1 Title Page

1.1 Titles

1.1.1 Full Title

Exploring the Current Landscape of Intravenous Infusion Practices and Errors

1.1.2 Short Title

ECLIPSE

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1.3 Protocol Details

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3 Abbreviations

A&E	Accident and Emergency
AAMI	Association for the Advancement of Medical Instrumentation
ADE	Adverse Drug Event
CHI+MED	Computer-Human Interaction for Medical Devices
CI	Chief Investigator
Co-I	Co-Investigator
ECLIPSE	Exploring the current Landscape of Intravenous Infusion Practices and Errors
EPSRC	Engineering and Physical Sciences Council
FDA	US Food and Drug Administration
HS&DR	Health Services and Delivery Research
ICU	Intensive Care Unit
IV	Intravenous
NCC MERP	National Co-ordinating Council for Medication Error Reporting and Prevention
PPI	Patient and Public Involvement
TBD	To Be Decided

4 Summary

Intravenous (IV) medication administration is essential in the therapeutic management of many patients. However, providing IV drug therapy is a complex process, and errors are unacceptably common. To reduce these errors, the introduction of automated infusion devices has been advocated (e.g. Murdoch and Cameron, 2008). However, little is known about the effect on patient safety of smart pumps or of how they are deployed, or about their likely impact in the UK.

This study seeks to explore the landscape of IV medication administration practices in UK hospitals and how these relate to rates and severity of medication administration errors. We aim to inform the debate on whether it is worth the NHS investing in smart pump technology, and if so, what other changes need to be made to ensure effectiveness of that investment. This might include particular approaches to staff training, integration with other systems such as electronic health records or computerised physician order entry systems, standardisation of medication practices, etc.

This is the first national study of this scale in England. It is also timely because there is a similar study already funded in the US, led by Professor David Bates; by collaborating with them and using similar methods and definitions, we will gain added value through transatlantic comparison and efficiencies through sharing of methodologies.

Summary of Research

RESEARCH QUESTION: How is IV medication (broadly understood to include IV fluids, blood products and nutrition where delivered intravenously) infused in UK hospitals, how often and why do errors occur in this process, what are best practices, and what is the likely impact of smart pumps on patient safety?

AIMS: To describe the rates, types, clinical importance and causes of errors involving infusion of IV medication in English hospitals, and to make recommendations for interventions with greatest potential for reducing harm from these errors.

METHODS AND ANALYSIS: ECLIPSE will be a multi-hospital study conducted over three phases for a total of 36 months. Phase 1 will be an audit of prescribed IV medication compared to what is actually given to gain data on the frequency and type of errors; Phase 2 will be an in-depth observational study to gain a rich understanding of the factors influencing those practices; and Phase 3 will focus on developing and disseminating recommendations based on the study. Hospitals will be invited to participate on the basis of a separate questionnaire-based survey we are conducting (using existing funding; ongoing) to establish current practices in terms of the management and use of infusion devices across England. We will invite 14 acute hospitals to participate, plus additional specialist paediatric and oncology units representing a range of practices in relation to IV medication administration.

The design of Phase 1 is based closely on an ongoing multi-centre study in the US, led by Bates, which will facilitate international comparisons. We are working with the Bates team and will use the same approach to quantitative data collection and analysis (in Phase 1 of our study), but supplement this with qualitative data analysis and effective patient involvement in research to gain a deeper understanding of how people, processes, practices, tools, policies and workarounds interact to affect performance in relation to infusion of IV medication (Phase 2 of our study). The Bates study, in turn, is based on methodology developed by Husch et al (2005).

Phase 1 will involve documenting IV medication administration practices and associated medication errors in a point-prevalence study in three clinical areas at each of 14 hospital sites, plus specialist paediatric and oncology units in some of these and other hospitals. To identify potential medication administration errors, trained staff will systematically compare the medication, dose, and infusion rate on each IV pump with those prescribed. Error rates will be calculated for different types of infusion and different clinical areas, and clinical importance will be assessed using standard methods as described below. Interviews and focus groups with staff will be conducted to understand hospital IV practices. This will deliver: an understanding of how IV infusions are administered across a sample of hospitals, focusing on differences in terms of the nursing practices, equipment, policies and processes involved; an account of the rates, types, and clinical importance of errors associated with infusion delivery; and enable an exploration of variance in the rates, types and clinical importance of errors in relation to mode of infusion delivery and clinical area.

Phase 2 sites will be selected on the basis of theoretically interesting comparisons from Phase 1, described in more detail below. For example, these might be sites where different kinds of errors have emerged, and also sites that use different technologies (e.g. smart pumps with hard or soft limits vs syringe drivers for comparable administrations). We will use our expertise in Human Factors (e.g. Rajkomar & Blandford 2012; Furniss et al 2011a) to conduct qualitative observations and interviews, exploring in depth why certain errors are more or less prevalent within each context. These studies will enable us to explore the causes of potential errors in depth, and to assess to what extent innovations in technology or practice, such as the introduction of smart pump technology, with or without related technologies (e.g. electronic prescribing or bar code readers), could have prevented such errors. It will also enable us to identify best practices in safe IV medication administration across different hospital contexts.

Phase 3 will synthesise the findings of Phases 1 and 2, including cross-site comparisons, leading to dissemination of results and recommendations. This will permit exploration of the reasons for any differences identified between England and the US as well as between English sites. We will hold workshops with NHS stakeholders, manufacturers, and patients to discuss our results and get feedback on best practices, further dissemination strategies and wider learning. This will result in recommendations to reduce IV medication error rates across different hospital settings within England.

OUTCOMES:

1. A description of the rates, types and clinical importance of errors involving infusion of IV medication in English hospitals.
2. A rich understanding of the causes of these errors and how they relate to infusion equipment, practices and patient interaction.
3. Recommendations relating to best practice in infusion device design, deployment and training, developed in conjunction with relevant healthcare professionals, both in general and for each participating site.

BENEFITS TO THE NHS: Our work will make recommendations as to how to reduce errors involving IV infusions, with particular reference to the use of infusion pump technology.

5 Background

The proposed study arises in part from our work on CHI+MED. CHI+MED (Computer-Human Interaction for Medical Devices: www.chi-med.ac.uk) is an EPSRC-funded project on the design and usability of interactive medical devices, including (but not limited to) infusion devices. Through that project, it has become evident that little is known about current practices around infusion administration in the UK. The proposed study also builds on Franklin's work on errors in medication administration, which has highlighted how little is known about error rates and causes within the UK setting. Further, it is exploiting a unique opportunity to work with, and build on, an ongoing study in the USA, led by David Bates (Brigham and Women's Hospital, Boston).

5.1 Literature Review

5.1.1 Intravenous medication and error

Intravenous (IV) medication is essential for many hospital inpatients. However, providing IV drug therapy is complex, and medication administration errors are unacceptably common. Much higher error rates have been reported than for non-IV doses, largely due to the additional complexity involved. Intravenous (IV) medication has been identified as a significant topic of concern by regulators, manufacturers and hospital managers due to the frequency and harm related to IV medication errors (AAMI/FDA 2010).

For studies using the gold standard method of structured observation of medication administration, published error rates vary from 18 to 173% of IV doses given (Franklin et al 2009). An international systematic review estimated the probability of making at least one error in preparation and administration of IV medication to be 0.73, with the most errors occurring at the reconstitution and administration steps (McDowell et al 2010). More recently, we found that medication administration errors were five times more likely in IV than non-IV doses (McLeod et al 2013). While many of these errors do not result in patient harm, some do, and even those errors which do not harm the patient can result in anxiety for staff and patients, and reduce patients' confidence in their healthcare.

To reduce errors associated with IV medication, the introduction of automated infusion devices or 'smart pumps' has been advocated (e.g. Murdoch and Cameron, 2008; Institute of Medicine 2000; Department of Health 2000). These 'smart pumps' incorporate software that checks programmed infusion rates against pre-set limits for each drug and clinical location, using customisable 'drug libraries', to reduce the risk of over- or under-infusion. Limits may be 'soft' (in which case they can be overridden) or 'hard' (where they cannot). Pumps may include a range of other features such as being networked and integrated with other systems, and most also allow administrative data, such as number and types of overrides, to be downloaded for analysis. Smart pumps can help with identifying and blocking some kinds of medication administration errors, but they cannot detect all possible errors, and their use comes at a cost, both financial and in terms of other changes (e.g. to policy and practice) that typically need to be introduced to make their use effective. While their use is not yet widespread in the UK, smart pumps are used in about 68% of US hospitals

(Pedersen et al, 2012). However, there are currently few data to provide an evidence base for their use in practice, and studies to date have proved inconclusive (Rothschild et al, 2005). Furthermore, none have been conducted in the UK where systems for prescribing and administering medication are very different to those in the US (Brock and Franklin 2007). We therefore know little about the effect on patient safety of using smart pumps in general and nothing about their likely impact in the UK.

Previous studies have explored the potential benefits of smart pump technology by analysing adverse events associated with IV infusions and assessing which could have been prevented by using smart pumps. For instance, Husch et al (2005) carried out a point-prevalence hospital-wide study of errors in IV infusions using standard infusion pumps, and identified infusion rate errors in 37 cases (8% of all infusions), and wrong medication in 14 cases (3%). However, they estimated that only one error would have been prevented by smart infusion pumps. More were judged to be potentially preventable if the pumps were integrated with other hospital systems, such as electronic prescribing and barcode assisted administration. In a small pilot study, O'Grady and Franklin (2006) identified medication administration errors in 4 (14%) of 29 IV doses, none of which were judged preventable by smart pumps.

In a recent review (Taxis and Franklin 2011), we identified only four experimental studies investigating the effectiveness of smart infusion pumps, all from North America. Three were carried out in clinical practice and one in a simulated environment. The review found inconclusive evidence for smart pump impact on patient safety. For instance, Rothschild et al (2005), in a randomized time series study, found that the use of smart pumps had no effect on the prevalence of serious errors and adverse drug events (ADEs). However, about 25% of the infusions in the cardiac surgery critical care unit were given without using the decision support software, and no hard limits were set. In contrast, Larsen et al (2005), in a before-and-after study in a paediatric setting, demonstrated a significant reduction in reported medication errors following the introduction of a combination of smart pumps, standard infusion concentrations and redesigned medication labels. However, the limitations of self-report data are well documented and the validity of this study is therefore weak.

5.1.2 Qualitative observational studies

Quantitative studies are essential for measuring the frequency and types of error. Qualitative studies complement these by being better placed to explain *why* measures are the way they are (Pope et al, 2002). This complementary approach is captured in Phases 1 (quantitative) and 2 (qualitative) of the project. Our on-going work on CHI+MED provides background data that has helped shape the direction of this project. Within CHI+MED, we have conducted situated studies of device use in practice, including the use of infusion devices in particular hospital settings.

To date we have carried out observational studies of infusion pump practice in an Intensive Care Unit (ICU) (Rajkomar & Blandford, 2012), a Haematology and Oncology Day Care Unit (Furniss et al., 2011a), an Oncology Ward, a Haematology ward (Gant, 2011), an Operating Theatre and an Accident and

Emergency (A&E) department. These have been complemented by interviews investigating infusion pump use across clinical contexts and hospitals; this includes interviews with device managers and trainers (Iacovides, Cox & Blandford, 2013) as well as nurses. These studies have found that infusion practices vary significantly between and within hospitals; for example, nurses in the A&E department studied made little use of infusion devices, so relied on the most senior nurses to maintain their competence in setting up infusions; for them, portability of devices and ease of loading the giving set were important considerations. In contrast, nurses in an ICU routinely used advanced functionality, frequently setting up several pumps in parallel to deliver different medications. Despite the drive towards standardising devices within institutions, it was apparent that not all clinical areas require the same functionality e.g. in some hospitals the bolus function is only used in critical care, while in others, it has been disabled; and whereas a pump's 10min pre-completion alarm might be useful for multitasking in a Day Care Unit, it is highly frustrating for patients and staff in Haematology where patients stay overnight in isolation rooms. Further, the introduction of increasingly complex devices places even greater demands on training. Through these studies, we have become aware of the challenges of IV administration, and of minimising error in that administration, but our focus has been on understanding the details of design and use rather than the broader questions of how IV medication can be most safely administered and comparing practices around different kinds of infusion devices, as proposed in ECLIPSE.

Others have also studied technology use in healthcare, with a focus on the relationship between technology design and vulnerability to errors. For example, Carayon et al (2010) studied how nurses use different infusion devices in different areas of a hospital. They compared the tasks actually carried out with the tasks as defined by ward protocol. They identified divergences in practice and highlighted ways in which these divergences increased overall system vulnerability. Pennathur et al (2013) took a complementary approach of studying a particular context (the operating theatre) and observing the use of the full range of technologies available in that space to derive implications for patient safety. Such studies provide a useful complement to the approach proposed in ECLIPSE, but no previous studies have brought together the perspectives of in-depth observational studies (such as these) and quantitative observational studies (as described above) to deliver both overview and detail on intravenous medication infusion practices and the roles of different infusion technologies and practices in minimising the risks of error that might result in patient harm.

5.2 Justification: Why this research is needed now

This work is important to both patients and the NHS, as laid out under the following standard headings:

5.2.1 Health need

As outlined above, medication errors are unacceptably common, and much higher error rates have been reported for intravenous (IV) medication compared to non-IV doses. A recent news report (http://www.bbc.co.uk/news/health-22594584) suggests that errors in the administration of even basic IV fluids for hydration lead to harm unacceptably frequently. Even errors which do not result

in patient harm can affect patient confidence in their healthcare and absorb valuable clinician time. Our work will lead to a better understanding of how often, and why, errors occur in the administration of IV infusions, identify best practice in minimising error, and deliver recommendations for how they can be prevented. A reduction in errors would lead to benefits in improving the health of our patients, as well as improving their confidence in their care.

5.2.2 Expressed need

The need for a reduction in medication errors within the NHS was first expressed by the Department of Health in 2000 in "An organisation with a memory" and then emphasised in 2004 with the publication of "Building a safer NHS for patients: Improving Medication Safety". In relation to errors involving IV medication, the National Patient Safety Agency (2004) produced a Safer Practice Notice on improving safety with infusion devices. This includes recommendations that NHS trusts review how infusion pump purchasing decisions are made, and evaluate the need for infusion devices before purchase. There is also increasing interest in the potential role of 'smart' infusion pumps (incorporating dose error reduction software) in preventing errors (Murdoch and Cameron, 2008), although pumps are expensive and require a substantial time investment to set up and maintain drug libraries, train staff, etc. (Upton, 2012). There is currently little evidence on which to base decisions about whether or not they are likely to reduce errors in UK hospitals, or under what circumstances. Understanding the causes of IV infusion errors in relation to IV pumps and the likely benefits of smart pumps is therefore highly relevant and important to the NHS. There are multiple competing technologies for scarce available resources, including electronic prescribing and bar-coding, which have potential to improve medication safety.

5.2.3 Sustained interest and intent

IV administration of medication is here to stay, and likely to become more prevalent as older and sicker patients become treatable with modern healthcare interventions. There are also ever-increasing expectations that technology can prevent errors within healthcare, but more technology is available than the NHS can afford in the near term. To ensure patients are getting the best possible care it will be vital to ensure technologies with the highest impact are chosen. It is therefore clear that interest in this area will be sustained and that our research will remain highly relevant and important to the needs of the NHS.

5.2.4 Capacity to generate new knowledge

There are many areas of uncertainty in relation to the causes of IV infusion administration errors, how the use of infusion pumps can increase or decrease the likelihoods of particular kinds of error, and the potential role of smart pumps in preventing error. As described above, there are few UK data on the prevalence and causes of errors involving IV medication (McLeod et al, 2013) and none on the role of infusion pumps. The international evidence on smart infusion pumps mostly originates in the USA, where very different systems are used for the prescribing, dispensing and administration of medication (Brock and Franklin, 2007), and even within the USA, the evidence is as yet inconclusive. Our work will therefore generate new knowledge with specific relevance to the English NHS, as well as contributing to the international literature in this field.

5.2.5 Organisational focus consistent with the HS&DR

The focus of our work is consistent with the mission of the HS&DR and the organisation and delivery of healthcare. We will produce guidance on the use of IV infusion pumps for the English NHS context, including education and training for the different groups of healthcare professionals, purchasing advice, and the potential role of smart pumps in error prevention. Active user involvement in this research will also give visibility to what is important to patients and their role in infusion administration, which is lacking in the literature and in practice at the moment.

5.2.6 Generalisable findings and prospects for change

Research in this area is likely to produce findings of value to NHS management as well as health care professionals, in relation to decision making about how IV infusion pumps, including smart pumps, may affect the occurrence of errors involving the administration of IV infusions. Most work in this field focuses on one organisation; we will include 14 organisations, plus specialist oncology and paediatrics services, in order to increase generalisability. NHS organisations are therefore likely to be able to use this information to bring about improvement.

5.2.7 Building on existing work

The research proposed contributes to building a coherent body of knowledge in the area of medication safety, IV medication administration and the use of infusion pumps. We currently know that errors occur too often in IV medication administration within the UK (McLeod et al, 2013) and that many errors involve bolus doses or the preparation of doses that require multiple steps (Taxis and Barber, 2003). However little is known about the role of IV infusion pumps in preventing or causing error. We will also build on existing work by using standard methods of identifying errors and assessing their clinical importance in order to facilitate comparison with existing literature, both nationally and internationally, and take into account recent recommendations for research into medication administration errors (McLeod et al, 2013). As described above, we will also build on existing work in CHI+MED that employs rich observations and qualitative data analysis to better understand clinical practices. Further, we will build on the ongoing Bates study to develop a complementary data set that supports international comparison. This link provides added value in two ways: firstly the collaboration gives us a “flying start” in terms of research protocol and analysis tools; secondly, it makes possible an international comparison that will give additional insights into the English data, and into possible interventions to reduce error in England.

To provide basic information on current practices in infusion pump management, such as whether pumps are standardised across a hospital or not, whether pumps are managed centrally or locally (in wards), whether smart pump technology is used in particular areas or hospital-wide, and whether smart pumps are used with hard or soft limits, we are in the process of conducting a survey of Trusts in England. At the time of writing, 38 responses have been received, representing 113 hospitals. Of those, 40% report using some form of smart pump technology in at least some clinical areas, and 29 respondents have expressed an interest in participating in future studies; both data collection and analysis are ongoing.

6 Specific aims of the study

6.1 Primary research question

How is IV medication (broadly understood to include IV fluids, blood products and nutrition where delivered intravenously) infused in UK hospitals, how often and why do errors occur in this process, what are best practices, and what is the likely impact of smart pumps on patient safety?

6.2 Aims and Objectives

The aims of ECLIPSE are to describe the rates, types, clinical importance and causes of errors involving infusion of IV medication in English hospitals, and to make recommendations for interventions with greatest potential for reducing harm from these errors.

More specific objectives of ECLIPSE are:

1) To describe how IV infusions are administered in a sample of 14 English hospitals plus additional specialist paediatric and oncology units, focusing on differences in terms of nursing practice, equipment, policies and processes, both within and between hospitals.
2) In our sample of 14 hospitals plus additional specialist units, to describe the rates, types, and clinical importance of errors associated with the following modes of infusion delivery, in critical care, general surgery, general medicine, paediatrics and oncology:
   - Gravity administration
   - Standard infusion pumps and syringe drivers
   - "Smart" infusion pumps and syringe drivers (with both hard and soft limits)
3) To explore variance in the rates, types and clinical importance of errors in relation to:
   - Mode of infusion delivery
   - Clinical area
4) To explore the causes of the errors that occur and the extent to which innovations in technology or practice, such as the introduction of smart pump technology, electronic prescribing or bar code readers could have prevented such errors.
5) To identify best practices in safe and effective IV medication administration across different hospital contexts, including issues that are important to patients as well as staff.
6) To establish how the findings differ from those of the ongoing US study, led by Bates, and to explore the reasons for any differences identified.
7) To propose recommendations to prevent IV medication errors across different hospital settings within England.

We consider it premature to include a trial to evaluate the clinical effectiveness of the resulting recommendations within ECLIPSE, as details of any such trial would be dependent on our findings. We will therefore identify suitable interventions and assess the feasibility and likely value of a trial to test these interventions as further work.

7 Study Design

The following sections outline the study design for each of the three phases of the project.

7.1 Phase 1

Phase 1 will comprise a quantitative study of the infusion of intravenous (IV) medication at 14 hospital sites plus additional specialist units, as described in more detail below. Phase 1 activities are shown in Table 1.

Table 1: Activities for Phase 1.

Activity	Activity / milestone
A	Ethical review preparation started once funding is confirmed.
B	Organise and run opening workshop on the principles and purpose of the study, to be run with representatives of up to 25 candidate hospitals. Organise and run a PPI workshop to involve patients in exploring consent issues and generating research questions to ask in Phase 2. Install and test REDCap data gathering tool.
C	Plan and run training for first two sites. Coordinators arrange access at their local sites. Data gathering at first two sites to start once ethics and research governance approvals in place.
D	Plan and run training for remaining sites. Coordinators arrange access at their local sites. Complete data gathering at these sites
E	Data analysis. Two papers published (one on English study; one on international comparison)
F	Context evaluation and feedback to participating sites.

7.1.1 Design and theoretical/conceptual framework:

Phase 1 of the proposed study mirrors and extends an ongoing study involving ten hospitals across the US. This study, in turn, replicates one conducted at a single hospital by Husch et al (2005). Data gathering involved recording the state of every infusion across the hospital at one point in the nine hours during which data gathering took place, and also recording the corresponding details from the medication administration record. All the errors were classified using the US National Co-ordinating Council for Medication Error Reporting and Prevention (NCC MERP) severity rating system (http://www.nccmerp.org/). As summarized above, that original study found an error in 66.9% of the 426 infusions observed (many of these errors were deviations from protocol that were assessed as being unlikely to cause patient harm). Of the 16 most serious errors (NCC MERP category D and above), only one was judged to be preventable using smart pump technology. Findings were reported in terms of descriptive statistics.

The ongoing Bates study replicates the method of the Husch et al (2005) study, but gathers data from multiple US hospitals, focusing on particular wards within those hospitals. In the Bates study:

- Ten US hospitals have been selected to participate, covering variations in hospital type and infusion practices. At each, a site coordinator has recruited two clinicians with different backgrounds (e.g. a nurse specializing in post-surgical care and one in

oncology) to do the data gathering, and those clinicians have been trained in the details of the data collection process.
- Within each hospital, four areas for data gathering have been identified: a medical ICU, a surgical ICU, a medical ward and a surgical ward.
- A data collection tool has been implemented using the REDCap software (Harris et al, 2009).
- Data collection has just been completed across all ten sites, and analysis is underway (June 2013).

The Bates team have made available to us:

- Their research protocol and all supporting documentation.
- Their training materials.
- Their data gathering tool.

Although all of these will need some adaptation for the English context (and the kinds of adaptations that we find necessary will, themselves, be a valuable source of information on some of the differences between US and English clinical practices and research culture), they represent an excellent starting point that gives immediate added value to the project. Further, while the primary data analysis for the English data will focus on the situation in England, we will also work directly with the Bates team on a comparative analysis of the two datasets, as described below. We have agreed that papers using the Bates protocol and tool will be co-authored with them.

This study extends the protocol of the Bates study by conducting interviews and focus groups with hospital staff after the analysis of the point prevalence study (see Activity F in Table 1). This will open up a dialogue with staff to talk about the results and the reasons for those results. This not only provides them with a channel for feedback but it will provide data to contextualise the results. We will aim to interview 4 staff from each site. These could include ward managers familiar with processes, nurses familiar with practice, device trainers familiar with training procedures, and safety and procurement staff for their experience and expertise. Interviews and focus groups will be recorded where consent is given. They will be transcribed, anonymised and analysed using qualitative data analysis techniques to recognise active and latent conditions that positively and negatively impact errors and performance.

7.2 Phase 2

This phase of the project will explore interesting contexts and practices from Phase 1 more deeply, so we are able to describe how practices differ and identify what aspects of the sociotechnical system have positive and negative effects on error types and rates. In Phase 2, the focus will be on developing a rich understanding of the factors that influence performance around IV medication administration. Phase 2 activities are shown in Table 2.

Table 2: Activities for Phase 2.

Activity	Activity / milestone
G	In-depth observational / interview studies at 2 sites in parallel
H	In-depth observational / interview studies at 2 further sites
J	In-depth observational / interview studies at 1 further site

7.2.1 Design and theoretical/conceptual framework:

Phase 2 will be a qualitative study based on observation and interviews. The point prevalence and context evaluation results of Phase 1 will be used to identify 5 areas (e.g. wards) for more detailed study (4 person-months per area). These will be selected on the basis of the most practically and theoretically interesting comparisons, e.g. where different kinds of errors or practices have been found. We will aim to include at least one using smart pumps with hard limits and one with soft limits. Our researchers will observe staff administering IV medication and setting up pumps in the study wards, supplemented by interviews, to further understand why certain errors occur within each context. The researchers will also establish what information, if any, patients are given about their infusion, what information they would like and if they have any interactions with the pump or infusion process. This will address objectives 4-5 (presented earlier) by examining the causes of error that occur (and whether smart pump technology could have prevented the errors), exploring the occurrence of, and reasons for, any workarounds in practice; and identifying best practices in safe IV medication administration.

Our data gathering and analysis will be driven from a human factors and sociotechnical system perspective. This emphasises how the safety and performance of a system is an emergent property of the ways the people, policy, practices, artefacts and equipment combine within it. This is consistent with system perspectives on human error, which look at the system rather than the individual. Our team has extensive experience in researching human error through controlled experimental studies (e.g. Li et al, 2008) and observational studies (e.g. Furniss et al 2011a). We give special attention to human-computer interaction (HCI) aspects, which emphasise the design, role and usability of technology in the sociotechnical system. We are leading methodological and theoretical development in 'distributed cognition' which have been used to help investigate the complexities of sociotechnical systems (e.g. Furniss & Blandford, 2006; Rajkomar & Blandford, 2012). By developing a better understanding of the system through observations and interviews, taking a 'distributed cognition' perspective, we have been able to situate error, reflect on its significance, and propose improvements to device design (Furniss et al., 2011a; Furniss et al., 2011c).

As a complementary perspective, we have explored 'resilience' and contributed theory on 'resilience strategies' which switches the focus from errors and what has gone wrong to the adaptive and intelligent ways that the system goes right (Furniss et al., 2011b, Furniss et al, 2014a). This theoretical perspective has been applied to nurses using infusion pumps in a Haematology and Oncology Day Care Unit, where different resilience strategies were observed such that some errors were prevented before they happened and others were recovered from when they occurred (Furniss et al., 2011d). These themes and others will be explored further in phase 2 of ECLIPSE. For example, in some situations the patient can have a role in infusion administration such as turning off alarms, advising the nurse on adjustments and nuances to their prescribed treatment, and checking for errors; however, the patient's role is neglected in the medical device literature (Furniss et al., 2014b). We are addressing this oversight by including

patients as participants. These patient-centric findings have the potential to inform practice through better consideration of the user.

7.3 Phase 3

The final phase of ECLIPSE focuses on synthesising and sharing findings from Phases 1 and 2, and making recommendations for future policy and practice. Findings will be compared across sites and with those of the on-going Bates study, triangulating between qualitative and quantitative findings and drawing out generalisations and contrasts across study contexts. We will hold at least three workshops with stakeholders in the NHS, manufacturers and patients. Phase 3 activities are shown in Table 3.

Table 3: Activities for Phase 3.

Activity	Activity / milestone
K	Draft report on clinical best practice in training, procurement and practice in infusion therapy. Work with the original participating hospitals and units to evaluate recommendations.
L	PPI workshop on disseminating findings effectively and responsibly. Further dissemination to the public will be shaped by this workshop.
M	Cross-site comparison. Prepare paper comparing practices and outcomes across the UK sites. Finalise and disseminate recommendations.
N	Convene workshop(s) for stakeholders across the NHS to disseminate findings (including production of brochures for procurement and policy)
P	International comparison. Prepare paper comparing practices and outcomes internationally.
Q	Workshop for manufacturers to present findings and discuss implications for future device / systems development.

7.3.1 Design and theoretical/conceptual framework:

In Phase 3 findings will be compared across sites and with those of the on-going US study, a report will be produced and the findings disseminated in the form of academic conference and journal papers. At a national level, we will work with the authors of the national IV guide (MEDUSA) and members of NAMDET (National Association of Medical Devices Educators and Trainers) to inform generalizable recommendations. Brochures will also be developed to guide procurement and future planning. Workshops with NHS stakeholders and manufacturers will be held to disseminate the findings from previous phases and based on these develop recommendations together with participants. A further PPI workshop is planned to ensure that patients are consulted about the most effective and sensitive ways for disseminating findings to the wider public. Phase 3 will address objectives 6-7 by establishing how the findings differ from those of the on-going US study and proposing recommendations to reduce IV medication error rates.

8 Study Groups

8.1 Phase 1

Hospitals will be invited to participate on the basis of the survey we are currently running to establish infusion device use across England; we will choose hospitals to represent a range of different practices. The survey aims to find out what types of devices are being used across areas, how they are managed and the extent to which smart pump technology is being used. In order to maximise differences between each site, selected hospitals will differ in terms of type, size, geographic location, NHS/private, standardisation of infusion devices and use of smart pump technology. Criteria will include that they:

- Are provisionally interested in participation
- Are representative of a wide range of hospitals:
    - Teaching / Non-teaching Hospitals
    - London / regions / provincial
    - Extent of use of smart / pump / gravity / syringe drivers
    - Range of suppliers of volumetric infusion pumps and syringe drivers
    - More general technological maturity (use of electronic prescribing, bar-code readers, integrated electronic health records, etc.)
    - Greater or lesser evidence of a strong patient safety culture (as indicated through measures such as implementation of patient safety alerts (AVMA, 2011) and NRLS Organisation Patient Safety Incident Reports)
    - Clinical specialties: tertiary / secondary referral centres [recognising that specialist hospitals may only provide certain kinds of care]

8.2 Phase 2

Sampling in Phase 2 will depend on the results of the initial point-prevalence study and contextual interviews (Phase 1). Five wards or sites will be selected for detailed study. They will be chosen based on:

- Local interest in participating
- Practical and theoretical interest of findings – e.g. fewest / most errors relative to number and complexity of administrations; unexpected types of errors; most severe errors.
- Maximum variation sampling (in terms of types of technology maturity, safety culture, clinical specialisms, etc., as in phase 1). In particular, at least one site will be using smart pumps with hard limits, one using smart pumps with soft limits, and one will not be using smart pumps.

8.3 Phase 3

We plan to involve three groups in separate workshops in this phase: stakeholders in the NHS, e.g. clinicians who participated in phases 1 and 2, Medical Device Safety Officers and Medication Safety Officers; representatives from manufacturers of IV infusion related equipment, e.g. infusion pump manufacturers; and patients who have experience of receiving IV infusions in hospital.

9 Recruitment

9.1 Phase 1

Participants from 25 hospitals/trusts will be invited to participate in a preparatory workshop (activity B in table 1); these will be the potential local coordinator and someone with patient safety responsibilities. The workshop will be informative about the issues, the study, the costs and benefits of participation. It will also be an opportunity to resolve any remaining questions about the detailed practicalities of data gathering and how clinicians and patients are informed about the study. From the 25 involved in the initial workshop, 14 will be selected for the study, based on the criteria outlined above. We will aim to include 8 hospital sites using smart pumps with dose error reduction systems (DERS), plus 6 which are not using DERS. In addition, we aim to include two children's hospitals.

Sampling:

In each participating hospital we will study three clinical areas (critical care, general medicine, general surgery). This set has been chosen to provide broad coverage across care areas while also mirroring as closely as possible the Bates study, recognising that UK hospitals do not typically have separate medical and surgical ICUs. However, we will also include additional paediatric and oncology areas, since these are areas where, at least anecdotally, errors are both more likely to occur and to have greater consequences. We will aim to study a paediatric and/or oncology area in 8 of the 14 hospital sites as above, plus 3 clinical areas (critical care, general surgery and general medicine) in each of two specialist children's hospitals, and a further six specialist oncology units representing a range of models of care. Depending on the sizes of wards and the prevalence of IV infusion use in that ward, an "area" may include multiple wards in which patients are receiving similar kinds of care. The aim will be to gather data from every infusion that is being administered to a patient at the time at which that patient is sampled, and to sample all occupied beds within a ward once during the day of data gathering. Wards will be selected with the aim of gathering data from 30-40 infusions during a day of observations (4-5 observations per hour).

We anticipate that this approach will yield data on approximately 2,100 infusions across the study sites. As noted above, O'Grady and Franklin (2006) identified an error rate of 14%. In addition to the medication errors identified, there were various procedural errors and Husch et al (2005) identified infusion rate errors in 37 cases (8% of all infusions). Taxis and Barber (2003) identified an overall error rate of 8%. We therefore anticipate an error rate of approximately 10% which translates to 210 errors in our 2,100 infusions with a precision of 1.29% and a 95% confidence interval of 8.71 to 11.29%.

Following the tradition established by Husch et al (2005), we will therefore be able to report a descriptive picture, and be able to compare, for example, critical care vs other wards, and use of smart pumps vs traditional ones, but will not seek to perform more complex multivariate analyses. Rather, the aim will be to use the quantitative analysis as a basis for better understanding contributing causal factors, through subsequent interviews and in-depth observations.

Every patient on IV medication on the days when observations are conducted on the chosen wards will be a potential participant. Patients will not receive payment for having details of their IV administration recorded. On approaching the patient the site observers will introduce themselves as appropriate and explain that they studying the quality of IV administration on the ward. The patient will be offered an information sheet if they would like further details about the work – see appendix for patient and staff information sheets.

The site coordinator will recruit two site observers. The site coordinators and the observers will receive training and an information sheet about their role (see appendix for information sheets). Contracts will be arranged to pay the site for the time the coordinator and observers spend doing the study.

The site coordinator will negotiate access to wards with the relevant ward managers. The site coordinators will seek written informed consent to conduct the studies from each ward manager (see appendix for information sheets and consent form). A staff information sheet will be available for staff wanting more information on the day of the observations (see appendix for patient and staff information sheets).

The site coordinator will arrange access to relevant staff for Activity F, which includes feedback of results and contextual interviews or focus group. An interview will last up to an hour, and a focus group up to two hours each. Interviews and focus groups will be conducted and recorded with informed consent by researchers on the project (see appendix for information sheets and consent form). Participants will not be paid. Sharing and reflecting on the study's findings should be of interest and value to the participant.

9.2 Phase 2

In our previous observational studies we found that we reached data saturation about 8 to 12 days into the study, using a mixture of direct observations of infusion administration, incidental observations of the ebb and flow of the ward, and informal chats with nursing staff during any down time. In phase 2 these observations will be complemented by more formal interviews with staff and patients.

Sampling:

Based on our previous experience, we expect to spend about two weeks data gathering in each of the five wards selected in Phase 2. In this time frame we would expect to directly observe 40 infusions being administered, have completed 50 hours of ward observations, 10 interviews with staff, and 10 interviews with patients. These figures are approximate as some contexts might not have as many infusions to observe as others, and some contexts will have patients that are unconscious or too unwell to be interviewed.

9.3 Phase 3

Data collection in this phase will be conducted through workshops, e.g. stakeholders in the NHS, manufacturers and patients.

Sampling:

Stakeholders in the NHS's workshops – these will be driven by theoretical and practical need, practical constraints and opportunity. For example, we are in discussion with NAMDET and NHS England to co-host talks and workshops for people like Medication Safety Officers and Medical Device Safety Officers. We also want to include stakeholders at sites who participated in phase 1.

Manufacturers' workshops – we have established contacts with leading manufacturers during the course of the project.

Patients' workshops – we recruited patients for a PPI workshop at the beginning of the project and would like to invite these patients back for a second workshop at the end of the project. We might also expand attendance by inviting patients who were interviewed in Phase 2 or patient representatives more widely.

10 Data

10.1 Phase 1

10.1.1 Data to be collected

10.1.1.1 Point Prevalence Study

Data gathering at each hospital will be devolved to the local coordinator, who will negotiate access to each clinical area and recruit a local nurse and pharmacist to do the data collection. These people will be trained based on the Bates protocol, including the various types of errors, using materials made available to us by the Bates group. Where possible, training will be face-to-face, but may be done remotely, using video link, for hospitals far removed from London. The local team will compare medication being administered with the medication, dose and rate prescribed to identify any discrepancies. For each of our clinical areas local investigators will follow this procedure:

- Obtain consent from the ward manager ahead of time and negotiate a date with them for data collection. Data collection dates will not be advertised more widely with ward staff so as to minimise possible changes in practice around the date of data collection.
- Provide information sheets (reviewed in the PPI workshop) for patients, and for any staff who request more information on the day of data collection.
- Enter the ward and move systematically around it, gathering data from each occupied bed once. If a patient is absent or being attended to then return when convenient.
- At each bed, record settings for every infusion device that is running. Data to be collected includes: whether they have a wristband, whether the wristband is correct, IV drugs and fluids, doses, rates, start times, expiry dates, whether a drug library has been used, if the drug is through the correct channel, and if the tubing is labelled in accordance with site procedures.
- Access the patient's medication administration record / prescription chart, and note details of all medications that should be being administered intravenously. Relevant data such as patient allergies to IV drugs will also be recorded.
- Nurse and pharmacist work together, each checking the data collected with the other.
- If a discrepancy between prescription and infusion is identified then record full details, and unobtrusively consult responsible nurse about it. Staff should be familiar with the project protocol for observing suspected errors (see appendix).

- Enter all data into REDCap tool (see below).
- Perform initial severity assessments for any errors identified.

Observations in each ward / unit will be made in a single day, with 8 hours per day. To identify and resolve issues in data gathering and analysis early on, training and data gathering will be completed at two sites before being extended to all other sites. The research team will oversee this activity, working with the site coordinators.

10.1.1.2 Analysis: Identifying error type and frequencies

To confirm that an error was present, both investigators will have to agree that an error has occurred. We will classify each error by type (Table 2). Multiple errors can occur in a single infusion. A standardised form will be used by observers for data collection and the data will be uploaded to a central REDCap database to enable cross-site comparison.

To facilitate comparison with the study of Bates et al, the severity of each error will be classified according to the NCC MERP index for categorizing medication errors. These categories, in ascending order of severity, range from capacity to cause error (A), through errors likely to cause temporary harm (E), to errors that would be likely to have resulted in death (I). The assigned severity rating will be based on the potential for the error to have resulted in patient harm if it had not been intercepted.

In line with Bates et al's study, procedural errors such as "no documented rate on medication label" or "missing patient identification bands" will be assigned a rating of "C" (an error occurred that reached the patient but did not cause harm). All other medication administration errors will be assessed based on the professional judgment and consensus of the local data collection team. Where agreement cannot be reached, a third investigator will review the event.

All errors assigned a severity rating of "D" or greater will be independently reviewed by members of the project team. The reviewers will be blinded to the original ratings. Final assignment of severity rating will be determined only after consensus among research team members and the original evaluators.

Table 2: Definitions of error types

Error Type	Definition
Medication administration errors	
1. Wrong Dose	The same medication but the dose is different from that prescribed.
2. Wrong Rate	A different rate is displayed on the pump from that prescribed. Also refers to weight-based doses calculated incorrectly including using the wrong patient weight.
3. Wrong Concentration	An amount of a medication in a unit of solution that is different from that prescribed.
4.Wrong Medication	A different fluid/medication/diluent as documented on the IV bag label is being infused compared with that prescribed.
5. Known Allergy	Medication is prescribed/administered despite the patient having a documented allergy or sensitivity to the drug.
6. Omitted Medication	The medication ordered was not administered.
7. Delay of Rate or Medication/Fluid Change	An order to change the medication or rate not carried out within 4 hours of the written order or per local policy.
8. No Documented Order	Fluids/medications are being administered but no order is present in medical record. This includes failure to document a verbal order.
Procedural errors	
1. No Rate Documented on IV Label	Applies both to items dispensed by the pharmacy and ward stock items (depending on local policy).
2. Incorrect Rate on IV Label	Rate documented on the medication label is different from that programmed into the pump. Applies both to items dispensed by pharmacy and ward stock items (depending on local policy).
3. Patient Identification Error	Patient either has no identification (ID) band on wrist, or information on their ID band is incorrect.

In parallel, we will also use an established method for assessing the severity of medication administration errors which we have developed and validated in the UK (Dean and Barber, 1999) which involves four experienced health care

professionals each assessing each error on a scale of 0 to 10, where zero represents an error with no potential consequences to the patient and ten an error which would result in death. The mean score across the four judges is then used as an index of severity. Use of the two different methods for assessing errors' severity will also allow us to compare the severity classifications obtained using NCC MERP with the scores obtained using the more time-consuming but potentially more robust Dean and Barber method.

The data will be analysed by calculating error rates in relation to site, clinical area and mode of delivery (e.g. gravity feed, type of volumetric pump). A cross-comparison with US data will also be carried out. This will involve:

- systematically reviewing all the data for each of the hospitals involved across the two countries, checking them for comparability,
- merging data where necessary (e.g. English hospitals do not typically separate medical and surgical ICUs, whereas that is common practice in the US, so the US data on different kinds of ICUs will be aggregated for comparison),
- removing data that is not comparable (e.g. the US study does not include paediatric wards or oncology units, whereas we propose to include these in the England study), and
- repeating the comparative analysis process (as already performed on the separate datasets) on the resulting dataset.

We have been working closely with the Bates group to ensure that a cross-cultural comparison will be facilitated by using similar forms, database, definitions of error types and definitions of error severity. Due to the nature of the study, Phase 1 will not require written consent from ward staff or patients but permission will be sought from the ward manager before collecting data within ward areas.

10.1.1.3 Post-study Contextual Interviews (Activity F)

Once data gathering in the point-prevalence study is complete, and analysis has begun, we will work directly with key staff in the participating hospitals and other specialist units to share our findings and better understand explanatory factors behind those findings (e.g., nursing practice, equipment, policies and processes, staff management, training and competency assessment in numerical and related skills). This will involve two-way dialogues with relevant members of staff including ward managers, senior nursing staff, patient safety specialists, medical electronics personnel, trainers, those with responsibility for procurement, and senior managers. These meetings will, where informed consent is given, combine report-back with recorded interviews or focus groups. These will focus on the participant's view of local policy and practice, their views on what works well and what changes are under consideration, and how we can present our findings to maximise learning, both locally and nationally, without compromising the confidentiality of either individuals or particular hospitals or Trusts.

10.1.2 Data handling and record keeping

10.1.2.1 Data transfer (handling, processing and storage)

For the point prevalence study, data from comparing prescriptions and administration of IV medication will be collected by the site observers in accordance with Section 11.1.1. This data will be entered into the REDCap tool

for statistical analysis, and the Chief Investigator, Ann Blandford will act as the data controller of such data for the study. This is expanded on in Section 11.2.2 below.

For Activity F, interview and focus group data will be collected by researchers on the project team in accordance with this protocol. The audio data will be put on a password protected computer before leaving the site. The data will be transcribed using a reputable and professional transcription service. The transcription will be anonymised and the original audio file will be deleted. The transcription will be stored on UCL password protected machines for qualitative analysis, and the Chief Investigator, Ann Blandford, will act as the data controller of such data for the study. This is expanded on in Section 11.2.3 below.

The Chief Investigator will process, store and dispose of data for the point prevalence study and Activity F in accordance with all applicable legal and regulatory requirements, including the Data Protection Act 1998 and any amendments thereto.

10.1.2.2 Point Prevalence Study

The protocol in Section 11.1.1 will be followed for data gathering. We are not interested in patient information other than to facilitate the collection and checking of IV administration data. Site observers will temporarily record the name and medical record number of patients when they are at their bedside in a notebook. They will use the name and medical record number to look up their medication orders to compare what is ordered with what is infusing at the bedside. They will not record their name, medical record number or any personally identifiable information in the database and they will dispose of the paper that they use to temporarily record names securely before they leave the clinical unit on the day they make rounds. After the observation sessions, site observers will be reminded not to record names or any type of identifier and no identifiers will be kept by the research study staff.

Site observers at each site will enter data into REDCap. The REDCap tool (www.project-redcap.org) is a widely used, secure and flexible web-based data collection tool used by hospitals and universities, including NIHR biomedical research units and UCL. The REDCap form will request study data which does not contain any personally identifiable information. Where free forms boxes exist, e.g. for notes and extra information, site observers who enter the data will be reminded not to record any personally identifiable information. This data, across all sites, will then be accessible for analysis by the research team.

10.1.2.3 Post-study Interviews (Activity F)

Where interviews and focus groups are recorded they will be transferred on to a password protected and encrypted laptop, and the original unprotected audio recording will be deleted, before leaving the site.

Recorded interviews and focus groups will be transcribed using a reputable and professional transcription service. After they have been transcribed the research team will anonymise them and the original audio file will be deleted. Each transcription will be coded so the research team can identify which transcription corresponds to which person at which site, i.e. pseudo anonymisation. The

master file to unlock this coding scheme will be encrypted and stored on a password-protected computer. Consent forms from these interviews and focus groups will be stored centrally at UCL in a locked filing cabinet controlled by the Chief Investigator.

10.1.3 Archiving

UCLH and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol).

The Chief Investigator confirms that she will archive the study master file at UCL for 5 years from the study end.

The Principal Investigator at each participating site agrees to archive his/her respective site's study documents for 5 years from the study end.

10.2 Phase 2

10.2.1 Data to be collected

Data collection will be focused on observational and interview data. Our researchers will observe staff administering IV medication and setting up pumps in the study wards, supplemented by interviews with staff with a variety of roles (managers, training and device maintenance, nurses and other staff who use infusion pumps and administer IV medication) to further understand why certain errors and practices occur within each context. Patients will also be interviewed to investigate their experience of, and role (if any) in, their infusion administration. Extensive field notes will be kept, interviews will be audio recorded with consent and photographs will be taken of contexts, devices and artefacts to support the analysis. Written consent will be sought from the ward manager while verbal consent will be required from individual staff during observation. Written consent will be obtained for formal interviews with staff and patients. An information leaflet about the observational study, with researcher contact details, will be created for distribution amongst staff and patients within the clinical areas taking part.

Data collection (and analysis) will focus on:

- social interactions around technology, including whether patients are involved in the set-up of IV administrations, e.g., what they are told about their medications and how alarms are responded to.
- what workarounds staff employ to achieve their goals with technology. Where soft limits are used on smart pumps, this will include whether, when, how and why staff work around those limits.
- How different technologies such as pumps, barcode readers, computerised physician order entry systems (CPOE) and vital signs monitoring devices are used together, and how each contributes towards patient safety.

Different modes of data gathering will be used flexibly to fit with working practices. These modes are outlined below.

Mode 1: Scheduled interviews with clinical staff. This will involve semi-structured interviews with clinical staff addressing issues and activities to

do with the administration of IV infusions. Interviews will be audio recorded if the participant has given consent to do, otherwise notes will be taken. The interviews will be organised with staff to minimise disruption to their work. The interviews will be conducted in private in a quiet room.

Mode 2: Informal conversation with staff between tasks and during quieter periods. This will involve talking to staff when there are naturally occurring breaks and lower quantities of work. This will generally focus on clarifying observations the researcher has made. Field notes will be taken.

Mode 3: Interviewing patients at the bedside. This will involve semi-structured interviews with patients around issues and activities to do with the administration of IV infusions. Written consent will be sought. Where permission is given the interview will be audio recorded, otherwise notes will be taken. All data will be anonymised for analysis and subsequent reports.

Mode 4: Photographs of medical devices and their situations of use will be taken. These will not focus on people, e.g. photos of medical devices will be taken when the heads and faces of people are out of shot.

Mode 5: Observing 'everyday' practice at the wards. This will involve observing staff and patients, their workflow, and their use of medical devices. The focus is on IV infusions, but these have to be understood in context.

Mode 6: Work-shadowing clinical staff. This will involve observing the working practices of clinical staff, particularly focusing on tasks to do with the administration of IV infusions, e.g. this might include calculating infusion rates, setting up devices, changing device settings, or performing the closing stages once a device has been used and finished with. Who to shadow and when will be agreed with the ward manager and staff involved.

10.2.2 Data handling and record keeping

Extensive field notes will be kept from the observational work in Phase 2, but the full names of people will not be recorded. Photos will focus on physical spaces and the arrangement of equipment. They will avoid identifiable shots of people and identifiable information on the ward, i.e. heads, faces and documents will be avoided, and where possible people will be entirely excluded from photos. The photos will be kept on a password protected and encrypted laptop.

Where interviews are recorded they will be transferred on to a password protected and encrypted laptop, and the original unprotected audio recording will be deleted, before leaving the site.

Recorded interviews will be transcribed using a reputable and professional transcription service. After they have been transcribed the research team will anonymise them and delete the audio file. Each transcription will be coded so the research team can identify which transcription corresponds to which person at which site, i.e. pseudo anonymisation. The master file to unlock this coding scheme will be encrypted and stored on a password-protected computer. Consent forms from these interviews and focus groups will be stored centrally at UCL in a locked filing cabinet controlled by the Chief Investigator.

10.2.3 Archiving

UCLH and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol).

The Chief Investigator confirms that she will archive the study master file at UCL for 5 years from the study end.

10.3 Phase 3

10.3.1 Data to be collected

The workshop activities and discussions will be audio recorded with participant consent. The workshops will be focused on the dissemination of the findings from previous phases and based on these develop recommendations together with stakeholders. Notes will be made and photos will be taken of any artefacts produced at the workshop, e.g. flip charts and PostIt Notes.

10.3.2 Data handling and record keeping

Notes will be summarised into digital form. Photos will be transferred to a password protected and encrypted laptop. Where workshops are audio recorded they will be transferred on to a password protected and encrypted laptop, and the original unprotected audio recording will be deleted at the end of the workshop.

Depending on the quality of data from the workshops audio recordings will either be summarised and deleted or transcribed using a reputable and professional transcription service. If they are transcribed the research team will anonymise them and the original audio file will be deleted. Each transcription will be coded so the research team can identify which data corresponds to which person at which workshop, i.e. pseudo anonymisation. The master file to unlock this coding scheme will be encrypted and stored on a password-protected computer. Consent forms from these workshops will be stored centrally at UCL in a locked filing cabinet controlled by the Chief Investigator.

10.3.3 Archiving

UCLH and each participating site recognise that there is an obligation to archive study-related documents at the end of the study (as such end is defined within this protocol).

The Chief Investigator confirms that she will archive the study master file at UCL for 5 years from the study end.

11 Statistical Considerations

This section is divided by the project's three phases.

11.1 Phase 1

11.1.1 Sample Size Calculation

The power calculation for this study was done in nQuery Advisor software (version 7.0), an industry standard software for Sample Size and Power

determination. Assuming an overall error rate of 10% in the UK (using the rate reported in the Husch's study (Husch et al 2005) and a precision of 1.29%, the proposed study would need 2100 observations to detect an error rate of 10% with a 95% confidence interval of 8.71 to 11.29%. With 490 observations in each area of critical care, general medicine and general surgery we would be able to detect an error rate of 10% with a 95% confidence interval of 7.34 to 12.66% (precision=2.66%). For the area of paediatrics, we would need 350 observations to detect a rate of 10% with a 95% confidence interval of 6.85 to 13.15% (precision=3.15%). With 280 observations in the area of oncology day care, we would be able to detect an error rate of 10% with a 95% confidence interval of 6.48 to 13.52% (precision=3.52%).

11.1.2 Analysis

For the point prevalence study, descriptive analyses will be performed on the data, which will compare different clinical contexts and different factors in IV medication administration.

For Activity F, qualitative data analysis will be performed to give a better insight into the findings, which will include developing an account of differences observed in the point prevalence study.

11.2 Phase 2

11.2.1 Sample Size Calculation

The sample size is based on our previous experience of conducting similar studies on CHI+MED, and our assessment of what is practically possible within our funding constraints and what will deliver both breadth and depth of analysis. Five sites will be chosen from those participating in phase 1. We expect to spend about two weeks data gathering to observe 40 direct infusions being administered, have 50 hours of ward observations, 10 interviews with staff, and 10 interviews with patients.

11.2.2 Analysis

Consistent with common forms of qualitative data analysis (e.g. Grounded Theory (Charmaz, 2006) and Thematic Analysis (Braun & Clarke, 2006)) we will explore themes and patterns that emerge from the observational and interview data. Data will be transcribed professionally and coded using Nvivo software will be used to manage the data and facilitate coding. Where applicable we will employ relevant human factors theory to gain further insight and give theoretical weight to our analysis. In particular, we expect to draw on theories of Distributed Cognition and Resilience as described above.

Findings will be reported back to local staff and managers, including local recommendations

Phase 2 will address objectives 4-5: exploring the causes of errors and workarounds, assessing whether and how innovations in technology or practice could affect performance and errors; and identifying best practices in safe and effective IV medication administration.

11.3 Phase 3

11.3.1 Sample Size Calculation

We have not specified a sample size for this phase but intend to hold at least three workshops with stakeholders in the NHS, manufacturers and patients. We expect to involve roughly 30 stakeholders from the NHS, at least four different leading manufacturers, and about 10 patients.

11.3.2 Analysis

Consistent with common forms of qualitative data analysis (e.g. Grounded Theory (Charmaz, 2006) and Thematic Analysis (Braun & Clarke, 2006)) we will explore themes and patterns that emerge from the workshop data. Data will be transcribed professionally and coded using Nvivo. Where applicable we will employ relevant human factors theory to gain further insight and give theoretical weight to our analysis.

12 Compliance

We do not have patients as subjects, who need to follow any new medical interventions or procedures to do with the study, and so their compliance to study procedures is not applicable at any phase of the study.

13 Ethical Considerations

This section is divided by the project's three phases.

13.1 Phase 1

This is an observational study of current practice with no change to patient care. There is extra scrutiny on IV administration so there is extra potential to catch errors that might otherwise have gone undetected. If IV medication errors are identified during site observation(s) the nurse will be discreetly notified about the error at the time of the observation so that it will be corrected.

If errors are suspected or observed, site observers and research staff should follow project's protocol: Protocol for observing suspected errors (see appendix). This protocol includes the establishment of a 'safety committee' to deal with ad hoc ethical advice for unanticipated issues.

At a local level the point prevalence study is like an audit of IV medication practice for each site. The sites then submit their results anonymously to the central research team for statistical analysis. So patients and their data only play a peripheral role at this stage of the project.

Patients are intentionally informed about the study's focus on quality improvement rather than errors as this could disturb them if they had not thought about the potential for error before. Asking them permission to record data about their IV administration and giving them an information sheet is polite, informative and proportionate to their level of involvement.

Full informed consent is disproportionate as their data is not being processed or stored for analysis, there is no change to their treatment, the work is done by

staff employed at the relevant sites, there is minimal risk to them and they could benefit from extra scrutiny on their medication administration. Furthermore, full informed consent would draw unwanted attention to why this quality improvement initiative was taking place and the topic of error, which could disturb patients.

If a patient is unconscious they will not be excluded from the study: their IV administration will be recorded and checked. We are not asking for patient's informed consent as they are only peripherally involved in the study and no data of theirs is processed. The extra scrutiny for unconscious patients could reveal undetected error, and this data is needed for a more complete picture for the study and quality improvement in the longer term.

Patient names and hospital numbers will only be recorded temporarily so their records can be cross-checked. This identifiable information will be disposed of securely once it is used. Furthermore, the REDCap tool will not afford the reporting of identifiable information and where it does (e.g. in free form text boxes) site observers will be reminded not to record it. This will ensure no personally identifiable information leaves the site. All study data will be accessed securely via REDCap. The Chief and Principal Investigators will oversee the overall data monitoring of the study and ensure that the study protocol of using de-identified data is followed.

Appropriate data management processes will be put in place so that results between sites are anonymous and kept secure (see Section 10.2). This minimises the risks of an identifiable 'error league table' between sites falling into the wrong hands. Appropriate reporting channels for each hospital will be identified, with assistance from the local Principal Investigator, to maximise learning and highlight good practice.

13.2 Phase 2

This qualitative study involves gathering information on the administration of IV infusions and related work practice through observations, interviews, and discussion. There are no interventions or changes to normal medical practice. The main risks and burdens to participants revolve around sharing information, which will remain confidential, and the potential inconvenience of observations. Observations should not be a burden and mitigating strategies include excluding sensitive cases from observation and not asking questions at inconvenient times.

- Clinical staff will be informed about the study and verbal consent will be sought prior to data collection.

- Given their indirect role, patients on the ward where observations are being made will be informed of the study verbally and offered a Patient Information Flyer, detailing what is happening and providing a channel to raise concerns, opt out of the observations, and to get more involved if they wish. Spending time with each patient to explain the study and seek informed consent would be a real cost in terms of patient time and has potential to disrupt the ward workflow. If patients choose to get more involved and discuss their experiences and opinions on IV infusions then informed consent will be sought. Their information will only be audio recorded with consent.

- No personal patient data will be collected where the patient has not consented, this includes patients that are asleep or unconscious.

- Approximately 10 semi-structured interviews per ward will be conducted with patients. Local nursing staff will identify patients for interview and will seek written consent..The interviews will be roughly half an hour in length. Any personal information will remain confidential. Audio recordings will be transcribed, anonymised and the original audio files destroyed.

- Approximately 10 semi-structured interviews per ward will be performed with clinical staff. The participants will be at different levels of seniority to get a broad perspective. The interviews will be roughly half an hour to an hour in length. Clinical staff will have the interview time factored into their working day so they do not miss their breaks and any personal information will remain confidential. Audio recordings will be transcribed, anonymised and the original audio files destroyed.

- Work-shadowing could seem intrusive to normal working practices, but staff will be reassured that we are not interested in their performance but want their help and expertise to find out how the system of IV infusion administration can be improved. Questions during work-shadowing will be directed at appropriate times to minimise disruption.

- It is important not to undermine the quality of care or the perceived quality of IV infusion administration, e.g. by emphasising flaws and error. The emphasis of the research will be on improving standards, particularly where staff and patients identify issues, which may include strategies they have developed to minimise error and best practices. Staff may become more sensitive to the possibility of errors and minor error. This should be viewed positively by staff and management as an improved awareness of risk is likely to make them more vigilant. The safety literature highlights that being 'sensitive to failure' is an important part of working safely.

13.3 Phase 3

The workshops will involve gathering information on the administration of IV infusions and related work practices. These will be conducted away from the clinical context and people will attend on a voluntary basis. The main risks and burdens to participants revolve around sharing information, which will remain confidential. Written consent will be sought from participants. Audio files will either be summarised and destroyed, or transcribed and destroyed. In both cases the remaining summary or transcription will be anonymised.

14 Finance and Insurance

Funding is secured from a £550k NIHR grant, from the Health Services and Delivery Research (HS&DR) stream. The study will be covered by NHS indemnity.

15 Reporting and Dissemination

Dissemination will take place throughout the project.

We will disseminate findings to practitioners using various strategies for building engagement. We will work closely with staff in participating hospitals to share findings through local seminars and through drafts of recommendations that will be refined through their feedback. Our experience in CHI+MED of developing and evaluating stakeholder documents will be a valuable foundation for this. In addition, we will organise two workshops in the latter half of the project: one focusing on healthcare professionals to disseminate and refine our recommendations, and one for other stakeholders such as manufacturers. The latter will build on connections that have already been established through our existing CHI+MED project, and will be informed by ongoing work in the US on the Infusion Systems Safety Initiative. We have established links with the Patient Safety group in NHS England, and will work with them where possible to ensure appropriate and effective dissemination.

As well as disseminating guidance through published documents, we will continue our practices (established in CHI+MED) of engaging the broader public through social media channels such as blogs (e.g. http://domfurniss.wordpress.com/, http://hciss.blogspot.co.uk/), twitter and youtube (e.g. http://www.chi-med.ac.uk/public/index.php#videos). We will develop patient-facing summaries of our results and recommendations.

Academic dissemination will include journal and conference publications, including papers to journals on patient safety (e.g. BMJ Quality and Safety), healthcare technology (e.g. Journal of Biomedical Informatics), and Human Factors (e.g. Human Factors Journal). This will include papers reporting the quantitative error study; a Human Factors paper; themed papers (e.g. comparing smart pumps and traditional infusion administration in terms of error rates and types); and papers comparing UK findings with those from the US.

Finally, our team are represented on key groups such as the Royal Pharmaceutical Society, the UK Clinical Pharmacy Association and the Guild of Hospital Pharmacists, and have established links with the Association of Teaching Hospital Pharmacists, and MEDUSA (the online IV administration guide used in many UK hospitals), providing further opportunities for dissemination of our findings and incorporation into practice. We have close links with the NIHR Imperial Patient Safety Translational Research Centre, where one of our co-investigators is a theme lead, and anticipate working with this Centre to aid further dissemination and translation of our findings

In order to ensure the impact of our research, we have planned pathways to target different groups, with different messages at different depths of engagement. For example:

15.1.1 IV infusion practice

1. The most immediate beneficiaries of our research will be the hospitals who participate in the study, and the patients that they treat. In order to achieve rapid local impact we will discuss findings with key staff in each hospital and deliver a written report relating to

each individual site for local use, which the hospitals will be able to use to inform changes of policy and procurement practice;
2. To influence IV infusion practice at a national level we will work with the authors of MEDUSA, the national IV administration guide, who work closely with Professor Franklin.
3. To impact infusion device training at a national level we will work with Paul Lee (Chair of NAMDET) to author an appropriate communication of our findings to NAMDET members. We will also present our findings at their annual conference;
4. To impact procurement and policy at a national level we will create printed and downloadable brochures that target procurement and policy concerns and summarise the main findings of this research;
5. We aim to raise awareness of these issues with practising clinicians by targeting peer-reviewed publications that they read, e.g. BMJ Quality and Safety;
6. To inform practice, design and procurement at an international level we will engage with the Infusion Systems Safety Initiative, hosted by AAMI. Pat Baird, systems engineer at Baxter Healthcare Corporation, who chairs this multidisciplinary group, is a member of the ECLIPSE Advisory Group. The Infusion Systems Safety Initiative includes manufacturers, clinicians, decision makers and researchers interested in the safety of infusion systems.
7. In order to influence future device design in the long term, our findings will feed into updates of CHI+MED stakeholder documents which will be sent to the primary manufacturers of infusion pumps.

15.1.2 Public engagement

8. We aim to raise awareness of the importance of human factors in medical technology through blogs, Twitter and YouTube, which are channels we have established on CH+MED.
9. We anticipate our findings contributing to a “guidebook” for patients being admitted to hospital that Professor Franklin is currently contributing to.
10. We will take advice through the planned PPI workshops on other means of disseminating findings to the public.

15.1.3 Academic impact

11. We aim to influence the international academic community through conference presentations and peer-reviewed publications describing current practice and the prevalence, causes and clinical importance of medication errors in IV infusions. Our collaboration with Bates’ group in Boston will facilitate academic dissemination.

We consider it premature to include a trial to evaluate the clinical effectiveness of the resulting recommendations within ECLIPSE, as details of any such trial would be dependent on our findings. We will therefore identify suitable interventions and assess the feasibility and likely value of a trial to test these interventions as further work. While it is not possible to give firm details at this stage, these are likely to focus on the types of pumps, the use of soft or hard limits, standardisation of practices, approaches to staff training, and the design of nursing protocols.

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