current Landscape of Intravenous Infusion Practices & Errors):

Debrief and focus group guides

This document provides the debrief and focus group guides that were developed in November 2015 as part of phase 1 of the ECLIPSE project.

After data gathering was completed at each site it was analysed by the research team and an individual report for that site was developed. This was presented to the site during the debrief and focus group sessions, along with a presentation, which acted as the main driver for what was discussed. We focused on what the individual sites found interesting, relevant and surprising about their own data.

1) Debrief guide

Introduction to purpose/scope

Consent

General reflections

- What were you expecting to find before starting the data collection? (e.g. were you expecting to find few/lots of errors, any particular kinds of errors, etc.)
- Did anything surprise you?
- What did you learn?
- What important errors did you observe?
    - Why do you consider those ones to be important
- Did you report any incidents as a result of the study?
- Have you identified any changes you would like to make or recommend to be made as a result of the data collection?
- Do you think how we have presented the findings is reflective of what you observed?
- What are the important findings from your perspective?
- Were there any insights that you had that were not captured in our data collection forms and/or report?

Specific queries about data

Examples:

- Can you explain in more detail how infusions are set up involving both a syringe and volumetric infusion from the same bag?
- In the errors classified as ‘other’ there are quite a few in which the infusion was stopped without a documented reason, what did you think was going on, do you have any theories/views about this, etc?

Habits

- Did you expect/observe any poor habits?
- Did you expect/observe any good habits?
- What practices are accepted as normal or ok when perhaps they shouldn’t be?

2) Focus group guide

Introduction and overview

Consent

Introductions

Aims/scope/plan of focus group - how the focus group will work

Overview of project

What the data collectors did (data collectors could present this?)/Methodology

Limitations

Site and summary of point prevalence findings (PPT presentation)

1. Overview of number/proportion of errors and discrepancies overall
2. Medication administration
3. Procedural and documentation
4. Miscellaneous
5. Clinical areas

General reflection on site findings overall

- Were you surprised by any of the findings?
- What are the important findings from your perspective?

General themes

- What do you think are the most important safety issues with IV infusions/infusion devices at your hospital/trust?
- Are IV practices a priority/on the patient safety agenda?
- What on-going patient safety initiatives, if any, are there related to IV infusions/infusion devices?
- Do you collect / review any IV-related data for quality improvement purposes?
- What changes would you like to see in either the design of devices or IV practices/policies?

Site specific questions driven by their results

- For example… patient ID bands in oncology day care // IV boluses given as infusions // what possible reasons are there for such low error/discrepancy rates in X.

Policies

- How do you feel about local policies and guidelines related to IV infusions?
    - who owns them, are they written well, easily accessible – where are they, well established in practice?
- Are policies enforced? How?
- What policies and or guidelines do you have for double-checking of IV medication? When should the double check take place? When does the double check take place?
- How do policies and/or guidelines (e.g. for labelling tubing or medication) impact on patient safety? How does the absence of policies impact on safety/errors?
- How do you feel policies/guidelines related to IV infusions impact on patient safety?

Infusions devices

- How is the type of pump/delivery method selected? Are there policies and/or guidelines around this?
    - Are gravity feeds used/allowed? In what circumstances?
    - When are IV boluses given as infusions, and vice versa?

Smart pumps/DERS sites

- Procurement/implementation
    - Was there a particular rationale for purchasing smart pumps?
    - Was there a rationale for implementing them in some areas and not others?
    - Would you anticipate extending the use of smart pumps into other areas in the future? If not, why not? Etc.
- How were they implemented? Who was involved?
    - What were the challenges and barriers for implementation, e.g. organisational barriers? What impact did these have? How were these overcome, if they were?
- Impact
    - How has the introduction of smart pumps impacted on practice?
    - Have you identified any benefits (i.e. for patient safety)?
    - Have you experienced any negative impacts or unintended consequences?
- Drug libraries
    - How were drug libraries developed? Who was responsible?
    - What is their scope? How comprehensive are they?
    - How are they maintained/updated?
    - What are the policies/expectations around the use of drug libraries? Are people expected to use it? How do you measure/monitor use?
- DERS
    - How were decisions about hard/soft limits made?
    - How do you monitor/respond to overrides, etc.
- Organisationally (if not covered above)
    - Are there broader benefits to the organisation, e.g. in having IV data which is easier to access, in reviewing IV practices prior to implementation
    - What are the organisational costs, e.g. in maintaining drug libraries, reviewing data, etc.

- What organisational barriers were experienced, e.g. we've heard anecdotes from other sites about groups disagreeing about the smart pump implementation and refusing to change their practices?

Non smart pump sites

- Have you considered, or are you considering introducing, smart pump technology?
  - What do you think about smart pumps technology?
  - What do you think the value of introducing smart pumps would be?
  - What do you think are the key challenges and costs of implementing smart pumps?

Training

- What training do nurses receive to support their use of pumps and IV practices?
- How do you think training might impact on the types of errors and discrepancies identified in this study?
- Is training standardised across all clinical areas or tailored depending on use?
- Who is involved in developing training? Who runs it? How is it organised?
- Any changes in training as a result of the data?

Summing up

- Is there anything else that we haven't discussed that you think is important for us to know? E.g. around training, technology/devices, etc…
- What we're doing now/next
  - How far we are along with sites in Phase 1
  - The selection of sites and what we will do in Phase 2
  - Workshops with clinicians and other stakeholders in Phase 3

Document B: Guidance on rating harm for observers (final version)

A Rough Guide to Harm Ratings

Purpose

The purpose of this document is to provide guidance on:

- The different types of errors and discrepancies you may encounter
- How you might apply the adapted NCC MERP severity rating categories to assess the likely harm associated with these errors/discrepancies

Definition of a medication administration error

We consider an intravenous medication administration error to be any deviation in the administration of an intravenous infusion from a doctor's written medication order, the hospital's intravenous policy and guidelines, or the manufacturer's instructions. This is taken to include the administration of medication to which the patient had a documented allergy or sensitivity; other aspects of the clinical appropriateness of the medication order and its administration are not assessed in this study.
We are also collecting data on other procedural or documentation discrepancies that do not meet the definition of a medication administration error. These include patients not wearing an identification wristband with the correct information, tubing not being tagged and labelled in accordance with local policy, and failure to document the administration of the medication in line with hospital policy. Intentional deviations from a medication order that contains a prescribing error, to avoid administering the erroneous medication, are not included as a medication administration error. However these events should be recorded and classified as documentation discrepancies if the medication order has not been amended prior to administration.

Eclipse Severity Rating Categories (Adapted From NCC MERP)

Harm	Category	Description
No Error	**A1**	Discrepancy but no error
	A2	Capacity to cause error
Error, no harm	**B**	An error occurred but is unlikely to reach the patient
	C	An error occurred but is unlikely to cause harm despite reaching the patient
	D	An error occurred that would be likely to have required increased monitoring and/or intervention to preclude harm
Error, harm	An error occurred that would be likely to have:	
	E	Caused temporary harm
	F	Caused temporary harm and prolonged hospitalization
	G	Contributed to or resulted in permanent harm
	H	Required intervention to sustain life
Error, death	**I**	An error occurred that would be likely to have contributed to or resulted in the patient's death

Examples Of Medication Administration Errors/Discrepancies And Suggested Harm Ratings

Case No.	Discrepancy/ Error Type	Observed infusion	Medication order/prescription	Notes	Suggested NCCMERP rating
1.	**Unauthorised medication or fluids / no documented order** i.e. Fluids/medications are being administered but no medication order is present. This includes failure to document a verbal order if these are permitted as per hospital policy.	Plasmalyte 148, 1000ml, 250ml/hr	No order on current drug chart	Patient had just arrived on the ward. Order was documented on previous drug chart, located in patient's notes in the doctors room	A1
2.		Plasmalyte 148, 1000ml	No order on current drug chart	Patient had just returned to the ward from theatre. The infusion was started in theatre and documented on the anaesthetic chart. [However as the patient was returning to the ward to be monitored over night it should have been documented on the drug chart]	A1
3.		Remifentanil, 50ml running at 4ml/hr	No current order on drug chart	Infusion had been stopped in the morning to allow the patient to wake up and the medication order crossed off, but the medical team had decided to sedate them again. The infusion was restarted, but without a written medication order.	C
4.		Heparin 1 unit/ml, 500ml running at 1ml/hr, over 24 hours	Verbal order, not documented on drug chart	Verbal order to maintain arterial line flush system and facilitate measurements via arterial line. It was appropriate to administer the line flush as non-administration could have	C

				caused patient harm, however there was sufficient opportunity for nursing staff to obtain a prescription as well as document the administration	
5.	**Wrong medication or IV fluid** i.e. A different fluid/medication/ diluent as documented on the IV bag (or bottle/syringe/ polyfuser) is being infused compared with that specified on the medication order or in local guidance.	Sodium chloride and glucose	Sodium chloride 0.9%	The rating given may depend on the concentration that was administered in this case.	C
6.	**Concentration discrepancy** i.e. An amount of a medication in a unit of solution that is different from that prescribed.				
7.	**Dose discrepancy** i.e. The same medication but the total dose is different from that prescribed.	0.9% saline with 0.3% KCl, 750ml @125ml/hr	0.9% saline with 0.3% KCl, 1000ml @125ml/hr		C
8.	**Rate discrepancies** i.e. A different rate is displayed on the pump from that prescribed. Also refers to weight-based rates calculated incorrectly including using the wrong patient weight.	Phosphates polyfusor 500ml, infusing at 42ml/hr	Phosphates polyfusor 500ml IV over 24hrs	At 42ml/hr the infusion was being given over 12hrs. However, the local IV guide says to give over “e.g. 6-12hrs”, max 500ml/day, and local data collectors were confident that the prescriber had not specifically requested 24 hours rather than 12 hours for a reason. This infusion is therefore appropriate as per	A1

				local guidelines but represents a documentation discrepancy since the medication order does not reflect local practice.	
9.		0.9% sodium chloride, 1000mls over 4 hours.	0.9% sodium chloride, 1000mls over 8 hours	Gravity infusion running too fast. At the time of observation the infusion had been running for 2 hours and half the bag had gone through. This may result in fluid overload but severity rating may depend on patient characteristics, e.g. age, heart condition, etc	D
10.		Heparin 200 units/h (2 ml/h)	Heparin 1300 units/h for venous thromboembolism	Pump inadvertently programmed for incorrect dose.	F
11.	**Delay of the dose or medication/fluid change** i.e. An order to change the medication or rate not carried out within 4 hours of the written medication order, or as per local policy.	0.9% sodium chloride, 1000mls. Not running at the time of observation	0.9% sodium chloride, 1000mls, 83ml/hr, over 12 hours	The infusion had been stopped while the patient went to x-ray. The patient had been back on the ward a while and the nurse had forgotten to restart the infusion. The patient may have become dehydrated without intervention	C
12.		No infusion running, previous bag finished at 9am. Observed at 13:20	Hartmanns, 1l over 10 hours at 100ml/hr	Nurse was aware that fluids were needed and stated no supply on the ward.	C
13.	**Omitted medication or IV fluids** i.e. The medication prescribed was not administered.	No infusion running	Sodium chloride 0.9%, 1l over 12 hours.	No reason documented	D
14.	**Allergy oversight** i.e. Medication is prescribed/administered				

	despite the patient having a documented allergy or sensitivity to the drug concerned.				
15.	**Expired drug** i.e. The expiry date on either the manufacturer or additive label has past.	Furosemide 50mls, 1.3ml/hr, running over 36 hours. Observed at 05/05/2015 11:10, documented start time 04/05/2015 10:55:00	Furosemide 50mls, 1.3ml/hr, running over 36 hours.	Infusion running for 36 hours but policy states it should be changed after 24 hours.	C
16.		Sodium Chloride 0.9% 500mls, 3ml/hr. Observed at 07/08/2015 14:30	Sodium Chloride 0.9% 500mls, 3ml/hr.	Expiry date/time 06/08/15 16:50	C
17.	**Roller clamp discrepancy** i.e. The roller clamp is not positioned appropriately/ correctly.	Phytomenadione(vit K) 10mg/100mL, 50mL/hr, observed at 9:49am but the infusion was not running	Phytomenadione(vit K) 10mg/100mL, 50mL/hr, administered at 9:02am	Clamp closed	C
18.	**Other discrepancies or errors** i.e. prescribing errors, wrong route of administration e.g. peripheral rather than central, wrong type of infusion device, etc	Noradrenaline, 8mg in 50mls @ 9.5mls/hour	Noradrenaline, 4mg in 50mls @ 9.5mls/hour	In this case, the doctor had prescribed double the standard strength but had not altered the standard written prescription accordingly. The nurse was aware that the doctor intended the double strength to be administered and there was a note attached to the pump to highlight this. Therefore the error here is not the concentration discrepancy but that the medication was administered without a correct written prescription. This was considered likely to require additional monitoring to ensure that the concentration	D

				of the next dose given was correct.	

PROCEDURAL OR DOCUMENTATION DISCREPANCIES / ERRORS

Case No.	Discrepancy/ Error Type	Examples	Suggested NCCMERP rating
1.	**Patient identification error***	Patient's hospital number was incorrect on wristband	A2
2.	i.e. Patient either has no identification (ID) band on wrist, or information on their ID band is incorrect.	Patient receiving an infusion was not wearing a wristband	A2
3.	**Wrong or missing information on additive label**	Ward name and start time were not specified on additive label, as required by hospital policy	A2
4.	i.e. Any incorrect or missing information on the additive label, as required by hospital policy.	Non-standard abbreviation used in place of drug name e.g. IVMP for methyl prednisolone	A2
5.	**Tubing not tagged correctly** Tagging or labelling of tubing is different (either missing or incorrect) from requirements according to hospital policy, or local practice.	Patient with more than one infusion running. Tubing was dated according to policy but tubes were not labelled with drug name as policy requires	A2
6.	**Documentation errors***	Administration start time was documented but no nursing signature to say IV had been started.	A2
7.	i.e. Medication/fluids administered but not correctly documented/signed on medication chart	No start/finish time documented on drug chart.	A2

*** Please note you will not be asked to rate these types of discrepancies. These will be automatically assigned an A2 rating by the research team. If you feel for any reason that this rating would be inappropriate in the particular circumstances, please make a note of this in the 'Comments' section on REDCap**

Document C: Phase 2 topic guide for semi-structured interviews with staff

ECLIPSE PHASE 2:
INTERVIEW GUIDE FOR INTERVIEWS WITH **STAFF**.
TOPIC GUIDE (JANUARY 2017)

INTRODUCTION

→ Introduction of interviewer, background and motivation for the study and what we'll talk about (scope).

The purpose of this interview is to explore your experience and understand how infusion therapy works in daily practice. We are trying to gain an insight into certain errors, practice and work-arounds in practice.
There are no right or wrong answers; the interview is simply about hearing your views on this topic and learning from your experience. Prior to this interview we collected data on intravenous infusions in phase 1 of the ECLIPSE study. This interview aims to give us more depth and understanding of practice and what this entails for you.

We will not use your name in any reports of this work and it will not be made known who took part. However, some of the things you say in the interviews might be used to illustrate and support the findings of the research. We will make every effort to make sure that these remain unidentifiable.

Are you happy for this interview to be tape recorded? Only researchers who are part of the team will have access to the recording and you will not be named on the verbatim transcriptions of the interview.

CONTEXT

1. **Could you first tell me about your role here in the hospital?**
   Prompts:
   - What are your responsibilities?
   - What are your interests in terms of IV practice at the hospital?

SPECIFIC QUESTIONS BASED ON FOCUS GROUP (PHASE 1)

Note: For some sites the answers to these questions might be found in the focus group data from phase 1 of the study, before conducting the staff interviews the observer/interviewer will review these data.

2. **Questions relating to training?**
   Prompts:
   - What training do nurses receive to support their use of pumps and IV practices?
   - How do you think training might impact on the types of errors and discrepancies identified in this study?
   - Is training standardised across all clinical areas or tailored depending on use?
   - Who is involved in developing training? Who runs it? How is it organised?
   - Any changes in training as result of the data?

3. **Questions relating to procurement?**
   Prompts:

- Was there a particular rationale for purchasing smart pumps?
- Was there a rationale for implementing them in some areas and not in others?
- Would you anticipate extending the use of smart pumps into other areas in the future? Why/why not?

4. **Questions relating to errors and discrepancy rates?**
   Prompts:
   - DERS sites: how were decisions about hard/soft limits made? How do you monitor/respond overrides etc.

5. **Questions relating to equipment, including smart pumps (how they have been implemented and perceived impact, or thoughts on investing in this technology)?**
   Prompts:
   - How is the type of pump/delivery method selected?
   - Are there policies and/or guidelines around this?
   - If at all, in what circumstances are gravity feeds used/allowed?
   - When are IV boluses given as infusions and vice versa?
   - What were the challenges and barriers for implementation, e.g. organisational barriers, of smart pumps? What impact did these have? How were these overcome, if they were?
   - How was the introduction of smart pumps impacted on practice?
   - Have you identified any benefits (i.e. for patient safety)?
   - Have you experienced any negative impacts or unintended consequences?
   - How were drug libraries developed? Who was/is responsible?
   - What is the scope of drug libraries? How comprehensive are they?
   - How are drug libraries maintained/updated?
   - What are the policies/expectations around the use of drug libraries? Are people expected to use it? How do you measure/monitor use?

   Prompts (organisational)
   - Are there broader benefits to the organisation, e.g. in having IV data which is easier to access, in reviewing IV practice prior to implementation?
   - What are the organisational costs, e.g. in maintaining drug libraries, reviewing data, etc.?
   - What organisational barriers were experienced, e.g. we've heard anecdotes from other sites about groups disagreeing about the smart pump implementation and refusing to change their practice?

6. **Policy and guidelines (their structure and the difference between policies and practice)?**
   Prompts:
   - How do you feel about local policies and guidelines relating to IV infusions?
   - Who owns them, are they written well, easily accessible, where are they, well established in practice?
   - How rigidly are policies enforced and how?
   - How do policies and/or guidelines (e.g. labelling of tubing) impact on patient safety? How does the absence of policies impact on safety/errors?

IV PRACTICE AND ADMINISTRATION

7. **What processes are there for quality improvement and monitoring in terms of IV administration at the organisational level?**
   Prompts:
   - What does the protocol say (e.g. double checking)? When should the double-check take place? When does it take place?
   - What do you think are the most important safety issues with IV infusions/infusion devices at your hospital/trust?

8. **What is the one thing you would do to change intravenous infusion practice for the better?**
   Prompts:
   - What would you do in the short term?
   - What would you do in the long term?

ROUND-UP

9. **Is there anything else that you think it would be useful to share on this topic?**
10. **Do you have any questions for me? Or any hopes or concerns for the project?**

Thank you very much for your time and your help with this study!

Notable comments/notes:

Document D: Phase 2 topic guide for semi-structured interviews with patients

ECLIPSE PHASE 2:
INTERVIEW GUIDE FOR INTERVIEWS WITH **PATIENTS**.
TOPIC GUIDE (JANUARY 2017)

INTRODUCTION

→ Introduction of interviewer, background and motivation for the study and what we'll talk about (scope).

The purpose of this interview is to explore your experience as a patient in receiving IV therapy. There are no right or wrong answers; the interview is simply about hearing your views on this topic and learning from your experience. This interview aims to give us more depth and understanding of practice and what this entails for you as a patient.

We will not use your name in any reports of this work and it will not be made known who took part. However, some of the things you say in the interviews might be used to illustrate and support the findings of the research. We will make every effort to make sure that these remain unidentifiable.

Are you happy for this interview to be tape recorded? Only researchers who are part of the team will have access to the recording and you will not be named in transcriptions of the interview.

Note: Interviews are planned to last for 30mins. **We might not have time for all of these questions so priority questions are underlined.**

CONTEXT

1. **Could you first tell me a little about your experience here as a patient?**
   Prompts:
   - How long have you been in hospital?
   - Have you been on this ward for long; how would you describe it?
   - How would you describe how you related to your IV infusion treatment? (e.g. inquisitive/uninterested, will speak up/won't speak up)

2. **Have you received many infusions as part of your treatment(s), either now or in the past?**

INTERACTION WITH STAFF

3. **<u>Could you talk me through what they do from your perspective in terms of IV treatment?</u>**
   Prompts:
   - Do all the staff administer IV infusions in the same way?
   - Do any of them do things differently that you like or don't like?
   - Could you describe a good time and a bad time?
   - Is there something you wish all of them would do, or perhaps they wouldn't do?

4. **<u>What information are you told, if any, about your infusions?</u>**
   Prompts:
   - Who gives you this information?
   - Are you happy with this level of information?
   - What information do you want?
   - Do you feel like you understand enough about your infusions?

5. **What information about intravenous infusions do you think would be useful to provide other patients? What would be the best way to share this information (e.g. leaflet)?**

6. **Do you like to know what's going on with your infusions in detail, or would you prefer it if the healthcare staff just got on with it?**
   (1 signifying you don't really want to know the detail and 10 signifying you really want to know what's going on) – why?

7. **How comfortable do you feel about raising questions or concerns about your infusions with staff?** (1 being not comfortable at all and 10 being completely comfortable) – why?

IV EXPERIENCE

8. **<u>Have you had any issues with how your infusions have been set-up?</u>**
   Prompts:
   - Or any issue with being on the infusions once they are set-up, day or night?
   - Are there any issues with the pumps that are used?

9. **<u>Have you used your own infusion pump directly (e.g. pushed any buttons)?</u>**
   Prompts:
   - Have you seen/heard about other patients doing so?

10. **<u>What's the one thing you would do to change intravenous infusion practice for the better?</u>**

ROUND-UP

11. **Is there anything else that you think it would be useful to share on this topic?**
12. **Do you have any questions for me? Or any hopes or concerns for the project?**

Thank you very much for your time and your help with this study!

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.