**Protocol for Work Package 1 (Professionals) Interviews**

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| Version Number and Date | 1.1 15 January 2013 *insert version number and date of each version during protocol development and before finalisation* |

*If the trial is multi-site, or has a coordinating Trial Centre, add specific details e.g. contact name, address etc below, otherwise delete these tables.*

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| Prof Robin Williams |  |  |  |
| WP1 lead | Signature |  | Date |

*Add details of Chief Investigator, Trial Statistician and any other relevant trial related staff as appropriate e.g. Trial Manager*

*The final version of the protocol should be signed off before distribution to trial staff, external sites etc.*

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Summary

A number of international benchmark studies have demonstrated that prescribing errors are common and are responsible for considerable, and potentially avoidable morbidity and mortality. Given the increasing complexity of prescribing decisions, the risk of prescribing-related iatrogenic harm is likely to increase yet further. There is then a pressing need to identify effective approaches to improving the safety of prescribing. Interest is converging on the potential offered by computerised order entry and related advanced decision support systems (henceforth referred to as ePrescribing systems). These systems however vary very considerably in functionality, inter-operability and costs.

This Programme aims to inform important national deliberations on the safe, effective and efficient procurement and implementation of ePrescribing systems into hospitals in England by:

* Describing the procurement, implementation, adoption and maintenance of the basic and more advanced ePrescribing systems;
* Estimating their effectiveness and cost-effectiveness;
* Developing best practice recommendations for procurement and a toolkit for their successful integration into NHS hospitals.

These aims will be met by performing a theoretically-informed, multi-method, context-rich, naturalistic evaluation using the principles of a stepped-wedge design. At least four in-depth longitudinal case studies in purposefully selected hospitals implementing ePrescribing systems of varying functionality and cost will be carried out.

The programme is organised into four complementary Work Packages (WPs)

• WP1: Procurement, implementation, adoption and connectivity

• WP2: Assessing impact on prescribing safety

• WP3: Health economics and a value of investment analysis

• WP4: Integration across WPs to develop recommendations and a toolkit for the NHS.

This protocol concerns Work Package 1 which aims to investigate the short- and longer-term impacts of introducing ePrescribing systems into hospitals.

# 1 INTRODUCTION

## 1.1 BACKGROUND

## Prescribing errors are common, costly and often result in considerable harm to patients (1-8). Work from a handful of predominantly US-based centres of excellence suggests that the risk of patients being inadvertently harmed by erroneous prescribing may be greatly reduced by the introduction of ePrescribing systems (9-11). Their development, procurement and implementation is therefore currently being pursued internationally (12).

## Current ePrescribing applications vary significantly in functionality and sophistication, these in essence ranging from basic computerised data entry applications (also sometimes known as computerised provider order entry (CPOE) or non-alerting systems) to more sophisticated systems offering advanced computerised decision support system (CDSS) functionality, which generate prescribing alerts (12). Computerised decision support systems are active knowledge systems, which use real-time patient-specific information to generate individualised prescribing advice. These more sophisticated systems tend to be integrated with existing local electronic health records to produce alerts (such as warnings and reminders) tailored to the individual case at hand.

## ePrescribing systems are now well established in UK primary care (13;14). Within secondary care, however, there are as yet very few implementations of ePrescribing systems, this in part reflecting the fact that hospital records have until recently tended to be paper-based. Widespread adoption of fully computerised prescribing systems has to date only been achieved in very few UK academic hospitals (such as the University Hospital Birmingham NHS Trust).

## Available systems range from the home-grown extensively tailored applications that have been developed over a number of years to the expanding array of commercially available off-the-shelf systems. Although home-grown systems tend to be more easily adopted by hospitals (this reflecting the strong sense of local clinical ownership), extensive systems’ customisation over time means that these are not easily transportable to other sites. In addition, very few hospitals have the necessary expertise or budgets to develop their own systems in-house. A key decision facing Trusts is therefore whether to persist with paper-based prescribing or to choose between the commercially available systems. This decision is likely to be shaped by a range of factors, including the ease of implementation, training implications, the time and cost investment necessary, and the anticipated benefits, particularly in relation to improving prescribing safety. Given the significant cost and resource implications involved, this decision should be an evidence-informed one, but this is currently not possible because there is a dearth of high quality evidence to draw upon (15). This Programme aims to begin to fill this important evidence gap.

## Whilst real-time prescribing support and electronic alerts/prompts have under some circumstances demonstrated benefit in improving clinicians’ prescribing behaviour and/or reducing error rates, there remains a small, but nonetheless important risk that the introduction of these systems may also have serious adverse impacts on patient outcomes (16-20). They can thus introduce new areas of clinical risk and unexpected threats to patient safety. Koppel and colleagues, for example, reported how fragmented computerised provider order entry displays prevented a coherent view of patients’ medication and how separation of functions facilitated double dosing (18). Another study has highlighted how systems’ implementation generated errors associated with the process of entering and retrieving information, and with communication and coordination processes (16). Similarly, we have found that many systems can produce clinically spurious alerts, which frustrate end-users and results in these commonly being over-ridden or ignored (17). More recent work has highlighted the potentially serious treatment delays that can inadvertently be associated with the introduction of ‘hard stops’ to reduce risk of serious prescribing errors (19;20).

## This highlights a need for careful evaluation of the introduction of such technologies. Unintended consequences of health information technologies are strongly linked to poor implementation strategies. This has been demonstrated not only in the UK, but also in many other areas of the world (21;22). Much work has, to date, been conducted at selected centres of excellence in the US and we now propose to build on this in order to understand the lessons that are transferable to the English NHS.

*Should include any reviews of previous studies, disease particulars, incidence, current treatment options, risks and benefits.*

## 1.2 RATIONALE FOR STUDY

## The outcomes of adopting new information systems depend upon the design and configuration of the computer system. The implementation strategy, training, systems’ maintenance, work reorganisation and development of new work practices are all influential in system deployments. Given the complex interactions between these various socio-technical factors, introducing new systems into hospitals may result in both positive and negative consequences. These effects may become visible across the lifecycle of the system(s), beginning with plans to procure the new systems and extending throughout their implementation and complete integration into adopting organisations (23-25). Longitudinal case studies are therefore needed to consider the evolution of use over time and identify factors determining the short- and longer-term impacts of these systems. It is anticipated that these factors will include the organisational learning achieved, identifiable impacts upon everyday working practices, and issues relating to communication across organisational boundaries, "hidden costs" and safety and risk arising from systems’ utilisation. Specific lessons arising from systems’ utilisation (e.g. functionality in different work settings), a variety of operating systems (e.g. computers-on-wheels and hand-held devices such as iPads), systems performance (including failures and down-time), clinicians’ responses to alerts and impacts upon clinical practice will be identified. The implications for the prescribing education of healthcare professionals will also be assessed (26).

Good communication and information sharing within a healthcare organisation and across organisational boundaries are critical for continuity of patient care. The Department of Health (DH) Discharge from Hospital: pathway, process and practice (27) called for effective communication between primary, secondary and social care. Research has indicated the impact of communication breakdown on prescribing and on the monitoring of patients following discharge from hospital (28), and a DH commissioned report (29) highlighted how the use of ePrescribing systems in hospitals can give staff quicker access to more reliable information and thus have the potential to improve patient safety. GPs may also require timely information from hospitals to support safer care after a patient has been discharged from hospital (30). WP 1 will therefore seek a better understanding of how different hospital ePrescribing systems impact on communication and local connectivity both within the hospital and in the wider health community. The focus of this study is particularly on the perspectives of those responsible for prescribing in order to investigate the consequences of the hospital ePrescribing systems for information flows (31). We will not be conducting interviews with or collecting data from patients under this protocol. Fieldwork with patients will be undertaken under a related but separate study, which will be the subject of a separate protocol, including any observational work, or work that may include access to patient medical records.

*Should include a clear explanation of the research question and hypothesis, justification for the study, including
- an explanation of why the study is appropriate, benefits to participants, health services, relevance to current policies etc;
- description of the indication, its diagnosis, incidence, current treatments, their limitations etc;
- description of the treatment under investigation;
- statement of what would be a worthwhile improvement in study outcomes and what evidence there is that the treatment under investigation may achieve this.*

# 2 STUDY OBJECTIVES

## 2.1 OBJECTIVES

Aim

To investigate the short- and longer-term impacts of introducing ePrescribing systems into hospitals.

We seek to achieve this aim by fulfilling three key objectives:

1. Describe the planned and actual implementation and adoption strategies;
2. Understand key professional stakeholders’ perspectives, by exploring individuals’ expectations, experiences, practices and perceived needs over time;
3. Understand the impact of hospital implemented ePrescribing systems on communication and connectivity both within hospital and with local primary care providers.

*Detail secondary endpoint(s)*

# 3 STUDY DESIGN

## A series of prospective case studies will be carried out to investigate the introduction and impact of ePrescribing systems of varying complexity and cost in a range of NHS hospitals. Longitudinal, socio-technical (32), qualitative, multi-site case studies will be carried out (33), treating each participating hospital as an individual, detailed case study of the socio-technical processes of procuring, implementing, adopting and maintaining an ePrescribing system.

*Detail:
- type of and length of study e.g. 24 week, multi-centre, randomised, double-blind, placebo controlled etc;
- duration e.g. what constitutes the treatment phase and the follow up phase;
- points in trial for measurement of outcomes;
- consider a schematic diagram of the study design.*

 *-duration of participant involvement*

*- detail any stopping rules for the study*

# 4 STUDY POPULATION

The study population will consist of diverse secondary care Trusts throughout England that are planning to or have begun to implement ePrescribing systems. Within each recruited hospital, we will use purposive sampling to identify a diverse range of professional stakeholders.

Four case studies are planned: 2 fine grained considerations of sites in hospitals that are planning to implement ePrescribing systems and 2 broader investigations in hospitals that have already begun implementation.

In addition, we will speak to professional stakeholders working to provide and implement electronic prescribing and related EHR technologies. These may include for example healthcare professionals, organisational and policy decision-makers, systems suppliers, technical specialists, managers and administrators, healthcare commissioners and members of representative bodies such as the British Medical Association.

*Detail:
Number of participants/volunteers, participant population, number of sites involved, length of recruitment period.*

# 5 PARTICIPANT SELECTION AND ENROLMENT

## 5.1 IDENTIFYING PARTICIPANTS

Purposive sampling (34) will be used to identify diverse secondary care trusts and to identify

a diverse range of stakeholders within the trust.

5.2 CONSENTING PARTICIPANTS

The research team will supply an information sheet to each participant upon invitation to interview. The participant will be encouraged to discuss any questions with the researcher at the beginning of the researcher meeting. Written consent to take part will then be requested prior to each interview, comprising a completed consent form signed by both researcher and participant. All fieldwork will be undertaken with due regard to maintaining the best interests of participants, and in particular ensuring that their confidentiality and anonymity are assured.

*Include details of any limitations regarding who will be designated to take informed consent from participants. Any limitations stated must be adhered to unless the protocol is amended accordingly and approved by the relevant organisations.*

*Detail the specific study assessments to be performed and the timepoints during the study - split by visit number if appropriate for clarity. It may be appropriate to prepare a table of assessments by visit.*

# 6 DATA COLLECTION

# Data collection is planned to take place over up to three key time periods: a baseline visit; a second round of data collection approximately six months later (where relevant, this corresponding to three-six months post the “go-live” date); and a final round of data collection 12-18 months after the baseline assessment. Contact will be maintained with key personnel in between visits so as to allow these schedules to be varied, as appropriate to maximise the opportunity to generate important insights. Each round of data collection is likely to take 4-6 weeks in the field.

# Data collection at each site will consist of semi-structured interviews (n=15-20 per visit), group interviews, and collection of documents to capture perspectives on the design, uptake, implementation and evolution of local ePrescribing systems.

# A complete set of relevant, local Trust documents, for example any business case for the system, training strategy documents, work process maps and annual reports will be requested. Documentation on the hospital’s technological infrastructure, hardware and the application being implemented (i.e., the software package, its functionalities configurability and costs) will also be collected.

# Semi-structured interviews and group interviews, guided by topic schedules, will be conducted with a diverse range of professionals. Interviewees will be healthcare professionals, organisational and policy decision-makers, systems suppliers, technical specialists, managers and administrators, healthcare commissioners and members of representative bodies such as the British Medical Association. The topic guides will explore interviewees’ expectations, experiences and perceived needs, including questions about perceptions of role threat and professional deskilling arising from the organisational systemisation of care and administrative staff (35,36). Interviews will also explore with staff the "hidden costs" in relation to implementing and adopting new IT systems (to support WP 3). Additional interviews will be sought from the systems’ suppliers. Interviews will, with permission, be recorded and transcribed verbatim together with accompanying field notes.

# Longitudinal analysis, and equivalent insights derived from comparative analysis of early and established adopters of systems, will examine changes in work processes as skills and routines in using ePrescribing systems become enhanced as technologies become embedded and optimised in the light of experience (what Arrow (37) described as “learning by doing”). This will highlight any dissonances and tensions between what should happen and what happens in practice, and in the light of this consider the potential consequences for dependability of operations and the possibility of giving rise to new and unanticipated risks.

Data generation will end when saturation has been reached and no new relevant data are being collected (38). The above described number of interviews are based on previous experience and should therefore be seen as indicative; these will be adjusted as necessary.

*Detail data to be collected, including:
- the source (e.g. questionnaire, medical notes, electronic data collection procedures);
- timepoints for collection (e.g. baseline, during treatment, during follow up);
- who will collect the data;
- details of any standardised tools (e.g. pain scores);
- describe any methods to maximise completeness of data collection (e.g. telephoning participants who have not returned questionnaires).*

*The Edinburgh Clinical Trials Unit (ECTU) can provide support - ACCORD facilitators will advise.*

# 7 DATA ANALYSIS

Qualitative data collection and analysis will be iterative (38), allowing emerging themes to be explored further and disconfirming evidence to be sought. Multiple data sources (documents and interviews) will allow researchers to triangulate case study evidence and identify where and how different data converge and diverge. Thematic analysis of longitudinal data collection will allow changes to be tracked over time; accessing a diverse range of interviewees will permit analysis by stakeholder group (39). Detailed within case analysis will be followed by analysis across cases to identify over-arching themes.

*Detail the sample size, precision or power calculation, dropout rates, relevant assumptions and justifications. Comment on an estimate of the recruitment period with justification that the required sample size will be achievable.*

*State if this information is detailed in a separate document.*

*Detail the variables to be used for assessment and how these will be reported (e.g. means, standard deviations, medians etc). Write detailed plans for analyses of primary and secondary outcomes including:
- summary measures to be reported;
- method of analysis
- plans for handling missing, used and spurious data, non compliers and withdrawals;
- plans for pre-defined subgroup analyses;
- statement regarding use of intention to treat analysis;
- details of any interim analysis;.*

# 8 STUDY MANAGEMENT AND OVERSIGHT ARRANGEMENTS

The study is managed fortnightly via team meetings and monthly management meetings which involve all of the Work Package leads. The Programme Steering Group meets quarterly and the Independent Programme Steering Group meets approximately 6 monthly. Following field work, researchers will be offered a debriefing session with a peer researcher to discuss any areas of specific concern which arose during data collection, and to agree actions arising from that concern if necessary.

*Suggested text only - amend as appropriate. Consider detailing a division of responsibilities of the Trial Management Group.*

*A Delegation Log must be in place at each site.*

*Establish monitoring for external sites and detail in the protocol. This text can be replaced with brief details of the monitoring if agreed with the ACCORD Senior Clinical Research Monitor.*

*CONSIDER REPORTING OF DEVIATIONS IN PUBLISHED WORK.*

*Detail procedures for peer review – these may be funder specific or involve an internal department.*

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**Participant Information Leaflet for WP1 Professional Interviews.**

**Investigating the implementation, adoption and effectiveness of ePrescribing systems in English hospitals: a mixed methods national evaluation**

**WP1 professionals study**

**Information Sheet for Participants**

You are being invited to take part in an interview as part of the above study. Please take time to read this information sheet before deciding whether to take part. This describes the goals of the study and what we are asking you to do. This Information Sheet also indicates how we will collect, store and use the data collected. Thank you for taking the time to read this leaflet. We appreciate you are busy and would like to thank you in advance for taking the time to read this leaflet and consider this request.

**Purpose of the study**

We are undertaking an ambitious multi-faceted programme of work to inform important national deliberations on the safe, effective and efficient procurement and implementation of ePrescribing systems into hospitals in England. In doing so, we wish to explore the experiences, attitudes and organisational consequences of implementation from the perspectives of key stakeholders.

**Why have I been chosen?**

You have been chosen because you are either a:

* Healthcare professional
* Member of administrative staff
* Member of IT support personnel
* Healthcare or technical manager
* Member of the implementation planning team
* Supplier of an ePrescribing product

at a hospital where ePrescribing systems have been or will soon be implemented. We would like to investigate the acceptability of the new system and invite you to be interviewed in order to gain insights into your views/opinions and experiences.

**Do I have to take part?**

It is up to you whether you wish to take part in an interview. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you do decide to take part you will need to complete the Consent Form prior to each interview, and should also keep this Information Sheet.

**What will happen if I decide to take part?**

We would like to invite you to be interviewed a maximum of three times throughout the implementation period of ePrescribing systems (over approximately two years). However, if you prefer to be interviewed only once or twice we will be very happy to arrange this. Most interviews will be one-to-one interviews which will take no longer than 30 minutes each so that the overall involvement of each participant will amount to no more than a total of two hours over the course of the project. For convenience, we will also give you the opportunity to conduct these interviews over the phone.

For some professionals (particularly system suppliers), we will hold group interviews of up to 6 participants, which will take up to one hour.

If you are unable to be interviewed at the time you are contacted, the interviewer will give you the option of choosing a new time to be interviewed. The interviews will be audio-taped, with your permission, a written account of the interview will be produced for the research team. This will have a unique participant number on it, but will not have your name or telephone number on it. All data obtained from the interviews will be used only for this study. You will be free to stop the interview at any time should you wish and we will destroy the audiotape if you asks us to do so.

**What are the possible disadvantages or risks of taking part?**

Taking part in an interview will take up some of your time. There are no risks involved in participating.

**What are the possible benefits of taking part?**

The implementation of ePrescribing systems involves considerable time and resources. Our role as researchers in this study is to discover if ePrescribing systems are delivering on the expected benefits, and also to discover how best to support their use in hospitals. Your participation in this interview will help us to assess how usable the new system is and to determine whether it meets your needs.

Participation in this study will provide us with the opportunity to help improve the efficiency with which you use ePrescribing systems, and also to provide us with data that can be provided to developers to both ensure the functionality provided is that which you require, and that the system design helps you make use of this functionality easily. Participation will also help you to keep abreast of this important development in the NHS.

**Will my participation in the study remain confidential?**

Yes. Transcripts from the interviews will be anonymised, and anything you say during an interview will be confidential.

However, in the case of a disclosure which is firmly believed by the researcher to have a bearing on patient safety, the researcher will be obliged to inform the relevant body. You will be informed if this situation arises.

**What will happen to the results of this study?**

The results of this study will help to inform local and national implementation of ePrescribing systems in hospitals. A report will be submitted to the National Institute for Health Research. The results of this study will be published in relevant journals and presented at conferences. No individual participant or site will be identifiable in any of the published material.

We are planning to archive all anonymised data collected so that they may be made available to researchers from the ePrescribing research team for further analysis in the future. You will be asked on the consent form whether you agree to this.

**Who is organising and funding this research?**

The research is organised by the University of Edinburgh in collaboration with the University of Nottingham, Harvard School of Public Health, and the University of Birmingham. It is an independent evaluation that is funded by the National Institute for Health Research.

**Who has reviewed the study?**

This study is a Service Evaluation and organisational approval has been obtained.

**What can I do if I have a complaint about the study?**

If you have any concerns or questions about this interview, please raise these with the lead researcher, or with any member of the research team conducting the study. The principal investigator for this study is Professor Aziz Sheikh at the University of Edinburgh. If you feel that you need to make a formal complaint, a complaint can be made using the NHS Complaints Procedure.

**Who do I contact for further information?**

For further information about this study please contact either the local research fellow or he chief investigator below:

Local Research Fellow:

[delete as appropriate]

Dr. Kathrin Cresswell, Centre for Population Health Sciences, The University of Edinburgh, Medical School, Teviot Place, Edinburgh, EH8 9AG.

Dr. Zoe Morrison, Centre for Population Health Sciences, The University of Edinburgh, Medical School, Teviot Place, Edinburgh, EH8 9AG.

Dr. Lisa Lee, Centre for Population Health Sciences, The University of Edinburgh, Medical School, Teviot Place, Edinburgh, EH8 9AG.

Dr Hajar Mozaffar, Institute for the Study of Science, Technology and Innovation, School of Social and Political Sciences, The University of Edinburgh

Old Surgeon's Hall Edinburgh EH1 1LZ

Chief Investigator: Professor Aziz Sheikh, Centre for Population Health Sciences, The University of Edinburgh, Medical School, Teviot Place, Edinburgh, EH8 9AG.

Thank you for taking the time to read this information sheet and for considering this request.

**Consent form for WP1 Professional Interviews.**

**Investigating the implementation, adoption and effectiveness of ePrescribing systems in English hospitals: a mixed methods national evaluation**

**WP1 Professionals**

**INTERVIEW CONSENT FORM**

**Please tick all the boxes and give this form back to the researcher. If you don’t feel able to all the boxes, or if you change your mind at any point, we will not include you in the research.**

|  |  |
| --- | --- |
|  | **Tick** |
| I have read the information sheet v1.1 dated 17.1.13 and asked any questions I want, which were answered to my satisfaction (Please note that the information sheet gives the names of people you can contact to discuss the study) |  |
| I have been informed of the objectives of the study, my role within it, and the tasks I am expected to undertake |  |
| I understand that I will be participating in a study to investigate my perceptions and experiences of ePrescribing systems |  |
| I understand that I am free to withdraw from the study at any time and without giving a reason for withdrawing |  |
| I have been reassured that the procedures adopted by the researcher to ensure my anonymity as a participant will be maintained |  |
| I understand that the research team will agree to erase my contribution to the audiotape of the interview should I request this |  |
| I have been provided with the contact details of the research team and have details of the complaints procedure that I can use if I wish to |  |
| I understand that if I make a disclosure during the course of my interview which has an implication for patient safety, the researcher will be obliged to inform the relevant bodies.  |  |
| I am happy to be quoted (for example, when the research is published) so long as my name isn’t mentioned. *[if not happy to be quoted, leave blank]* |  |
| I agree to participate in the study |  |
| I am willing for my anonymised data to be archived and made available for further research  |  |

Name of participant (capitals): …….…….…………………………..……………………………………….

Signed:

………………………………………………….… Date: ………………..

Name of researcher (capitals): …….…….…………………………..……………………………………….

Signed:

………………………………………………….… Date: ………………..

**I would prefer a face-to-face/telephone interview *[please delete as appropriate]***

**I agree to be contacted again for a follow-up interview (please tick)**

**Protocol for WP1 Professional observations**

**Investigating the implementation, adoption and effectiveness of ePrescribing systems in English hospitals: a mixed methods national evaluation:**

**Work Package 1 ethnographic study**

|  |  |
| --- | --- |
| Sponsors | University Birmingham Hospitals NHS Foundation Trust *or insert alternative co-sponsor details or amend text to sponsor and insert details as appropriate* |
| Funder | NIHR |
| Funding Reference Number | RP-PG 1209 10099 *insert funding reference number before finalisation* |
| Chief Investigators | Prof Robin Williams  |
| Co Investigator | Prof Aziz Sheikh |
| Co Investigator | Dr Jamie Colman |
| Co Investigator | Mr Anthony Chuter |
| Co Investigator | Ms Ann Slee |
| Co Investigator | Prof Tony Avery |
| Co Investigator | Prof Richard Lilford |
| Co Investigator | Prof Jill Schofield |
| Co Investigator | Dr Zoe Morrison |
| Co Investigator | Dr Kathrin Cresswell |
| Co Investigator | Dr Ann Robertson |
| Co Investigator | Dr Sarah Crowe |
| Co Investigator | Prof David Bates |
| Co Investigator | Laurence Blake  |
| Co Investigator | Alan Girling |
| Version Number and Date | 1.2 28 November 2013*insert version number and date of each version during protocol development and before finalisation* |

*If the trial is multi-site, or has a coordinating Trial Centre, add specific details e.g. contact name, address etc below, otherwise delete these tables.*

|  |  |
| --- | --- |
| **Chief Investigator**Prof Robin Williams *email* | **Researcher**Zoe Morrison *name*The University of Edinburgh *address**email* |
| **Researcher**Dr Lisa LeeThe University of Edinburgh | **Researcher**Miss Hajar MozaffarThe University of Edinburgh |
| **Dr Kathrin Cresswell****The University of Edinburgh**  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| Prof Robin Williams |  |  |  |
| Chief Investigator | Signature |  | Date |

*Add details of Chief Investigator, Trial Statistician and any other relevant trial related staff as appropriate e.g. Trial Manager*

*The final version of the protocol should be signed off before distribution to trial staff, external sites etc.*

*To update the table of contents, highlight the existing table of contents, click ‘Insert’, ‘Reference’, ‘Index and Tables’ and ‘OK’.*

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LIST OF ABBREVIATIONS

|  |  |
| --- | --- |
| CDSS | computerised decision support system  |
| CPOE | computerised provider order entry |
| EPMA | Electronic Prescribing and Medicines Administration systems |
| DH | Department of Health |
| NHS | National Health Service |
| UK  | United Kingdom |
| WP | Work package |

***Compile a list of abbreviations as appropriate.***

**Summary**

A number of international benchmark studies have demonstrated that prescribing errors are common and are responsible for considerable, and potentially avoidable morbidity and mortality. Given the increasing complexity of prescribing decisions, the risk of prescribing-related iatrogenic harm is likely to increase yet further. There is then a pressing need to identify effective approaches to improving the safety of prescribing. Interest is converging on the potential offered by computerised order entry and related advanced decision support systems (henceforth referred to as ePrescribing systems). These systems however vary very considerably in functionality, inter-operability and costs.

This Programme aims to inform important national deliberations on the safe, effective and efficient procurement and implementation of ePrescribing systems into hospitals in England by:

* Describing the procurement, implementation, adoption and maintenance of the basic and more advanced ePrescribing systems;
* Estimating their effectiveness and cost-effectiveness;
* Developing best practice recommendations for procurement and a toolkit for their successful integration into NHS hospitals.

These aims will be met by performing a theoretically-informed, multi-method, context-rich, naturalistic evaluation using the principles of a stepped-wedge design. Four in-depth longitudinal case studies in purposefully selected hospitals implementing ePrescribing systems of varying functionality and cost will be carried out.

The programme is organised into four complementary Work Packages (WPs)

• WP1: Procurement, implementation, adoption and connectivity

• WP2: Assessing impact on prescribing safety

• WP3: Health economics and a value of investment analysis

• WP4: Integration across WPs to develop recommendations and a toolkit for the NHS.

This protocol concerns Work Package 1 which aims to investigate the short- and longer-term impacts of introducing ePrescribing systems into hospitals.

# 1 INTRODUCTION

## 1.1 BACKGROUND

## Prescribing errors are common, costly and often result in considerable harm to patients (1-8). Work from a handful of predominantly US-based centres of excellence suggests that the risk of patients being inadvertently harmed by erroneous prescribing may be greatly reduced by the introduction of ePrescribing systems (9-11). Their development, procurement and implementation is therefore currently being pursued internationally (12).

## Current ePrescribing applications vary significantly in functionality and sophistication, these in essence ranging from basic computerised data entry applications (also sometimes known as computerised provider order entry (CPOE) or non-alerting systems) to more sophisticated systems offering advanced computerised decision support system (CDSS) functionality, which generate prescribing alerts (12). Computerised decision support systems are active knowledge systems, which use real-time patient-specific information to generate individualised prescribing advice. These more sophisticated systems tend to be integrated with existing local electronic health records to produce alerts (such as warnings and reminders) tailored to the individual case at hand.

## ePrescribing systems are now well established in UK primary care (13;14). Within secondary care, however, there are as yet very few implementations of ePrescribing systems, this in part reflecting the fact that hospital records have until recently tended to be paper-based. Widespread adoption of fully computerised prescribing systems has to date only been achieved in very few UK academic hospitals (such as the University Hospital Birmingham NHS Trust).

## Available systems range from the home-grown extensively tailored applications that have been developed over a number of years to the expanding array of commercially available off-the-shelf systems. Although home-grown systems tend to be more easily adopted by hospitals (this reflecting the strong sense of local clinical ownership), extensive systems’ customisation over time means that these are not easily transportable to other sites. In addition, very few hospitals have the necessary expertise or budgets to develop their own systems in-house. A key decision facing Trusts is therefore whether to persist with paper-based prescribing or to choose between the commercially available systems. This decision is likely to be shaped by a range of factors, including the ease of implementation, training implications, the time and cost investment necessary, and the anticipated benefits, particularly in relation to improving prescribing safety. Given the significant cost and resource implications involved, this decision should be an evidence-informed one, but this is currently not possible because there is a dearth of high quality evidence to draw upon (15). This Programme aims to begin to fill this important evidence gap.

## Whilst real-time prescribing support and electronic alerts/prompts have under some circumstances demonstrated benefit in improving clinicians’ prescribing behaviour and/or reducing error rates, there remains a small, but nonetheless important risk that the introduction of these systems may also have serious adverse impacts on patient outcomes (16-20). They can thus introduce new areas of clinical risk and unexpected threats to patient safety. Koppel and colleagues, for example, reported how fragmented computerised provider order entry displays prevented a coherent view of patients’ medication and how separation of functions facilitated double dosing (18). Another study has highlighted how systems’ implementation generated errors associated with the process of entering and retrieving information, and with communication and coordination processes (16). Similarly, we have found that many systems can produce clinically spurious alerts, which frustrate end-users and results in these commonly being over-ridden or ignored (17). More recent work has highlighted the potentially serious treatment delays that can inadvertently be associated with the introduction of ‘hard stops’ to reduce risk of serious prescribing errors (19;20).

## This highlights a need for careful evaluation of the introduction of such technologies. Unintended consequences of health information technologies are strongly linked to poor implementation strategies. This has been demonstrated not only in the UK, but also in many other areas of the world (21;22). Much work has, to date, been conducted at selected centres of excellence in the US and we now propose to build on this in order to understand the lessons that are transferable to the English NHS.

*Should include any reviews of previous studies, disease particulars, incidence, current treatment options, risks and benefits.*

## 1.2 RATIONALE FOR STUDY

## The outcomes of adopting new information systems depend upon the design and configuration of the computer system. The implementation strategy, training, systems’ maintenance, work reorganisation and development of new work practices are all influential in systems’ deployments. Given the complex interactions between these various socio-technical factors, introducing new systems into hospitals may result in both positive and negative consequences. These effects can often be seen across the systems’ lifecycle, beginning with plans to procure the new systems and extending throughout integration (23-25). Longitudinal case studies are therefore needed to consider the evolution of use over time and identify factors determining the short- and longer-term impacts of these systems. It is anticipated that these factors will include the organisational learning achieved, identifiable impacts upon everyday working practices, and issues relating to communication across organisational boundaries, "hidden costs" and safety and risk arising from systems’ utilisation. Specific lessons arising from systems’ utilisation (e.g. functionality in different work settings), a variety of operating systems (e.g. computers-on-wheels and hand-held devices such as iPads), systems performance (including failures and down-time), clinicians responses to alerts and impacts upon clinical practice will be identified. The implications for the prescribing education of healthcare professionals will also be assessed (26).

Good communication and information sharing within a healthcare organisation and across organisational boundaries are critical for continuity of patient care. The Department of Health (DH) Discharge from Hospital: pathway, process and practice (27) called for effective communication between primary, secondary and social care. Research has indicated the impact of communication breakdown on prescribing and on the monitoring of patients following discharge from hospital (28), and a DH commissioned report (29) highlighted how the use of ePrescribing systems in hospitals can give staff quicker access to more reliable information and thus have the potential to improve patient safety. GPs may also require timely information from hospitals to support safer care after a patient has been discharged from hospital (30).

WP 1 will therefore seek a better understanding of how different hospital ePrescribing systems impact on communication and local connectivity both within the hospital and in the wider health community. The focus of this study is particularly on the perspectives of those responsible for prescribing in order to investigate the consequences of the hospital ePrescribing systems for information flows (31).

*Should include a clear explanation of the research question and hypothesis, justification for the study, including
- an explanation of why the study is appropriate, benefits to participants, health services, relevance to current policies etc;
- description of the indication, its diagnosis, incidence, current treatments, their limitations etc;
- description of the treatment under investigation;
- statement of what would be a worthwhile improvement in study outcomes and what evidence there is that the treatment under investigation may achieve this.*

# 2 STUDY OBJECTIVES

## 2.1 OBJECTIVES

Aim

To investigate the short- and longer-term impacts of introducing ePrescribing systems into hospitals.

We seek to achieve this aim by fulfilling three key objectives:

1. Describe the planned and actual implementation and adoption strategies;
2. Understand key professional stakeholders’ perspectives, by exploring individuals’ experiences and practices over time;
3. Understand the impact of hospital implemented ePrescribing systems on communication and connectivity both within hospital and with local primary care providers.

*Detail secondary endpoint(s)*

# 3 STUDY DESIGN

## This is a longitudinal series of on-site observations and gathering of field notes. A series of prospective case studies will be carried out to investigate the introduction and impact of ePrescribing systems of varying complexity and cost in a range of NHS hospitals. Longitudinal, socio-technical (32), qualitative, multi-site case studies will be carried out (33), treating each participating hospital as an individual, detailed case study of the socio-technical processes of procuring, implementing, adopting and maintaining an ePrescribing system.

*Detail:
- type of and length of study e.g. 24 week, multi-centre, randomised, double-blind, placebo controlled etc;
- duration e.g. what constitutes the treatment phase and the follow up phase;
- points in trial for measurement of outcomes;
- consider a schematic diagram of the study design.*

 *-duration of participant involvement*

*- detail any stopping rules for the study*

# 4 STUDY POPULATION

The study population will consist of diverse secondary care Trusts throughout England that are planning to or have begun to implement ePrescribing systems. Within each recruited hospital, we will use purposive sampling to identify a diverse range of staff stakeholders within those sites.

Four case studies are planned: 2 fine grained considerations of sites in hospitals that are planning to implement ePrescribing systems and 2 broader investigations in hospitals that have already begun implementation. Up to 15 staff participants per site will recruited.

*Detail:
Number of participants/volunteers, participant population, number of sites involved, length of recruitment period.*

# 5 PARTICIPANT SELECTION AND ENROLMENT

## 5.1 IDENTIFYING PARTICIPANTS

Purposive sampling (34) will be used to identify diverse secondary care trusts and to identify

a diverse range of stakeholders within the trust.

5.2 CONSENTING PARTICIPANTS

Target professionals being observed will be supplied with an information sheet prior to being observed. Written consent to take part will then be requested.

*Post hoc* consent will be requested from any individuals who are observed during this process, who were not consented prior to the period of observation taking place. This will include an option for the data collected during the observation to be destroyed.

All fieldwork will be undertaken with due regard to maintaining the best interests of participants, and in particular ensuring that their confidentiality and anonymity are assured *Include details of any limitations regarding who will be designated to take informed consent from participants. Any limitations stated must be adhered to unless the protocol is amended accordingly and approved by the relevant organisations.*

1. *State if withdrawn subjects will be replaced – this may be covered in the statistics section or in a separate statistical analysis plan.*

*Novel compounds may not have a SmPC. In this scenario, the Investigator’s Brochure (IB) can be reference but should not be appended to the protocol.*

*Detail licensed indications, if study drug will be used outside its licensed indications, contraindications and expected side effects. It may be useful to list known side effects in a table for clarity.*

*If more than one IMP will be administered in the study, add additional sections as appropriate.*

*Detail other drugs that are not allowed during the study due to e.g. interaction with the study drug, an effect on study outcome etc. Provide a specific list of prohibited drugs for clarity. Also comment on what will happen if a prohibited medication is taken during the study.*

*Detail the specific study assessments to be performed and the timepoints during the study - split by visit number if appropriate for clarity. It may be appropriate to prepare a table of assessments by visit.*

# 6 DATA COLLECTION

# Data collection is planned to take place up to three key time periods: a baseline visit; a second round of data collection approximately six months later (where relevant, this corresponding to three-six months post the “go-live” date); and a final round of data collection 12-18 months or more after the baseline assessment. Contact will be maintained with key personnel in between visits so as to allow these schedules to be varied, as appropriate to maximise the opportunity to generate important insights. Each round of data collection is likely to take 4-6 weeks in the field.

# Data collection at each site will involve a longitudinal series of on-site observations (1-4 hours per observation) and gathering of field notes (35) relating to the conduct of everyday work and the use and impact of ePrescribing systems on practices and processes. This will make use of qualitative ethnographic methods, but will consist of unconcealed observation where the researcher has a defined research boundary, rather than participant observation in order to acquire an insider’s knowledge.

# On-site observations with health professionals will record how systems influence working practices. Interactions between clinicians and the new ePrescribing systems, patients and healthcare professionals and between healthcare professions, e.g. doctors and pharmacists, will be focussed on in order to understand how the configuration of hardware and software impacts upon patterns in use of time and trends in communications during clinical care. Observations of staff participants while they are using prescribing systems (paper or electronic) will necessarily be on hospital wards, and in the presence of NHS patients. However, observations will not include the recording of any patient identifiable data. We will ask research participants (staff) to alert patients to the presence of the researcher, highlighting that declining the presence of the researcher will not affect their care. If a patient objects to the presence of the researcher, the researcher will remove themselves immediately from that interaction. If the patient does not object, then the observation will begin. Recordings will not begin until after the patient has confirmed their identity and / or any other identifiable information. If the patient discloses such information during an obvervation, this will be deleted from the audio-recording immediately.

# Longitudinal analysis, and equivalent insights derived from comparative analysis of early and established adopters of systems, will examine changes in work processes as skills and routines in using ePrescribing systems become enhanced as technologies become embedded and optimised in the light of experience (what Arrow (39) described as “learning by doing”). Ethnography (involving purposive, multi-site and longitudinal studies) has proved useful in seeking to understand difficulties encountered in developing large scale health infrastructures (36). This approach, whereby provisional understandings of the locations to be studied together with the specific research concerns jointly determine the choice of research setting, will be used to gather information relating to local enactments and elaborations of systems’ use. This information will allow comparison between local governance, user accountability arrangements and situated practice (this encompassing, for example, the role of user discretion and use of workarounds) (40).This will highlight any dissonances and tensions between what should happen and what happens in practice, and in the light of this consider the potential consequences for dependability of operations and the possibility of giving rise to new and unanticipated risks.

Data generation will end when saturation has been reached and no new relevant data are being collected (41). The above described numbers of observations are based on previous experience and should therefore be seen as indicative; these will be adjusted as necessary.

*Detail data to be collected, including:
- the source (e.g. questionnaire, medical notes, electronic data collection procedures);
- timepoints for collection (e.g. baseline, during treatment, during follow up);
- who will collect the data;
- details of any standardised tools (e.g. pain scores);
- describe any methods to maximise completeness of data collection (e.g. telephoning participants who have not returned questionnaires).*

*The Edinburgh Clinical Trials Unit (ECTU) can provide support - ACCORD facilitators will advise.*

# 7 DATA ANALYSIS

# Qualitative data collection and analysis will be iterative (41), allowing emerging themes to be explored further and disconfirming evidence to be sought. Multiple data sources (documents, interviews and observations) from our linked Work Package 1 protocols including interviews with professionals and patients will allow researchers to triangulate case study evidence and identify where and how different data converge and diverge. Thematic analysis of longitudinal data collection will allow changes to be tracked over time; accessing a diverse range of interviewees and locations for observation will permit analysis by stakeholder group (42). Detailed within case analysis will be followed by analysis across cases to identify over-arching themes.

*Detail the sample size, precision or power calculation, dropout rates, relevant assumptions and justifications. Comment on an estimate of the recruitment period with justification that the required sample size will be achievable.*

*State if this information is detailed in a separate document.*

*Detail the variables to be used for assessment and how these will be reported (e.g. means, standard deviations, medians etc). Write detailed plans for analyses of primary and secondary outcomes including:
- summary measures to be reported;
- method of analysis
- plans for handling missing, used and spurious data, non compliers and withdrawals;
- plans for pre-defined subgroup analyses;
- statement regarding use of intention to treat analysis;
- details of any interim analysis;.*

# 8 STUDY MANAGEMENT AND OVERSIGHT ARRANGEMENTS

The study is managed fortnightly via team meetings and monthly management meetings which involve all of the Work Package leads. The Programme Steering Group meets quarterly and the Independent Programme Steering Group meets approximately 6 monthly.

*Suggested text only - amend as appropriate. Consider detailing a division of responsibilities of the Trial Management Group.*

*A Delegation Log must be in place at each site.*

*Establish monitoring for external sites and detail in the protocol. This text can be replaced with brief details of the monitoring if agreed with the ACCORD Senior Clinical Research Monitor.*

*CONSIDER REPORTING OF DEVIATIONS IN PUBLISHED WORK.*

*Detail procedures for peer review – these may be funder specific or involve an internal department.*

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**Participant Information Leaflet for WP1 Observations**

**Investigating the implementation, adoption and effectiveness of ePrescribing systems in English hospitals: a mixed methods national evaluation**

**Work Package 1 ethnographic study**

**Information Sheet for Participants**

You are being invited to take part in the above study. Please take time to read this information sheet before deciding whether to take part. This describes the goals of the study and what we are asking you to do. This Information Sheet also indicates how we will collect, store and use the data collected. Thank you for taking the time to read this leaflet. We appreciate you are busy and would like to thank you in advance for taking the time to read this leaflet and consider this request.

**Purpose of the study**

We are undertaking an ambitious multi-faceted programme of work to inform important national deliberations on the safe, effective and efficient procurement and implementation of ePrescribing systems into hospitals in England. In doing so, we wish to explore the experiences, attitudes and organisational consequences of implementation from the perspectives of key stakeholders. This part of the programme involves an ethnographic study. This involves observing people in their natural setting. In this case, one of the study researchers will observe staff during the course of their work to see how ePrescribing systems affect work practices and processes.

**Why have I been invited?**

You have been invited because you are either a:

* Healthcare professional
* Member of administrative staff
* Member of IT support personnel
* Healthcare or technical manager
* Member of the implementation planning team

at a hospital where ePrescribing systems have been or will soon be implemented. We would like to investigate the impact of ePrescribing systems on practices and processes and invite you to be observed in order to gain insights into this.

**Do I have to take part?**

No, It is up to you whether you wish to take part in an observation. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you do decide to take part you will need to complete the Consent Form, and should also keep this Information Sheet.

**What will happen if I decide to take part?**

We would like to invite you to be observed at your workplace, during working hours, while you are carrying our prescribing related activities. We would invite you to do this for a maximum of three times throughout the implementation period of ePrescribing systems (over approximately two years). However, if you prefer to be observed only once or twice we will be very happy to arrange this. Most observations will take between one and four hours each. The person observing you will be one of the research team [name person here].

If you are unable to be observed at the time you are contacted, the researcher will give you the option of choosing a new time to be observed. We would like to observe people while they conduct their everyday work so that we can observe the use and impact of ePrescribing systems on practices and processes. The observations will be audio-taped, with your permission, a written account of the observation will be produced for the research team. This will have a unique participant number on it, but will not have your name or telephone number on it. You will be free to stop the observations at any time should you wish and we will destroy the recording if you ask us to do so.

If you are being observed during a time when you are communicating with an NHS patient, we will ask you to alert the patient to the presence of the researcher. We will ask you to state that declining this will not affect their care. If a patient objects to the presence of the researcher, the researcher will remove herself from the interaction immediately. If the patient does not object, then the observation will begin. All data gathered will be kept confidential. Recordings will not begin until after the patient has confirmed their identity and / or any other identifiable information. If the patient discloses such information during an obvervation, this will be deleted from the audio-recording immediately.

**What are the possible disadvantages or risks of taking part?**

Taking part in an observation will take up some of your time. There are no risks involved in participating.

**What are the possible benefits of taking part?**

The implementation of ePrescribing systems involves considerable time and resources. Our role as researchers in this study is to discover if ePrescribing systems are delivering on the expected benefits, and also to discover how best to support their use in hospitals. Your participation in this study will help us to assess how usable the new system is and to determine whether it meets your needs.

Participation in this study will provide us with the opportunity to help improve the efficiency with which you use ePrescribing systems, and also to provide us with data that can be provided to developers to both ensure the functionality provided is that which you require, and that the system design helps you make use of this functionality easily. Participation will also help you to keep abreast of this important development in the NHS.

**Will my participation in the study remain confidential?**

Yes. All recordings from the observations will be anonymised, and anything you say during an observation will be confidential.

However, in the case of a disclosure which is firmly believed by the researcher to have a bearing on patient safety, the researcher will be obliged to inform the relevant body. You will be informed if this situation arises.

**What will happen to the results of this study?**

The results of this study will help to inform local and national implementation of ePrescribing systems in hospitals. A report will be submitted to the National Institute for Health Research. The results of this study will be published in relevant journals and presented at conferences. No individual participant or site will be identifiable in any of the published material.

We are planning to archive all anonymised data collected so that they may be made available to researchers from the ePrescribing research team for further analysis in the future. You will be asked on the consent form whether you agree to this.

**Who is organising and funding this research?**

The research is organised by the University of Edinburgh in collaboration with the University of Nottingham, Harvard School of Public Health, and the University of Birmingham. It is an independent evaluation that is funded by the National Institute for Health Research.

**Who has reviewed the study?**

This study has been ethically reviewed by the University of Edinburgh Centre for Population Health Sciences Ethics Committee and from [xx name trust].

**What can I do if I have a complaint about the study?**

If you have any concerns or questions about this study, please raise these with the lead researcher, or with any member of the research team conducting the study. The principal investigator for this study is Professor Robin Williams at the University of Edinburgh. If you feel that you need to make a formal complaint, a complaint can be made using the NHS Complaints Procedure.

**Who do I contact for further information?**

For further information about this study please contact either the local research fellow or the chief investigator below:

Local Research Fellow:

[delete as appropriate]

Dr. Kathrin Cresswell, Centre for Population Health Sciences, The University of Edinburgh, Medical School, Teviot Place, Edinburgh, EH8 9AG. Tel: (0131) 650 9241; Fax: 0131 650 9119; email: kathrin.beyer@ed.ac.uk

Dr. Zoe Morrison, Centre for Population Health Sciences, The University of Edinburgh, Medical School, Teviot Place, Edinburgh, EH8 9AG. Tel: (0131) 651 4147; Fax: 0131 650 9119; email: zoe.morrison@ed.ac.uk

Dr. Lisa Lee, Centre for Population Health Sciences, The University of Edinburgh, Medical School, Teviot Place, Edinburgh, EH8 9AG. Tel: 07879 470535; Fax: 0131 650 9119; email: lisa.lee@ed.ac.uk

Miss Hajar Mozaffar, Centre for Population Health Sciences, The University of Edinburgh, Medical School, Teviot Place, Edinburgh, EH8 9AG. tel 07846 991188, email H.mozaffar@ed.ac.uk

Chief Investigator: Professor Robin Williams, Institute for the Study of Science, Technology and Innovation, School of Social and Political Sciences, The University of Edinburgh

Old Surgeon's Hall Edinburgh EH1 1LZ Tel 44 (0)131 650 6387 ; Fax: 0131 650 9119; email: robin.williams@ed.ac.uk

Thank you for taking the time to read this information sheet and for considering this request.

**Consent form for WP1 Professional Observations.**

**Investigating the implementation, adoption and effectiveness of ePrescribing systems in English hospitals: a mixed methods national evaluation**

**WP1 Ethnographic Study**

**CONSENT FORM**

**Please initial all the boxes and give this form back to the researcher. If you don’t feel able to consent to all the boxes, or if you change your mind at any point, we will not include you in the research.**

|  |  |
| --- | --- |
|  | initial |
| I have read and understand the information leaflet (version 1.0 18.11.2013) for the above study. |  |
| I have been consulted about my participation and I have had the opportunity to ask questions about the study and understand what is involved. |  |
| I understand that the study will involve observing me during the course of my work.  |  |
| I understand that all of the information about me recorded for this project will be anonymised and will not compromise my confidentiality in any way. If the results of the study are published it will not be possible to identify information about me. |  |
| I understand that the observation will be audio recorded using digital equipment and agree to the recording of my observation being transcribed (typed up) by the research secretary, or by an external company where necessary. |  |
| I understand that if I say something during the observation which has an implication for patient safety, the researcher will have to tell the relevant bodies. |  |
| I agree that in the (unlikely) event of a loss of capacity, the research team can retain data collected from me, and continue to use it confidentially in connection with this research. |  |
| I am willing for my anonymised data to be archived and made available for further research. |  |
| I understand that I can withdraw from the study at any time, without giving any reason and without legal rights being affected. |  |
| I give consent to take part in the above study. |  |

**PTO**

|  |
| --- |
| Name of participant |
| Signature of participant | Date |
| Name of person taking consent |
| Job title |
| Signature of person taking consent | Date  |

One copy to be retained by researcher, one copy to be retained by the participant.

**Indicative Topic Guide for WP1 Professional interviews and observations.**

### T1 Interview topic guide – decision-makers, implementation team members and IT staff

* Interviewee’s background including current position in the organisation and specific role in relation to the system;
* Details of the system and status;
* Views on development of the system: design, uptake, implementation, evolution;
* Important local considerations for example timelines, resources, infrastructure;
* Training and support provided (initial and ongoing);
* Collaboration with the software developer (configurability, management process);
* Data quality and systems’ reliability issues;
* How are data produced by the system utilised?
* Lessons learned
* Perceived/anticipated consequences of the system on the quality of care, information flow, patient experience, roles and practices of healthcare professionals, the organisation, the local community;
* Views on how systems will integrate with existing local and national systems;
* Expectations and perceptions (the future, benefits realised or to be realised);
* Perceived changes over time;
* Integration with other hospital systems.

### T1 Interview topic guide - NHS staff (the users of the system)

* Interviewee’s background including current position in the organisation and specific role in relation to the ePrescribing system;
* Details of the system (previous systems, decision to implement, choice of system and integration with other systems);
* Views on how systems will integrate with existing local and national systems;
* Perceived/anticipated consequences of the system on the quality of care, information flow, patient experience, roles and practices of healthcare professionals, the organisation, the local community;
* How the interviewee uses the system;
* Training received and ongoing support;
* IT literacy and skills;
* Initial, current and ongoing problems and concerns;
* Changes that the user would like to see happening in the system and in relation to the implementation strategy;
* Changes in work practices (new practices, workarounds, impact on the way the team functions and on patients) and perceptions surrounding skills and knowledge.

From Cresswell et al Evaluation of medium-term consequences of implementing commercial computerized physician order entry and clinical decision support prescribing systems in two 'early adopter' hospitals. J Am Med Inform Assoc. 2014 Oct;21(e2):e194-202 by permission of Oxford University Press

### T2 Interview topic guide - NHS staff (the users of the system)

* Interviewee’s background including current position in the organisation and specific role in relation to the system;
* Details of the system and status;
* Accounts of how the system has been developed/ embedded into work practices since implementation;
* Local adaptations necessary to ‘make it work’, including ‘high profile’ local examples of success/ adverse events, organisational expectations and priorities;
* Ways in which the system has impacted upon rhythms of work (e.g. timings, flows, routines);
* Differences in working practices, including specialty, local, national and international differences in roles and responsibilities.
* Work undertaken to map business processes and work re-organisation;
* Links to other projects in the Trust (e.g. LEAN, business change and quality improvement);
* Processes relating to the medicines cupboard and pharmacy stocks on the ward (e.g. duplicate orders coming to the ward, availability of non-stock medications, workloads – additional ordering, pharmacists’ availability);
* Data quality and systems’ reliability issues;
* How are data produced by the system utilised?
* Lessons learned
* Perceived/anticipated consequences of the system on the quality of care, information flow, patient experience, roles and practices of healthcare professionals, the organisation, the local community.

**Protocol for Work Package 1 (Patient ) Interviews**

**Investigating the implementation, adoption and effectiveness of ePrescribing systems in English hospitals: a mixed methods national evaluation**

|  |  |
| --- | --- |
| Funder | NIHR |
| Funding Reference Number | RP-PG 1209 10099 *insert funding reference number before finalisation* |
| Chief Investigators | Prof Robin Williams |
| Co Investigator | Prof Aziz Sheikh |
| Co Investigator | Dr Jamie Coleman |
| Co Investigator | Mr Anthony Chuter |
| Co Investigator | Ms Ann Slee |
| Co Investigator | Prof Tony Avery |
| Co Investigator | Prof Richard Lilford |
| Co Investigator | Prof Jill Schofield |
| Co Investigator | Dr Zoe Morrison |
| Co Investigator | Dr Kathrin Cresswell |
| Co Investigator | Dr Ann Robertson |
| Co Investigator | Dr Sarah Crowe |
| Co Investigator | Prof David Bates |
| Programme Administrator | Mrs Rosemary Porteous |
| Project Management | Dr Lucy McCloughan  |
| REC Number |       *insert REC number before finalisation* |
| Version Number and Date | V1.2 11 July 2013 |

*If the trial is multi-site, or has a coordinating Trial Centre, add specific details e.g. contact name, address etc below, otherwise delete these tables.*

|  |  |
| --- | --- |
| **Chief Investigator**Prof Robin Williams*email* | **Researcher**Dr Lisa Lee *name*Centre for Population Health Sciences The University of Edinburgh, Medical School, Teviot PlaceEdinburgh EH8 9AG *address**email* |

|  |  |  |  |
| --- | --- | --- | --- |
| Prof Robin Williams |  |  |  |
| Chief Investigator | Signature |  | Date |

*Add details of Chief Investigator, Trial Statistician and any other relevant trial related staff as appropriate e.g. Trial Manager*

*The final version of the protocol should be signed off before distribution to trial staff, external sites etc.*

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1. LIST OF ABBREVIATIONS

|  |  |
| --- | --- |
| EPMA | Electronic Prescribing and Medicines Administration systems |
| EPP | Expert Patients Programme |
| EPP CIC | Expert Patients Programme Community Interest Company |
| GP | General Practice |
| IDDT | [Insulin Dependent Diabetes Trust](http://iddt.org/) |
| NCT | National Childbirth Trust |
| NHS | National Health Service |
| PALS | Patient and Advice Liaison Service |
| PPI | Public and Patient Involvement  |
| UK  | United Kingdom |
| WP | Work package |

Summary

A number of international benchmark studies have demonstrated that prescribing errors are common and are responsible for considerable, and potentially avoidable morbidity and mortality. Given the increasing complexity of prescribing decisions, the risk of prescribing-related iatrogenic harm is likely to increase yet further. There is then a pressing need to identify effective approaches to improving the safety of prescribing. Interest is converging on the potential offered by computerised order entry and related advanced decision support systems (henceforth referred to as Electronic Prescribing and Medicines Administration systems or EPMA). These systems however vary considerably in functionality, inter-operability and costs. This Programme aims to inform important national deliberations on the safe, effective and efficient procurement and implementation of EPMA systems into hospitals in England by:

* Describing the procurement, implementation, adoption and maintenance of the basic and more advanced EPMA systems;
* Estimating their effectiveness and cost-effectiveness;
* Developing best practice recommendations for procurement and a toolkit for their successful integration into NHS hospitals.

These aims will be met by performing a theoretically-informed, multi-method, context-rich, naturalistic evaluation using the principles of a stepped-wedge design. At least four in-depth longitudinal case studies in purposefully selected hospitals implementing EPMA systems of varying functionality and cost will be carried out. The programme is organised into four complementary Work Packages (WPs):

• WP1: Procurement, implementation, adoption and connectivity

• WP2: Assessing impact on prescribing safety

• WP3: Health economics and a value of investment analysis

• WP4: Integration across WPs to develop recommendations and a toolkit for the NHS.

This protocol concerns a Patient Experience Study within Work Package 1 which aims to investigate the short- and longer-term implications for and impacts on patients of introducing EPMA systems into hospitals.

# INTRODUCTION

## BACKGROUND

Prescribing errors are common, costly and often result in considerable harm to patients (1-8). Work from a handful of predominantly US-based centres of excellence suggests that the risk of patients being inadvertently harmed by erroneous prescribing may be greatly reduced by the introduction of EPMA systems (9-11). Their development, procurement and implementation are therefore currently being pursued internationally (12). Whilst real-time prescribing support and electronic alerts/prompts have under some circumstances demonstrated benefits in improving clinicians’ prescribing behaviour and/or reducing error rates, there remains a small, but nonetheless important risk that the introduction of these systems may also have serious adverse impacts on patient outcomes (13-17). They can thus introduce new areas of clinical risk and unexpected threats to patient safety. Koppel and colleagues, for example, reported how fragmented computerised provider order entry displays prevented a coherent view of patients’ medication and how separation of functions facilitated double dosing (15). Another study has highlighted how systems’ implementation generated errors associated with the process of entering and retrieving information, and with communication and coordination processes (13). Similarly, we have found that many systems can produce clinically spurious alerts, which frustrate end-users and result in these commonly being over-ridden or ignored (14). More recent work has highlighted the potentially serious treatment delays that can inadvertently be associated with the introduction of ‘hard stops’ to reduce risk of serious prescribing errors (16,17).

This highlights a need for careful evaluation of the introduction of such technologies not only from the point of view of Trusts implementing EPMA systems as carried out by Work Package 1, but also from the perspective of patients or their carers and other stakeholders such as GPs. Indeed, these groups may be affected by the use of prescribing systems as a result of a reduction in prescribing errors, or of changes in working practices and information flow.

##

## RATIONALE FOR STUDY

In order to improve the chances of successfully implementing any new technology, demonstrating its value to users is key (18). Case studies undertaken to date with professional participants as part of Work Package 1 (WP1- under a separate protocol) have considered this question from the point of view of suppliers, managers and healthcare professionals. Yet what value patients, their carers and those caring for them in the community (such as GPs) believe they may derive, or otherwise, from the introduction of EPMA systems, has not been fully explored and warrants closer examination. The rationale for introducing EPMA systems in hospitals has been based on expectations of improved safety (9, 10, 11)

By capturing the views of patients, carers, groups representing patients as well as GPs, the Patient Experience Study will offer a deeper understanding of the risks and benefits (actual and anticipated) of introducing EPMA systems in hospitals, and the extent to which such systems can support the primary / secondary care interface. The Patient Experience Study will therefore seek to provide more detailed insights into how a hospital EPMA system can impact on communication and local connectivity both within the hospital and in the wider health community, and what consequences this may have for patient care. Furthermore, it will help determine whether certain groups of patients are at higher risk of experiencing prescribing errors (delay, omission, commission), because they suffer conditions which call for repeated and complex changes in prescription regimens as they switch between primary, secondary and self-care.

# STUDY OBJECTIVES

The main aim of this study is to understand the role, significance and consequences of a hospital’s implementation and adoption of an EPMA system for patients. It will do so by exploring some of the perceived benefits of introducing EPMA systems, focusing in particular on the experiences and expectations surrounding EPMA use from the perspective of patients, carers, patient representative groups and GPs.

The key objectives of the study are therefore:

* To understand issues affecting patients in relation to prescribing and medicine management in a hospital setting, and their experience of the prescribing process and its impact of the perceived quality of care
* To determine the implications of the level and type of information provided to patients regarding the use of EPMA, as well as patients’ understanding/knowledge and expectations of the system and accompanying prescribing processes
* To explore changes in the interaction between healthcare professionals and patients in a hospital setting using EPMA (for instance in relation to patients’ face-to-face contact with pharmacists and doctors), and assess how this impacts on the patient experience
* To investigate changes to the administration of medication as a result of the introduction of EPMA (e.g. for the timely delivery of pain relief)
* To examine consequences of EPMA use (existing and potential) on patients receiving complex / high risk prescribing (Heparin, Warfarin, Insulin) and those with long-term and chronic conditions with a particular focus on patients with diabetes, co-morbidities, or renal diseases
* To define the impact of EPMA use on medication reconciliation (admission and discharge)
* To assess changes in the information flow between hospitals and GPs in order to understand the extent to which EPMA systems can improve the primary/secondary care interface

# STUDY DESIGN

The earlier WP1 research carried out as part of the Programme, as well as research elsewhere (24), have helped to identify five areas where observable changes following the introduction of EPMA systems may be present or anticipated: (a) at admission and discharge (medicine reconciliation), (b) when liaising with GPs, (c) among patients with long-term and chronic illnesses (including co-morbidities), especially diabetes and renal diseases (d) in relation to particular prescribing events such as delayed medication for pain relief (e) in respect to the prescribing of complex drugs such as Warfarin, Heparin and Insulin. The Patient Experience Study will seek to capture patient experiences of these areas of change through interviews with patients, carers, GPs and individuals with expertise and in-depth knowledge of issues affecting the patient experience. A range of background data either publicly available or obtained as part of WP1 data collection will be drawn on to help define the key variables that impact on patients’ experiences and expectations. Hospital Trust documents relating specifically to the implications for patients of EPMA adoption, such as guidance to clinicians, internal reports or patient information leaflets, as well as early findings from the Programme’s Work Package 1 will thus be used here. The findings will be drawn on to inform other Work Packages in the Programme and will contribute to the recommendations and guidance which will be developed as part of the Work Package 4 implementation and adoption support toolkit aimed at NHS managers.

# STUDY POPULATION

The bulk of the data generated by the Patient Experience Study will focus specifically on experiences and expectations of prescribing with and without EPMA systems, and will therefore explore the questions set out above through interviews with a number of key informants. These participants are categorised according to the perspectives it is hoped they will bring to the study.

## Hospital Site and Linked GP Practices

In order to obtain a detailed and personal account of patients’ experiences and expectations of EPMA, and to explore comprehensively issues relating to perceived consequences for the medication process, discharge and the primary/secondary care interface, interviews at a WP1 case study hospital (St George’s Hospital, London) and at the GP practices linked to it will be carried out (see Table 1 and Table 2 below). The Patient Experience Study will take place initially at only one hospital case study site and its linked GP practices. Data will be collected at further case study sites and attached GP practices if this is deemed necessary (for instance if the data obtained remain inconclusive). The exact number of interviews will be determined by when saturation is achieved and that no new themes are emerging from the interviews, although it is estimated that in total approximately 30 interviews will be required for this component of the Patient Experience Study.

*Table 1. Hospital Site Planned Interviews*

|  |  |  |  |
| --- | --- | --- | --- |
| Participants | Reasons for inclusion/selection criteria |  Number of interviews | Type of interview and duration |
| Patients or Carers | * purposefully selected patients, or carers, on medical and surgical wards referred to the study via a range of local contact points PALS staff, EPP tutors, doctors, nurses.
 | * Referred patients/carers

(25-30) | * Semi-structured interviews (approximately 15 mins, face-to-face)
 |

***Detail:
Number of participants/volunteers, participant population, number of sites involved, length of recruitment period.***

*Table 2. Hospital Site Linked GP Practices*

|  |  |  |  |
| --- | --- | --- | --- |
| Participants | Reasons for inclusion/selection criteria |  Number of interviews | Type of interview and duration |
| GPs and/or GP practice managers | * Knowledge of issues affecting patients, esp. relating to discharge, and primary/secondary care interface.
 | * GPs or Practice Managers (5-10)
 | * Telephone based semi-structured interview with GPs/ Practice Manager (approximately 15 minutes)
 |

## Patient Groups and Organisations

Individual patients with sporadic interactions with health services are not well placed to evaluate the prescribing systems used and assess their consequences which may be diffuse and only emerge over extended timeframes. It is therefore important to draw on individuals and groups with extended experience and involvement who can allow more detailed overarching insights across sites into issues affecting a larger number of patients, and who can therefore act as representatives and advocates for patient concerns. Established patient groups together with patient-centred charities will be approached, and in total up to 30 interviews with key individuals across these organisations will be carried out to better understand the implications for patients of EPMA systems. The table below offers an overview of anticipated face-to-face or telephone interviews with key bodies and charities representing the views and experiences of patients.

*Table 3. Patient Representative Groups and Organisation Planned Interviews*

|  |  |  |  |
| --- | --- | --- | --- |
| Organisations | Reasons for inclusion | Interviewees (n) | Interview type and duration |
| Expert Patients Programme Community Interest Company (EPP CIC) | * Run courses for individuals living with long-term health conditions.
* have access to and interact with wide range of patients dealing with long-term conditions
* run courses aimed specifically at helping patients manage their medication
 | * Tutors (8-10)
 | * Telephone based semi-structured interview, up to maximum 30 minutes each.
 |
| PALS National Network; Patients Association  | * have knowledge of issues and concerns affecting patients
* may refer or alert individual patients to the Study
 | * PALS officer national and local site (2)
* Senior Policy and Campaigns Officer (1)
 | * Semi-structured, up to 30 minutes (face-to-face or telephone)
 |
| Diabetes UK; Age Concern; British Pain Society; Anticoagulation Europe; Lifeblood; IDDT; Neurological Alliance; National Standing Commission on Carers; Pain UK; UK National Kidney Federation; British Heart Foundation; Rare Diseases UK; NCT; Healthcare Quality Improvement Partnership | * have expertise on prescribing errors and safety improvement for patients with higher risk of experiencing medication errors/delays, or receiving high risk/complex prescribing
 | * Senior Policy/Research & Strategy; National Clinical Audit Lead; Commission Member (17)
 | * One semi-structured interview per organisation, up to 30 minutes each (face-to-face or telephone)
 |
| Patient Experience Network; NHS Institute for Innovation and Improvement  | * have insight into how patient experiences are/can be used for improved healthcare delivery through their work on engagement
 | * Director, Patient Experience Network (1)
* Head of Engagement and Experience (1)
 | * Semi-structured, up to 30 minutes each (face-to-face or telephone)
 |

# PARTICIPANT SELECTION AND ENROLMENT

## IDENTIFYING PARTICIPANTS

Participants in the Patient Experience Study can be split into three broad categories:

1. Patients/Carers
2. GPs and GP Practice Managers
3. Patient representative groups and other points of contact for patients

Category 1 participants will be self-selected following a verbal invitation from local nursing staff to take part in the Study and from posters placed around the hospital. Patients will be selected from both medical and surgical wards, where (a) the EPMA system will be or has been implemented and (b) where quantiative data measuring prescription safety as part of Work Package 2 of the Programme is also being collected. Invitations will be issued to participants meeting all the inclusion criteria, and represent groups of patients defined as being, or to have previously been, at greater risk of experiencing prescribing errors, or other significant event related to the introduction and use of EPMA systems, as well as patients receiving more complex prescribing such as Warfarin, Insulin or Heparin. Eligible patients on the ward will only be invited to take part if available and if judged well enough to do so by the ward sister, following prior consultation with relevant staff on the ward. In the event that a high number of participants meet the inclusion criteria, those participants aligning to the greatest number of areas of interest, or seen as most likely to experience or have experienced prescribing related events, will be prioritised. The initial acceptance to take part will be taken verbally by the nursing staff. Where appropriate, the participant may be the person caring for a patient, as this person will in some circumstances have responsibility for the patient’s prescriptions and medication, especially when out of hospital. This will be determined in consultation with staff, and/or when approaching potential participants.

Category 2 participants will involve a strategic selection of General Practices linked to the Hospital Site, who will be invited to take part in a short telephone based interview. This selection will be based on GPs who have cared for or are caring for patients who have been admitted onto a medical or surgical ward at the case study hospital site. Participant GPs do not have to be the GPs of patient participants. No data will be collected to establish any link between individual patients and GPs, and therefore any participation by a GP caring for a patient participant will be coincidental and no association will be recorded.

Category 3 participants will be purposefully selected to represent expert views on the impact of EPMA for patients and will be approached directly by the researcher. Key individuals within the organisations and groups (c.f. table 3) will be contacted initially via email, and this will be followed-up where appropriate with a telephone call to explain the aims and methods of the research and determine inclusion in the Study. A two week period within which potential participants may respond to the invitation will be made available, at which point a final reminder will be sent out notifying them that no further invitations to participate will be sent regarding the Study unless a response is received.

## Inclusion Criteria

Patient participants must meet one of the following criteria:

* Receiving complex/high risk prescriptions (Insulin/Heparin/Warfarin)
* Suffering from a long-term or chronic condition, or co-morbidities
* A renal patient
* Receiving / has received while in hospital pain management medication

Carer participants must be the carer or relative of a patient meeting one of the criteria above.

## Exclusion Criteria

Patient Participants will be excluded from participation either temporarily or indefinitely if they are

* Under the age of 18
* Unable to provide informed consent
* Deemed not well enough to be interviewed by ward staff
* Temporarily unavailable (e.g. sleeping or receiving treatment).

## CONSENTING PARTICIPANTS

The researcher will supply an information sheet to each participant upon the start of the interview. In the case of telephone based interviews, this will be emailed ahead of the interview. For category 1 participants, the information sheet will be provided by the nursing staff once they have received initial verbal acceptance from the patient. Where possible, the information sheet will be provided to patient participants at least 24 hours before the interview. However a 24 hour window may not always be available if the period between the identification of a suitable patient participant and his or her discharge is less than 24 hours. Every effort will be made in such instances to provide the information sheet at the earliest opportunity, and the researcher will ensure at the start of the interview that the participant has had a chance to read the information sheet, and will if necessary and appropriate, read through the document with the participant. In consultation with both staff and the patient, the most suitable place for the interview will be established, although it is expected that this will be either at the patient’s bedside, in the discharge lounge or other similar waiting area. The participant will be encouraged to discuss any questions with the researcher at the beginning of the meeting. Written consent to take part will then be requested prior to each interview, comprising a completed consent form signed by both researcher and participant. Category 2 participants will also be offered the option of taking part in up to three interviews in total as part of the three data collection periods (see section 6 below). Participants wishing to take part in further interviews will be asked to confirm this and provide their contact details on the consent form.

Where interviews are telephone based, informed consent will be obtained initially verbally at the start of the interview. All telephone calls will start with a statement that ‘this conversation is being recorded’. A consent form will also be supplied by the researcher via email and may be returned electronically so that where possible written consent can be documented. All fieldwork will be undertaken with due regard to maintaining the best interests of participants, and in particular ensuring that their confidentiality and anonymity are assured.

# DATA COLLECTION

Data collection for category 1 and 2 participants is planned to take place over a period of three data collection periods, each lasting 4-8 weeks: the first will take place before the implementation of an EPMA system, the second will be carried out immediately after its implementation and the third will be scheduled for 12 months after the implementation. It is expected that data collection will commence at the case study hospital site in September 2013, in order to align to WP2 data collection measuring prescribing safety at the same site. Where possible the same participant will be interviewed during these three data collection periods in order to allow changes to be observed. In the case of category 1 participants, this will only be possible if they have had further hospital stays around the time of the data collection, and if they have previously indicated their interest in taking part in further interviews. Data collection from category 3 participants will take place over a single extended 8-10 week period as EPMA implementation at an individual hospital site will have no or minimal impact on data obtained from these participants, whose perspective will instead be drawn on national rather than local experiences.

The interviews will seek to understand perceived risks and benefits for patients associated with the adoption of EPMA systems**.** The interviews will also explore patients’ understanding/knowledge and expectations of the systems and prescription processes, how they perceive EPMA systems to have impacted on their interaction with healthcare professionals, specific changes in the delivery of drugs and medications, and the information flow between hospitals and GPs both from the point of view of patients/carers and GPs.

# DATA ANALYSIS

The interview data will be audio recorded, transcribed and then analysed to examine patients’ experiences, knowledge, and the perceived advantages and disadvantages of EPMA systems and of prescription and medicines management more generally. Transcription will be carried out by the Programme administrator, using a University of Edinburgh computer. In the event that some transcription needs to be outsourced due to illness or capacity issues, this will be outsourced to a trusted Transcription Service called “1st Class”, based in Dalkeith, Mid Lothian. The data analysis will be carried out by Programme researchers using University of Edinburgh computers. Data will be securely stored on the University of Edinburgh Medicine and Veterinary Medicine Server in a folder on accessible to Programme staff. Remote desktop access to this folder using secure access mechanisms via the University of Edinburgh will also be used. The data analysis will be carried out with the assistance of a qualitative data analysis software package (NVivo) to facilitate a more systematic and integrated approach, and will be guided, following the initial coding, by a thematic analysis that will allow the exploration of theories and hypotheses advanced in the literature. The first stage of the analysis will therefore focus on data management to define initial sets of themes and items of interest, which will help establish how the data will be coded. The analysis will then be guided by key themes relating to the needs, desires and consequences for patients surrounding the use of IT in healthcare settings (25-29), such as when an EPMA system is being implemented in a hospital, including how the use of such systems may affect patient safety, interactions with healthcare providers as well as their health and well-being (both physical and emotional). It is hoped that this analysis will therefore provide a more accurate picture of patients’ responses to new IT systems in healthcare and of the shifts such systems may produce not only in terms of patients’ expectations but also in relation to the nature and quality of the care they may receive. Such findings will offer a critical form of engagement, and may be especially helpful to support hospitals in understanding patient needs and in communicating to their patients, changes which are taking place or are anticipated as a result of the implementation and adoption of EPMA systems. Respondent validation of the analysis will not be possible in the Study as contact may not be maintained with the subject after the interview. However it is hoped that validity will be achieved through clear, appropriate and consistent methods, and through discussions with the research team and the PPI group, regarding the analytical approach and coding used.

***Detail the sample size, precision or power calculation, dropout rates, relevant assumptions and justifications. Comment on an estimate of the recruitment period with justification that the required sample size will be achievable.***

***State if this information is detailed in a separate document.***

# STUDY MANAGEMENT AND OVERSIGHT ARRANGEMENTS

The Study is managed fortnightly via team meetings and monthly management meetings which involve all of the Work Package leads. The Programme Steering Group meets quarterly and the Independent Programme Steering Group meets bi-annually. Following fieldwork, the researcher will be offered a debriefing session with a peer researcher to discuss any areas of specific concern which arose during data collection, and to agree actions arising from that concern if necessary. The local researcher interviewing patients will be CRB checked, and will continuously consult with staff to ensure that data collection is appropriate on any given occasion, and that its impact remains minimal to both staff and patients.

The Programme’s PPI Group has been and will continue to be closely involved in this Study in order to ensure that patient concerns are taken into account in the design of the study itself. This has included review of drafts of the Patient Experience Study design as well as a group discussion which has sought to establish the most appropriate methodological approach and identify themes relevant to the aims of the research whilst safeguarding patients’ views and rights. The PPI Group has also reviewed the participant information leaflets and consent forms which will be provided to all study participants. Their input will continue throughout the duration of the study, notably through the monthly management meetings and quarterly meetings which are attended by the Programme’s PPI lead.

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**Participation Information Leaflet for WP1 Patient Interviews.**

**TELL US WHAT YOU THINK …**

**Would you like to tell us about your experience of being prescribed and taking medicines in hospital? A team of researchers is trying to find out what patients think of prescribing and medicine administration in this hospital, and how new electronic prescribing systems are affecting the patient’s experience.**

**If you would like to take part in this research, please read this leaflet as it gives you important information about the study and what you will need to do.**

**What is this study about?**

This hospital has or will soon be bringing in a new electronic prescribing system. This means that your healthcare team will prescribe your medicine using a computer system designed to make prescribing safer and more efficient. The study is trying to find out what patients and their carers think about the way prescribing happens in this hospital and about how medicines are given to and taken by patients. This will help the researchers understand what patients want and need when it comes to prescribing. The new electronic prescribing system is not yet used in your hospital.

**Why have I been invited?**

You have been chosen because you are either:

1. a hospital patient
2. a carer for a person who is a patient

and we want to hear your views on how medicines are prescribed and what changes may happen once a new electronic prescribing system is here.

**What will happen if I decide to take part?**

If you take part, the researcher will ask you to complete a consent form to make sure that you are happy to take part in the study. Most people will be given about a day to decide whether you would like to take part or not, but we might ask some people sooner, if they are about to leave hospital. If you agree to take part in the study, the researcher will then interview you and ask you some questions about prescribing and medicines, how you think an electronic prescribing system might affect or is affecting the patient experience. We would also like to invite you to talk to us again once the new system is being used at this hospital. All interviews will be one-to-one interviews and will take about 15 minutes each. We will audio-record with your permission the interview and a written account will be produced for the research team. This will have a unique participant number on it, but it will not have your name or telephone number on it. You can stop the interview at any time if you want to and we will destroy the audio recording if you ask us to do so.

**Do I have to take part?**

It is up to you if you want to take part. If you do, you can leave the study at any time, and without giving a reason. If you decide that you do not want to take part, or if you decide to leave the study, this will not have any impact on the level of care you receive. If you do decide to take part you will need to fill out the Consent Form before the interview, and you should also keep this Information Sheet.

**What are the possible disadvantages or risks of taking part?**

Taking part in an interview will take up some of your time. You might experience upset if you are discussing an difficult episode during an interview. You can stop the interview at any time.

**What are the possible benefits of taking part?**

There is no direct benefit to you in taking part in this study. We want to find out if electronic Prescribing systems are delivering on their expected benefits, and how best to support their use in hospitals. Telling us what you think will help us understand how the new system is affecting patient care and if it is meeting the needs of patients.

**Will my participation in the study remain confidential?**

Yes. The transcript from the interview will not have any names on it, and anything you say during an interview will be confidential. However, if you say something which is firmly believed by the researcher to have an effect on patient safety, the researcher will be obliged to inform the relevant body. You will be informed if this happens.

**What will happen to the results of this study?**

The results of this study will help to inform local and national implementation of ePrescribing systems in hospitals. A report will be sent to the National Institute for Health Research. The results of this study will be published in relevant journals and presented at conferences. No individual participant or site will be identifiable in any of the published material. If you would like to see the results of the study, we can send them to you.

We are planning to archive all anonymised data collected so that they may be made available to researchers for related studies further analysis in the future. You will be asked on the consent form whether you agree to this.

**Who is organising and funding this research?**

The research is organised by the University of Edinburgh in collaboration with the University of Nottingham, Harvard School of Public Health, and University Hospitals Birmingham NHS Foundation Trust. It is an independent evaluation that is funded by the National Institute for Health Research.

**Who has reviewed the study?**

This study has been reviewed by the NRES Committee London - London Bridge reference **13/LO/1202**, and given management approval by the xxx NHS organisation.

**Independent Contact**

If you would like to speak to someone independent about taking part in the research, you can contact **Mrs Michele MacNab** on **0131 650 9671.** Mrs MacNab is a health researcher at the University of Edinburgh, but she is not involved in this study. She can give you an independent view on what would be involved in taking part in this study.

**What if something goes wrong?** We think it is extremely unlikely that anything serious will go wrong. If, however, you are harmed by taking part or if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated, you can use the normal National Health Service complaints mechanisms.

**If you wish to make a complaint about the study** please contact

The Complaints and Improvements Department
St George’s Hospital, Blackshaw Road, London, SW17 0QT

or email **complaints.compliments@stgeorges.nhs.uk**.

**Who do I contact for further information?**

For further information about this study please contact either the Lead Researcher or the Chief Investigator below:

Lead Researcher:

Dr. Lisa Lee, Research Fellow, Centre for Population Health Sciences, The University of Edinburgh, Medical School, Teviot Place, Edinburgh, EH8 9AG. Tel: 07879 470535; Fax: 0131 650 9119; email: lisa.lee@ed.ac.uk

Chief Investigator:

Professor Robin Williams, Director, Institute for the Study of Science, Technology and Innovation, University of Edinburgh Institute for the Study of Science, Technology and Innovation, Old Surgeons' Hall, High School Yards, Edinburgh

EH1 1LZ. Email robin.williams@ed.ac.uk

**You can also visit our website:**

<http://www.cphs.mvm.ed.ac.uk/projects/eprescribing/index.html>

Thank you for taking the time to read this information sheet and for considering this request.

**Consent form for WP1 Patient Interviews.**

**Investigating the implementation, adoption and effectiveness of ePrescribing systems in English hospitals: a mixed methods national evaluation**

**WP1 Patient Experience Study**

**PATIENT / CARER INTERVIEW CONSENT FORM**

**Please initial all the boxes and give this form back to the researcher. If you don’t feel able to consent to all the boxes, or if you change your mind at any point, we will not include you in the research.**

|  |  |
| --- | --- |
|  | initial |
| I have read and understand the information leaflet (version 1.2 23 September 2013) for the above study. |  |
| I have been consulted about my participation and I have had the opportunity to ask questions about the study and understand what is involved. |  |
| I understand that the study will involve me giving information about prescribing and medicines, and about ePrescribing.  |  |
| I understand that all of the information about me recorded for this project will not have my name on it and what I say will remain confidential unless it has implications for patient safety. If the results of the study are published it will not be possible to identify information about me. |  |
| I understand that the interview will be recorded using digital equipment and agree to the recording of my interview being transcribed (typed up) by the research secretary, or by an external company where necessary. |  |
| I understand that if I say something during the interview which has an implication for patient safety, the researcher will have to tell the relevant bodies. |  |
| I agree to my general practitioner being informed of my participation in the study |  |
| I agree that in the (unlikely) event of a loss of capacity, the research team can retain data collected from me, and continue to use it confidentially in connection with this research. |  |
| I am willing for my anonymised data to be archived and made available for further research. |  |
| I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor(s), from regulatory authorities or from the NHS Trust where it is relevant to my taking part in this research. I give permission for those individuals to have access to my records. |  |
| I understand that I can withdraw from the study at any time, without giving any reason and without my medical care or legal rights being affected. |  |
| I give consent to take part in the above study. |  |

|  |
| --- |
| Name of participant  |
| Signature of participant | Date |
| Name of person taking consent |
| Signature of person taking consent | Date  |

One copy to be retained by researcher, one copy to be retained by the participant.

**Indicative Topic Guide for WP1 Patient interviews**

***Category 1 Participants: Patients and carers***

1. Were you [or the patient you care for] on any medication before coming into hospital? If yes:
	1. If yes, how did the hospital staff here gather that information? (prompts: ‘ did they ask you?, did they have the information from your GP?)
	2. What did you think of the way that information was gathered? (prompts: efficient, had to repeat myself several times, confusing, frustrating, helpful, …)
2. Do you know if you [the patient] have been prescribed any medicines while you [patient] have been in hospital? If yes:
	1. Are they your regular medication? Why/why not?
	2. What did you think of the process for getting that medication to you? (prompts – slow/fast, had to wait for doctor, drug chart missing, lots/little face-to-face interaction with staff, anything else that was noticed?)
	3. What do you think would improve that process?
3. This hospital is about to start / has started using an electronic prescribing system, which means that instead of using pen and paper to prescribe, staff will put all the information concerning your prescription onto a computer system. This is to make prescribing safer and more efficient. What do you think about the use of computer systems for prescribing? (*prompts:* do you think it will improve the delivery of your care, does it worry you, do you find it normal in this day and age that computers should be used in this way?)
4. (If already in use) – Have you noticed that prescribing in this hospital is being done on a computer?
	1. [ If yes] What in particular have you noticed about prescribing in this hospital?
5. Have you been given / seen any information about the use of an electronic prescribing system in this hospital?
	1. If yes, what information were you given and did you find it helpful?
	2. If no, would you have liked to be told about it?
6. In what ways, has using the computer for prescribing affected at all in your view, the way in which the staff have interacted with you, or have done their job? (*prompts*: very quick to get the medicines, staff seem un/happy about the system, patients see staff less/more, feel safer)
7. What concerns, if any, do you have about getting and taking your medication or any further prescriptions after you leave the hospital?
8. How much information would you expect your GP to receive about the medication you have been given while in hospital, and that you may need to take after leaving?
9. Is there anything else you would like to tell me about prescribing and your medication, or electronic prescribing systems?

***Category 2 Participants: GPs***

1. Background
2. What issues do your patients face when entering and leaving hospital in relation to their medicines? (issues related to medicine reconciliation)
3. What are the implications for your patients when taking their regular medication in hospital? (availability of patient’s usual medication at hospital, patient’s ability to follow usual practices of self-administration/ carer administration)?
4. What are in your view the benefits of hospital electronic prescribing systems for your patients, especially in relation to improved communication between the hospital and your GP practice?
5. What concerns, if any, do you have regarding the introduction of electronic prescribing systems?
6. What information if any have you received from the hospital regarding the introduction of an electronic prescribing system?
	1. Is this level/type of information adequate?
	2. Are you passing this information on to your patients?
	3. What (other) information would like to have regarding the roll-out of this system at the hospital?
7. *After implementation only:* Have you noticed any changes relating to prescribing and medicine management since the introduction of the hospital’s electronic prescribing system:
	1. What changes?
	2. How have you noticed them? (personal experience/ patient feedback/ change in procedures?)
	3. When did these changes happen?
8. Any other comments?

***Category 3 participants: Patient Representative Organisations/Charities***

1. Interviewee’s background
2. What issues do the patients you represent face in relation to prescribing and medicine management?
3. How prevalent for the patients you represent, are prescribing errors and other prescribing related problems?
4. What are the implications of these for your patients?
5. What improvements could be made to current policy and practice to improve the patient’s experience of prescribing and medicine administration and of their hospital stay more generally?
6. To what extent do electronic prescribing systems address these areas of improvement?
7. What other benefits, if any, do you think electronic prescribing systems in hospitals can have on the patient’s experience in terms of:
	1. safety
	2. quality of care
	3. efficiency in the delivery of care
8. What other impact or concerns do you have relating to the introduction and use of electronic prescribing systems in hospitals?
9. In what ways are those concerns specific to the patients you represent?
10. Any other comments?

**Sample Interview Topic Guides, PPI Strategy Evaluation.**

**Topic guide, final eP PPI evaluation interviews, 2016**

1. Reflections on the past year (what’s gone well, what hasn’t)

Looking back over the whole Programme:

1. Describe how your views on PPI have altered over the course of the eP Programme
2. How would you summarise your attitude to PPI in HIT-related research now?
3. How would you describe the impacts of PPI on the eP Programme
4. in terms of process; b) in terms of outcomes?
5. In terms of learning lessons about PPI in HIT-related research from our eP experience, what would you say were the most important messages for us to pass on for future projects and programmes?
6. Any other comments or suggestions?

