

Qualitative Protocol Development Tool

The research protocol forms an essential part of a research project. It is a full description of the research study and will act as a 'manual' for members of the research team to ensure adherence to the methods outlined. As the study gets underway, it can then be used to monitor the study's progress and evaluate its outcomes.

The protocol should go into as much detail about the research project as possible, to enable the review bodies to fully understand your study.

The use of this collated consensus guidance and template is not mandatory. The guidance and template are published as standards to encourage and enable responsible research.

The document will:

- Support researchers developing protocols where the sponsor does not already use a template
- Support sponsors wishing to develop template protocols in line with national guidance
- Support sponsors to review their existing protocol template to ensure that it is in line with national guidance.

A protocol which contains all the elements that review bodies consider is less likely to be delayed during the review process because there will be less likelihood that the review body will require clarification from the applicant.

We would appreciate self-declaration of how you've used this template so we are able to measure its uptake.

Please indicate the compatibility of this template with any existing templates you already use by stating one of the following on the front of each submitted protocol:

- **This protocol has regard for the HRA guidance and order of content; OR**
- **This protocol has regard for the HRA guidance; OR**
- **This protocol does not have regard to the HRA guidance and order of content**

Effects of user testing injectable medicines guidance – phase 1

FULL/LONG TITLE OF THE STUDY

Impact of systematic user testing of written guidance on the rate of moderate to severe errors made by hospital nurses during *in situ* simulation of the preparation and administration of an intravenous medicine: phase 1 – user testing

SHORT STUDY TITLE / ACRONYM

Effects of user testing injectable medicines guidance – phase 1

PROTOCOL VERSION NUMBER AND DATE

Draft 1.2
4th September, 2019

RESEARCH REFERENCE NUMBERS

IRAS Number:	235214
SPONSORS Number:	N/A
FUNDERS Number:	TRF-2017-10-006

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SIGNATURE PAGE

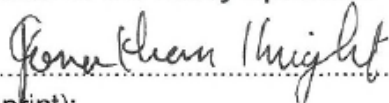
The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor’s SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature:



Date: 25/1/2018

Name (please print):

JONATHAN KNIGHT

Position:

PRO-VICE - CHANCELLOR RESEARCH

Chief Investigator:

Signature:



Date:

11/01/2018

Name: (please print):

Matthew Jones

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KEY STUDY CONTACTS

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Study Co-ordinator	See Chief Investigator
Sponsor	<p>University of Bath Contact: Prof Jonathan Knight Pro-Vice-Chancellor for Research University of Bath, Bath, BA2 7AY. Telephone: 01225 383162 Email: pro-vc-research@bath.ac.uk</p>
Funder(s)	<p>National Institute for Health Research, Trainees Co-ordinating Centre, Leeds Innovation Centre, 103 Clarendon Road, Leeds, LS2 9DF. Telephone: 0113 346 6260 Fax: 0113 346 6272 Email: tcc@nih.ac.uk</p>
Key Protocol Contributors	<p>Dr Matthew Jones, Chief Investigator (see above).</p> <p>Prof DK Theo Raynor School of Healthcare, Baines Wing, University of Leeds, Leeds, LS2 9JT. Telephone: 0113 3431228 Email: d.k.raynor@leeds.ac.uk</p> <p>Prof Margaret Watson Department of Pharmacy and Pharmacology, University of Bath, Bath, BA2 7AY. Telephone: 01225 386787 Email: m.c.watson@bath.ac.uk</p>

STUDY SUMMARY

Study Title	Impact of systematic user testing of written guidance on the rate of moderate to severe errors made by hospital nurses during <i>in situ</i> simulation of the preparation and administration of an intravenous medicine: phase 1 – user testing
Short title	Effects of user testing injectable medicines guidance – phase 1
Study Design	Iterative user testing interviews
Study Participants	Qualified nurses or midwives registered with the Nursing and Midwifery Council, who are accredited to prepare and administer intravenous medicines in an organisation providing NHS care and who have done this during at least 50% of working shifts during the past six months (or since authorisation if this was granted more recently).
Planned Size of Sample (if applicable)	30
Follow up duration (if applicable)	N/A
Planned Study Period	March to December 2018
Research Question/Aim(s)	<p>Research question (whole study): Is it possible to reduce the incidence of medication errors by improving the content, wording, structure and formatting of written documents providing technical information to health professionals?</p> <p>Objectives for the entire study are:</p> <ol style="list-style-type: none"> 1. To identify and resolve problems in a typical NHS Injectable Medicines Guide (IMG) monograph using systematic user testing. 2. To compare the rates of preparation and administration errors associated with use of the original and user tested IMG monograph. 3. To determine whether systematic user testing of the IMG is a cost-effective approach to improving patient safety. 4. To advise the IMG Advisory Board on generic lessons learned during user testing which could be introduced to the entire guide during the next revision cycle. <p>Only objectives 1 and 4 will be addressed during phase 1 of the study (this protocol).</p>

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FUNDING AND SUPPORT IN KIND

FUNDER(S)	FINANCIAL AND NON FINANCIAL SUPPORT GIVEN
National Institute for Health Research, Trainees Co-ordinating Centre, Leeds Innovation Centre, 103 Clarendon Road, Leeds, LS2 9DF. Telephone: 0113 346 6260 Fax: 0113 346 6272 Email: tcc@nih.ac.uk	£173,064
Prof Margaret Watson Department of Pharmacy and Pharmacology, University of Bath, Bath, BA2 7AY. Telephone: 01225 386787 Email: m.c.watson@bath.ac.uk	Research advice
Prof DK Theo Raynor School of Healthcare, Baines Wing, University of Leeds, Leeds, LS2 9JT. Telephone: 0113 3431228 Email: d.k.raynor@leeds.ac.uk	Research advice
Prof Bryony Dean Franklin UCL School of Pharmacy, 29-30 Brunswick Square, London, WC1N 1AX. Telephone: 020 7874 1280 Email: bryony.deanfranklin@ucl.ac.uk	Research advice
Dr Rebecca Kandiyali School of Social and Community Medicine, Office BG3/4 Oakfield House, Oakfield House, Oakfield Grove, Clifton, Bristol, BS8 2BN. Telephone: 0117 33 14088 Email: rebecca.kandiyali@bristol.ac.uk	Research advice

ROLE OF STUDY SPONSOR AND FUNDER

The funder had/will have no influence on the design, conduct, data analysis and interpretation, manuscript writing and dissemination of results associated with this study. The sponsor had/will have final approval on the design and conduct of this study, but no influence on the data analysis and interpretation, manuscript writing and dissemination of results associated with this study.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

Study Advisory Group

A Study Advisory Group will be established to:

- Provide advice and support
- Provide advice on current NHS priorities in this area
- Provide advice on current NHS practice in this area
- Oversee the completion of the project in accordance with the principles of Good Clinical Practice
- Advise and assist with dissemination of findings to NHS stakeholders

This group can be considered independent of the investigators and sponsor, as it will be chaired by a member who is not a researcher or employed by the sponsoring organisation.

As the participants in this study will be NHS nurses, members of the Study Advisory Group will also play a participant involvement role, by providing advice on study design, study documentation and recruitment. Additional advice on study document design and recruitment will also be sought from independent nurses.

Lay Advisors

Two lay advisors will be recruited to assist with the dissemination of the findings of this study to a lay audience. They will be invited to observe user testing and the *in situ* simulation phases of this study and to share their experiences via suitable lay forums. They will also assist with the dissemination of the final results of the study to a lay audience.

Individuals

Dr Matthew Jones, NIHR Transitional Research Fellow, University of Bath will act as Chief Investigator. He will lead and carry out all aspects of the design, conduct, data analysis and interpretation, manuscript writing and dissemination of results associated with this study.

Prof Margaret Watson, University of Bath will provide research support to the Chief Investigator by providing expert advice and mentoring in relation to all aspects of the design, conduct, data analysis and interpretation, manuscript writing and dissemination of results associated with this study.

Prof DK Theo Raynor, University of Leeds, will provide training supervision to the Chief Investigator by providing expert advice and mentoring in relation to the design, conduct, data analysis and interpretation, manuscript writing and dissemination of results of the user testing work programme of this study.

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Prof Bryony Dean Franklin, University College London, will provide training supervision to the Chief Investigator by providing expert advice and mentoring in relation to the design, conduct, data analysis and interpretation, manuscript writing and dissemination of results of the *in situ* simulation work programme of this study.

Dr Rebecca Kandiyali, University of Bristol, will provide training supervision to the Chief Investigator by providing expert advice and mentoring in relation to the design, conduct, data analysis and interpretation, manuscript writing and dissemination of results of the health economic analysis work programme of this study.

PROTOCOL CONTRIBUTORS

This protocol was written by the Chief Investigator (Dr Matthew Jones) with advice from Prof Theo Raynor (University of Leeds) and Prof Margaret Watson (University of Bath), research advisors for this study.

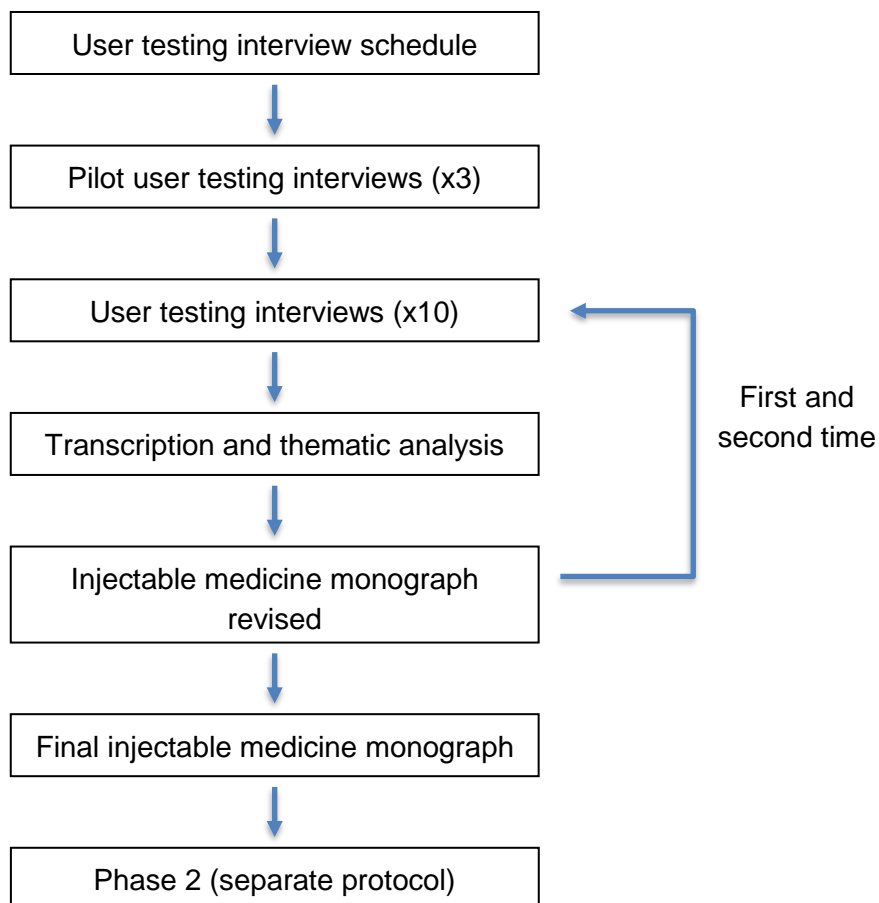
Potential research participants have been involved with the design of this study via the Study Advisory Group.

KEY WORDS:

Injections, Intravenous
Medication Errors
Guideline Adherence
Information Science

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STUDY FLOW CHART



STUDY PROTOCOL

1 BACKGROUND

There is little previous research investigating tools for preparing and testing technical information about medicines aimed at health professionals: only one study has been identified, which applied systematic user testing to improve the presentation of the Summary of Product Characteristics for two medicines^[1]. Thus no systematic review in this area is possible.

A considerable number of studies have been carried out in the related fields of patient medicines information and clinical guideline production. In these areas, systematic user testing has been shown to improve understanding and decrease reading time^[1-4]. Recently published guidance on the implementation of clinical guidelines recommends user testing^[5] and it is required in the development of patient information leaflets for licensed medicines^[4]. User testing is therefore the current “gold standard” method for improving patient information and the presentation of information to clinical guideline committees.

The major advantage of user testing is that it is based on potential users reading the document to locate key information and correctly use it to recommend appropriate actions and the reasons for them^[4]. Problems and potential solutions are therefore identified. Iterative rounds of interviews with potential users are followed by document revision, until all problems are resolved^[1,4,6]. Each interview involves direct questions to determine whether the interviewee can locate and use key points of information, followed by a semi-structured interview to explore opinions of more general issues (e.g. structure of the document, language used). This ensures that participants only give feedback once they have experience of using a document to locate information.

During phase 1 (outlined in this protocol), this study will investigate the application of user testing to the NHS Injectable Medicines Guide (IMG). Standard user testing methodology will be applied to revise the IMG monograph for a high-risk medicine. The “users” during this process will be hospital and community nurses who regularly prepare and administer intravenous medicines. In phase 2 (not part of this protocol), the study will then investigate the outcomes achieved as a result of user testing, by measuring the effect of this process on the occurrence of medication errors in a randomised *in situ* simulation experiment carried out with hospital nurses on duty in their usual clinical environment.

2 RATIONALE

Medication errors are a serious and persistent problem in all healthcare systems. The number of reported errors has increased year-on-year, to more than 100,000 in England and Wales^[7]. A review of reports between 2005 and 2010 found that 17% of errors resulted in patient harm, including 822 cases of death or severe harm^[7]. The incidence of errors is higher for injectable medicines, with systematic reviews suggesting an error rate of 35-50%^[8,9]. In November 2016, an alert was issued highlighting 2200 reports since 2013 of incidents with just one intravenous medicine (phenytoin), resulting in four deaths, five cases of severe harm and 121 cases of moderate harm^[10].

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In 2007, the National Patient Safety Agency required healthcare providers to provide protocols for the administration of injectable medicines^[11], such as the NHS Injectable Medicines Guide (IMG). This is used by nurses in more than 125 hospitals to guide the administration of individual doses and is accessed more than 1.5 million times per year^[12,13]. Such guidance must be written carefully, as difficulty finding relevant, unambiguous information in technical documents has been linked to serious medication errors^[14-16]. Systematic reviews of factors contributing to patient safety incidents therefore include contradictory, incomprehensible or poor quality information^[17,18]. It is therefore concerning that the IMG has been described as too detailed and confusing to likely users^[13,19]. This suggests that improvements to the presentation of the information in the IMG might result in fewer errors. Such concerns are shared by the IMG advisory board (Susan Keeling, IMG Project Manager, personal communication, 28/10/2016).

The IMG is therefore the ideal case study to use to investigate the wider question of whether improved written documents providing technical information to health professionals can reduce the incidence of medication errors.

As has already been discussed, systematic user testing is the gold standard approach for improving the quality of written documents. However, the effect of user testing medicines information on the behaviour of readers has not been previously investigated, as the previous studies outlined above have measured outcomes such as understanding and reading time^[1-4]. This study will therefore add to the understanding of the outcomes achieved by user testing, by measuring the effect of this process on the occurrence of medication errors.

3 THEORETICAL FRAMEWORK

Two theoretical frameworks underlie this study. The first is Reason’s Generic Error Modelling System (Figure 1), which was developed to categorise the psychological causes of human error in a variety of settings (including healthcare)^[20]:

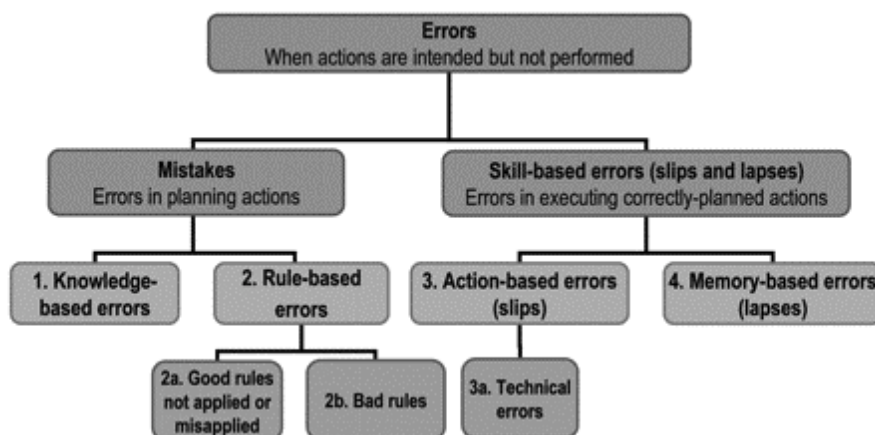


Figure 1: diagrammatic representation of Reason’s Generic Error Modelling System. Reproduced from reference^[21].

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Knowledge and rule-based medication errors are common^[22] and can be avoided by ensuring healthcare professionals are well informed about the medicines in use^[23]. This explains why contradictory, incomprehensible or poor quality information is a recognised cause of medication errors^[17,18] and therefore provides the theoretical basis for improving patient safety by improving the quality of the Injectable Medicines Guide.

The second theoretical framework was developed by Rosenbaum to describe the user experience of a designed artefact, specifically documents used in the development of evidence-based clinical guidelines^[24]. It is based on previous frameworks and the findings of Rosenbaum’s own work with documents used by the Cochrane Collaboration. The framework describes eight facets of a user’s experience of a document and how the relative importance of these facets changes as the user become more familiar with it.

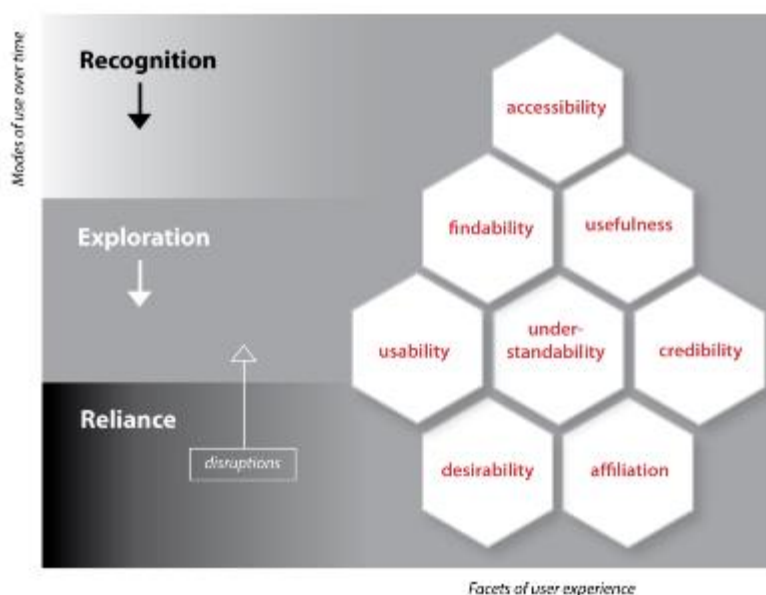


Figure 2: Rosenbaum’s user experience framework^[24]

The various facets of user experience in this framework can be briefly defined as^[24]:

- Accessibility: are there physical barriers to users gaining access to the document?
- Findability: can users locate what they are looking for?
- Usefulness: does the document have practical value for users?
- Usability: how easy and satisfying is the document to use?
- Understandability: this covers two types of comprehension. Firstly, do users understand what type of document they are looking at? And secondly, do users correct understand the content of the document in the way that the author intended?
- Credibility: is the document trustworthy?
- Desirability: is the document something the user wants or has a positive emotional response to?
- Affiliation: do users believe the document is intended to be used by “someone like me”?

The three modes of use over time can be briefly defined as:

- Recognition: the process by which users locate a document and categorise it uses
- Exploration: the process by which users understand how to they should use a document
- Reliance: users no longer ask “how to use” a document, but rely upon it as they attend to the primary task at hand. Disruptions may occur in this mode, which move the user back into the exploration mode.

Rosenbaum’s user experience framework will therefore be used to provide a theoretical underpinning to the design and analysis of the user testing interviews, to ensure that all aspects of a user’s experience are explored.

4 RESEARCH QUESTION/AIM(S)

Research question (whole study): Is it possible to reduce the incidence of medication errors by improving the content, wording, structure and formatting of written documents providing technical information to health professionals?

This question will be investigated using the NHS Injectable Medicines Guide as a case study from one of the highest risk routes of medicines administration.

4.1 Objectives

Objectives for the entire study are:

1. To identify and resolve problems in typical NHS Injectable Medicines Guide (IMG) monographs using systematic user testing.
2. To compare the rates of preparation and administration errors associated with use of the original and user tested IMG monographs.
3. To determine whether systematic user testing of the IMG is a cost-effective approach to improving patient safety.
4. To advise the IMG Advisory Board on generic lessons learned during user testing which could be introduced to the entire guide during the next revision cycle.

Only objectives 1 and 4 will be addressed during phase 1 of the study (this protocol).

1.2 Outcome

By applying user testing to the IMG during phase 1, revised monographs will be produced. If this results in fewer errors during phase 2, it would be the first demonstration that user testing of technical information about medicines can address one of the known causes of errors. This would show that user testing can improve the safety of the IMG and the approach could be introduced to the entire guide. It would also suggest that the safety of the numerous other examples of technical information about medicines aimed at health professionals could be improved by user testing.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYSIS

On the advice of the Study Advisory Group, the IMG monographs for intravenous voriconazole and aminophylline will be the subject of this study. Voriconazole is an appropriate case study because it is widely used and nationally recognised as a high risk injectable medicine^[25]. Finally, the preparation and administration of these medicines includes all the major steps commonly required for intravenous medicines: reconstitution, dilution, short injection, short and continuous infusions.

To prevent participants using prior knowledge of vancomycin, before user testing the monograph will be “anonymised” by changing:

- Any mention of “voriconazole” to “bathicillin”
- Any mention of “aminophylline” to “unimycin”

Standard user testing methodology will be employed, involving iterative rounds of semi-structured interviews with potential users followed by document revision^[1,4,6].

An interview schedule will be prepared by the Chief Investigator based on previously published user testing research, the Rosenbaum user experience framework (see Section 3) and the IMG monograph for voriconazole and aminophylline. Each interview will include direct questions to determine whether the interviewee can locate and correctly use specific points of information to recommend appropriate actions and the reasons for them. These questions will be followed by a semi-structured interview to explore opinions of more general issues (e.g. structure of the document, sub-headings, language used). The draft interview schedule will be circulated to the study Advisory Group for comment, before being tested in three pilot interviews. The interview schedule may evolve as data collection progresses, to ensure it adequately reflects issues raised during preceding interviews.

Interviews will be carried out in person by the Chief Investigator in a private location convenient to the participant. They will be audio recorded using two encrypted digital recorders (one as a backup), and the interviewer will make field notes. As soon as practical, the recordings will be transferred to the University of Bath’s secure research data storage facility and deleted from the digital recorders. Subsequently, the interview recordings will be transcribed by experienced transcribers employed by the host university. The Chief Investigator will remove any information which could potentially be used to identify a research participant from the transcripts before subsequent analysis.

The data collection techniques will be piloted with three participants before substantive data collection begins. Data from the pilot phase will only be included in the main study if there are no substantive changes to the interview schedule or interview technique following the pilot.

The primary outcome of each round will be the proportion of participants able to find and correctly use each specific point of information. This will be scored by the Chief Investigator using a list of appropriate actions and explanations. However, the full transcript of each interview will also be subject to thematic analysis, following the six stages described by Braun and Clarke^[26]. This is an approach which allows the identification of recurrent themes and the exploration of their meaning^[4,26]. Nvivo software will be used during this process.

After each round of user testing and data analysis, the IMG monographs will be revised based on the participants' responses and information design best practice^[27-29]. The revised monograph will then be tested in subsequent rounds.

The costs of the interviews, data analysis and monograph revision process will be recorded throughout this phase for use in a health economic analysis during a later phase of the study. These will principally be the Chief Investigator's time to collect and analyse data, and revise the monograph, and the participants' time reviewing draft monographs.

All electronic data will be stored on the University of Bath's secure research data storage facility. Original copies of paper data sources (e.g. field notes) will be stored in a locked cabinet at the University of Bath. The data will be accessible only to the research team (Chief Investigator and above named advisors), sponsor's representatives and (in the case of recordings) the transcribers (University of Bath employees). Data will be shared with team members outside the University of Bath using the secure files.bath file sharing facility (www.bath.ac.uk/guides/access-and-share-your-work-online-using-files-bath/). Data will be stored for a minimum of ten years, in accordance with the University of Bath Research Data Policy (www.bath.ac.uk/research/data/policy/). Suitable anonymised data may be made available via the University of Bath Research Data Archive (<https://researchdata.bath.ac.uk/>).

6 STUDY SETTING

Qualified nurses will be recruited via at least three NHS hospitals. However, recruited staff will be interviewed in their own time. The location of the interviews may be at the participating organisations, but may also be elsewhere, including privately hired venues and the University of Bath. This is to provide maximum flexibility to meet the needs of participants, as this research method only requires a safe, quiet and undisturbed location.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria

- Qualified nurse or midwife registered with the Nursing and Midwifery Council
- Authorised to prepare and administer intravenous medicines in an organisation which provides NHS care
- Has prepared and administered intravenous medicines during at least half of working shifts during the past six months (or since authorisation if this was granted more recently)

7.1.2 Exclusion criteria

- Has participated in a previous round of user testing for this study
- Does not consent to interview being audio-recorded

7.2 Sampling

7.2.1 Size of sample

The pilot phase will involve three participants. This will be followed by three rounds of user testing, each interviewing ten new participants.

This sample size is based on standard user testing methodology^[1,4,6]. As this is a form of diagnostic testing – finding out where documents do not work, and remedying problems using expert information writing and design practice – large numbers of participants are not needed. Experience shows that most significant flaws in a document are identified by the first few participants^[6]. Hence, a formal sample size calculation is not appropriate^[6,30].

7.2.2 Sampling technique

As is standard practice in systematic user testing, participants for each round will be purposefully selected to include a range of nursing experience^[1,4,6], based on the following sampling matrix. This approach will ensure that user feedback is obtained from a diverse sample which represents the range of relevant nursing experience found within the NHS. This will ensure that the final user tested document is useful for a wide range of nurses:

Number of years accredited to prepare and administer IV medicines	Hospital 1	Hospital 2	Hospital 3
<5 years	2 nurses	2 nurse	1 nurse
≥5 years	2 nurses	2 nurse	1 nurse

A cut off of five years of experience preparing and administering intravenous medicines was chosen because evidence suggests that the number of errors with which a nurse is involved decreases over the first four to six years of their nursing experience^[31-34]. In particular, one study found that the risk of intravenous medicine administration errors decreased with each year of a nurse's experience up to six years^[31].

Each round of user testing will recruit new participants, to reduce bias related to previous participants having learned about the study monograph during their past interview.

7.3 Recruitment

7.3.1 Sample identification

Each site will advertise the study to eligible staff via email, intranet sites, leaflets, posters and promotion via the nursing hierarchy. Participating sites will identify staff who potentially meeting the inclusion/exclusion criteria for targeting with the above advertising methods. Interested staff will be invited to contact the Chief Investigator if they meet believe they meet the inclusion/exclusion criteria and would like to participate. At this point, potential participants will be required to share identifiable personal information with the Chief Investigator, such as contact details, employer and details of nursing experience, to be used for eligibility screening.

Participants' reasonable travel expenses will be reimbursed at University of Bath rates (www.bath.ac.uk/finance-procurement/guidance/travel-expenses/mileage-rates/index.html). In addition, participants will be offered a £25 shopping voucher to acknowledge their time contribution.

7.3.2 Consent

Informed consent will be obtained from all participants and recorded in writing immediately prior to their interview. Interviews will not commence unless consent is obtained and documented.

Participants will be provided with a paper or electronic copy of the approved participant information leaflet and consent form at least 24 hours in advance of their agreed interview appointment. Immediately prior to their interview, the Chief Investigator will discuss the contents of the participant information leaflet with the participant, highlighting the nature and objectives of the study and possible risks associated with participation. The participant will be given the opportunity to ask questions about any aspect of the study they do not fully understand. As participants in this study will be qualified, practising nurses, it is very likely that all potential participants will have capacity to consent. If the potential participant demonstrates the ability to retain and understand the information provided about the study, they will be deemed capable and asked to complete the consent form.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk

This study presents a very low risk of harm to study participants. In non-interventional, interview-based studies such as this, the major risk is that of causing distress to participants through the discussion of upsetting situations. However, in this study, participants will be NHS staff (rather than patients) and interviews will focus on discussing the anonymised IMG monograph, rather than previous or anticipated real life events. The risk of causing distress to participants is consequently very small. Should a participant become distressed, the interview (and recording) will be paused to allow them to compose themselves. The interview will then only be continued once the participant is composed and if they wish to do so.

The subject matter of the interviews also makes the disclosure of a participant's intention to harm themselves or others extremely unlikely.

8.2 Research Ethics Committee (REC) and other regulatory review & reports

As participants in this study are NHS staff, review by an NHS Research Ethics Committee is not required. However, a favourable opinion will be sought from the University of Bath Research Ethics Approval Committee for Health for this protocol, informed consent forms and other relevant documents e.g. advertisements.

Should any study amendments be required, the Chief Investigator will submit information to the University of Bath Research Ethics Approval Committee for Health in order for them to issue a favourable opinion for the amendment.

Regulatory Review & Compliance

Approval from the Health Research Authority will be obtained before the study commences. Before the study commences at any particular site, the Chief Investigator will ensure that the R&D department of that site has formally confirmed their capacity and capability to deliver the study.

Should any study amendments be required, the Chief Investigator (in agreement with the sponsor) will submit information to the Health Research Authority in order for them to issue approval for the amendment. The Chief Investigator will then work with study sites' R&D departments so they can put the necessary arrangements in place to implement the amendment and to confirm their support for the study as amended.

Amendments

Amendments will be submitted for approval and communicated as described above. The decision to make amendments will be made and implemented by the Chief Investigator, in line with advice from the Study Advisory Group and research advisors. The Sponsor will categorise amendments as substantial or

non-substantial in line with the current version of the University of Bath amendments process. Amendment history will be tracked through the use of version numbers of all documents and Appendix 3 of this protocol.

8.3 Peer review

The proposal for this study was reviewed through the NIHR fellowship application process. This involved two rounds of review by a funding panel and peer review by three external experts. In addition, this protocol has been reviewed by Prof Theo Raynor (University of Leeds, one of the study research advisors and a leading researcher of the user testing technique) and Prof Margaret Watson (University of Bath).

8.4 Patient & Public Involvement

Two members of the public will be invited to become lay advisors for the study. The role of these advisors will be to assist with the dissemination of the research to a lay audience. They will be recruited via patient groups associated with the participating organisations. They will be invited to find out about the research from an early stage and observe data collection, to ensure more successful involvement and dissemination.

In addition to the above, users were involved in the development of this study and its associated documents, specifically nurses and pharmacists, who will be the participants and end users of the research.

A series of discussions were undertaken with a range of pharmacists and nurses involved with the design and use of the Injectable Medicines Guide, including members of the IMG advisory board, the UK Medicines Information network and the National Infusion and Vascular Access Society.

These discussions covered the importance of the research question, the appropriateness of the proposed methods, the feasibility of carrying out the research and possible improvements. Feedback from these discussions confirmed that this is a timely project addressing a real need faced by practitioners. People emphasised that the IMG is currently written with little consideration for the needs of end users and gave examples from their own experience of the resultant problems. User testing was therefore viewed very favourably, from the perspective of potential participants and from the perspective of future IMG users. These conversations influenced this protocol by suggesting the inclusion of community nurses in the user testing.

The Study Advisory Group (described above) will give practising nurses and pharmacists ongoing involvement in the management of this study and dissemination of the findings.

8.5 Protocol compliance

The Chief Investigator will collect and analyse all data, so protocol deviations are less likely than in larger studies. However, accidental protocol deviations can occur at any time.

A serious deviation from the protocol is defined as a one which is likely to effect to a significant degree:

- i. The safety or physical or mental integrity of the participants of the study, or
- ii. The scientific value of the study

A protocol deviation may be identified through routine monitoring, internal audits or during the day to day running of the study. The Chief Investigator will make an assessment of the severity of the deviation. If it is classified as a 'serious deviation' according to the definition above the sponsor will be notified within 24 hours.

Non-serious deviations (according to the definition above) will be documented e.g. in the field notes relating to the interview in questions. These deviations will be included and considered when the study report is produced, as they may have an impact on the analysis of data. However, non-serious deviations from the protocol which are found to frequently recur are not acceptable. They will be classified as a 'serious deviation' and immediate action will be taken to ensure they do not recur

8.6 Data protection and participant confidentiality

All investigators must comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and uphold the Act's core principles.

Personal information will be collected via consent forms, demographic data collection forms and audio recordings.

Audio recordings will be made using encrypted, password protected digital recorders. As soon as possible after the interview, the recording will be transferred to a password protected folder in the University of Bath's secure managed data storage facility, and deleted from the recorder. Recordings will subsequently be transcribed. Transcriptions will also be stored in a password protected folder in the University of Bath's secure managed data storage facility and will be anonymised by replacing any potentially identifiable information with an unrelated sequence of characters.

Data collection forms and consent forms will be returned to the University of Bath as soon as possible after completion, where they will be stored in a locked cabinet in a locked office. Demographic data will be transcribed to a file stored in a password protected folder in the University of Bath's secure managed data storage facility.

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Recordings, transcriptions and demographic data will be identified using only a unique participant number. The key linking these numbers to recognisable individuals will be stored in a separate secure location at the University of Bath and destroyed at the end of the research.

Access to data will be limited to the Chief Investigator, research advisors, transcribers (recordings and transcriptions only, all transcribers will be University of Bath employees) and sponsor's representatives.

Data will be shared with team members outside the University of Bath using the secure files.bath file sharing facility (www.bath.ac.uk/guides/access-and-share-your-work-online-using-files-bath/). Data will be stored for ten years, in accordance with the University of Bath Research Data Policy (www.bath.ac.uk/research/data/policy/). Suitable anonymised data may be made available via the University of Bath Research Data Archive (<https://researchdata.bath.ac.uk/>).

8.7 Indemnity

The University of Bath has arranged Public Liability insurance to cover the legal liability of the University as Research Sponsor in the eventuality of harm to a research participant arising from management of the research by the University.

The University of Bath holds Professional Indemnity insurance to cover the legal liability of the University as Research Sponsor and/or as the employer of staff engaged in the research, for harm to participants arising from the design of the research, where the research protocol was designed by the University.

The University of Bath's Public Liability and Professional Indemnity insurance policies provide an indemnity to our employees for their potential liability for harm to participants during the conduct of the research.

8.8 Access to the final study dataset

Access to the final dataset will be limited to the Chief Investigator, research advisors and sponsor's representatives. In addition, suitable anonymised data may be made available via the University of Bath Research Data Archive (<https://researchdata.bath.ac.uk/>).

9 DISSEMINATION POLICY

9.1 Dissemination policy

Data arising from this study will be owned by the University of Bath. On completion of the study, data will be analysed and tabulated and a Final Study Report submitted to the NIHR. This report will be accessible via the NIHR. The Chief Investigator will have the right to publish any of the study data, subject to acknowledgement and approval of the submission by the NIHR.

Participants who express an interest in finding out about the results of the study will be sent a copy of the final study report.

The study protocol, final study report and anonymised participant level dataset will be made publically available via the University of Bath Research Data Archive (<https://researchdata.bath.ac.uk/>) at the conclusion of the study.

9.2 Authorship eligibility guidelines and any intended use of professional writers

The author of the final study report will be the Chief Investigator. Authorship of academic publications arising from this study will be determined according to the International Committee of Medical Journal Editors criteria for defining the role of authors and contributors:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

See: www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html

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11. APPENDICES

11.1 Appendix 1 – Required documentation

- CV of Chief Investigator
- Participant information sheet
- Consent form
- Interview schedule
- Interview data collection form
- Recruitment email
- Recruitment posters

11.2 Appendix 2 – Schedule of Procedures

Procedures	Visits
	Interview
Informed consent	x
User testing interview	x

13.3 Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	1.1	2 nd March 2018	Matthew Jones	Test monograph changed from phenytoin to vancomycin, as suggested by Study Advisory Group. Amendments section revised to state that categorisation as substantial/non-

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				<p>substantial will be made by the sponsor, in line with University of Bath guidance.</p> <p>Minor changes to participant information sheet and ethnicity question removed from demographic data collection, as suggested by University of Bath Research Ethics Approval Committee for Health.</p>
2	1.2	4 th September 2019	Matthew Jones	<p>Retrospective amendments to reflect how study was completed:</p> <ul style="list-style-type: none"> • Test monographs changed to voriconazole and aminophylline following pilot study in April 2018, on advice of study advisory group. • No nurses were recruited via the two community care organisations approached, so recruitment section amended to reflect that nurses were only recruited from three hospitals.