RESEARCH PROTOCOL:

AN EVALUATION OF THE ROLE OF COMMUNITY PHARMACISTS IN OPTIMISING SAFE AND APPROPRIATE MEDICINES USE IN RESPONSE TO PATIENT REQUESTS FOR EMERGENCY SUPPLIES.

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INTRODUCTION

Emergency supply of prescription only medicines

Medicines legislation lays down provisions for the emergency supply of prescription-only medicines[1]. For the purposes of this proposal, an emergency supply is defined as a request from a patient to provide a prescribed medicine when no prescription is presented at the time of the request. Here the term is inclusive of both the supply of medicines without a prescription under the emergency supply regulations at the request of a patient (as defined in the Medicines Act), and the loan of medication made by community pharmacists prior to a prescription being obtained. It is a means by which pharmacists are able to assist patients out of hours, or when they are away from home, to ensure that their supplies of medicines are not disrupted. The provision of this service can cause dilemmas, as pharmacists are obliged by law to ensure there is an 'immediate need' for the requested medicine, whilst simultaneously considering the well-being of the patient and the consequences of not supplying.

Review of the literature

An initial literature search regarding emergency supply indicates very limited studies, which are over ten years old. A 1998 survey by O'Neill et al[2] examined the frequency and characteristics of emergency supply, and the pharmacists' views of the process. The survey (of 243 pharmacists in the South East) found that the frequency of emergency supplies requested by patients ranged from no requests in the last 12 months, to at least one a day, with approximately two thirds reporting receiving requests at least monthly, and a third of these at least once a week. 'Loans', where no payment is taken for the medicine, but a prescription is promised, were considered separately in the survey. These showed even higher figures (73% at least monthly, and 47% at least once a week), with 11% reporting that loans were made on a daily basis. A range of reasons were given for the refusal to supply, most commonly that immediate need had not been established (73% of respondents reported this as a reason for non-supply). The majority of participants perceived this as an important service for patients, although over three quarters felt that the process was open to misuse. A contemporaneous study by Osman *et al*. reported that 75% of pharmacists interviewed had 'loaned' reliever inhalers to asthma patients[3].

The use of pharmacy medication records (PMRs) to facilitate the emergency supply process was documented by Rogers *et al.* in 1994[4], and pharmacists described legal and ethical dilemmas relating to emergency supplies in interviews by Hibbert *et al.* in 2000[5]. More recent work also highlights the process of emergency supply as a site of ethical and legal dilemmas (Cooper et al, 2007[6]; Chaar, 2009[7]; Deans, 2010[8]). Evidence for the extent to which the dilemmas posed by emergency supply are still experienced by pharmacists can be found in pharmacy-related networks and educational provision: The *Chemist and Druggist* has included three emergency supply related scenarios in its 'Ethical Dilemmas' section, and the *Locum Voice* internet discussion area had a long running thread on the topic. Many of the studies referenced here emphasise the wide range of decision-making and justifications cited by pharmacists, yet there remains no clear guidance as to what constitutes 'immediate need'. Similarly, whilst the majority of accounts show that pharmacists consider themselves to act in the patient's best interests, the literature does not explore what impact supply or refusal may have on patients.

NW Primary Care Pharmacy Research Group

This project has been developed by a workgroup of the NW Primary Care Pharmacy Research Group, which is facilitated by the NW Primary Care Research Network (PCRN). This workgroup is actively involved in building research capacity among community pharmacists in the Region. The steering group includes academic members from the Region's three Schools of Pharmacy (Liverpool John Moores University, the University of Manchester, and the University of Central Lancashire), practising community pharmacists, and a primary care trust pharmacist.

The research group and PCRN have recruited their first cohort of ten community pharmacists to prepare themselves and their practice setting for doing research – both as participants in other trials, and as leaders of their own research. These Research-ready pharmacists have been recruited from both independent and multiple pharmacy companies in Cheshire and Merseyside. Each of these pharmacies were chosen because they were close to a GP practice that is recognised as a research-active practice, and three of the pharmacies in the pilot are co-located with the medical practice.

AIMS AND OBJECTIVES

The overarching aim of the study is to inform best practice regarding the delivery of an emergency supply service of prescription-only medicines in community pharmacies, including the support required by pharmacists, and to identify how it may be integrated into established health and social care provision in order to fulfil its potential to maximise adherence.

The study has primary and secondary aims with associated objectives. The Primary aim is to explore the operation of the emergency supply service undertaken by community pharmacists. The secondary aim is to engage and enhance community pharmacists' involvement in, and experience of, pharmacy practice research.

The objectives associated with the primary aim are:

- To describe and analyse emergency supply activity regarding:
    - The frequency and characteristics of requests (P1);
    - The views and attitudes of service providers, including the incidence and resolution of dilemmas (P2);
    - The views of service users and other stakeholders, including general practitioners (P3).

- To explore how this convenient, patient-focused service does, and could, form an integral and coordinated component of health and social care pathways (P4)

The objectives associated with the secondary aim are:

- To become familiar with the following aspects of research methodology:
    - Developing a coding framework (S1);
    - Processes of obtaining informed consent (S2);
    - Necessity of protecting the confidentiality of the data (S3);
    - Recruitment of patients to pharmacy-based studies, including reflection upon avoiding subtle coercion by virtue of their power in providing the service (S4);
    - Presenting findings to a mixed audience in an accessible manner, and not over-stating results (S5).

- To become adept at the following data collection techniques:
    - Consistent and complete recording of robust quantitative data about their practice (S6);
    - Techniques associated with semi-structured telephone interviewing, such as following the topic guide and using follow-up prompts effectively, how to record the interview (S7);
    - Taking feedback in order to inform recommendations of the study (S8)

OVERVIEW OF THE STUDY

This multi-phased study utilises both quantitative and qualitative approaches and the data collection, in the main, is by novice research-orientated community pharmacists. Triangulation of the data from each phase of the study will provide a rounded understanding of the service enhancing the validity and reliability of the study outcomes.

Qualitative methodology has been included in this study because of the lack of published literature in this area. Using semi-structured interviews and focus groups will encourage participants to give their own understanding and experiences of the relevant topics enabling them to voice aspects that have not been predicated or prioritised.

The participants involved in the various phases of the study are patients, community pharmacists and general practitioners and practice staff. The number of participants in each phase varies and is considered to be appropriate for reaching theoretical saturation whereby there are no new data emerging from the study, and for the resources allocated to this project. A schematic of the study with approximate dates for each phase is attached (Study schematic, version 1, 1st October 2012).

An experienced research assistant (RA), with support from the Research Team, will facilitate the recruitment, management, support and training of the community pharmacists, as well as complete a literature search, obtain relevant governance approval, undertake data collection and analysis, and report writing.

Phase 1: Clinical audit of emergency supply of prescribed medicines

This phase involves community pharmacists, specifically recruited to the study, documenting the emergency supply of prescribed medicines to patients, in order to quantify the number and types of emergency supply being undertaken.

This phase addresses the following primary and secondary objectives P1, S1 and S6 (see Aims and Objectives above).

This audit phase of the study has been included to ensure a comprehensive overview of the study.

Phase 2: Interviews with service providers

Phase 2 involves up to three community pharmacists from Phase 1 undertaking recorded telephone interviews with the other pharmacists from Phase 1. The focus of the interview is to review the incidence of dilemmas and concerns that have arisen in the emergency supply of medicines, principally to determine if and how these were resolved.

This phase of the study addresses the following primary and secondary objectives: P1, P2, S2, S3 and S7.

Phase 3: Follow-up interviews with service users

This phase of the study involves the RA completing a recorded telephone interview with patients who have requested an emergency supply of prescribed medication from pharmacists involved in Phase 1 of the study. The focus of the follow-up interview, which will be no longer than 15 minutes, will be to determine patients' views and experiences of the service (including how they knew it existed), as well as the impact it might have on the continuity of their medicines supply, and resulting adherence.

This phase of the study will address primary and secondary objectives P3 and S4.

Phase 4: Dissemination of interim study findings to local general practice teams

Phase 4 involves the community pharmacists from Phase 1 presenting the interim study findings to their local general practice team, and using focus group methodology, to obtain their views of the emergency supply service and its impact on the medical practice workflow and patient wellbeing. A further meeting, following the same format and involving up two volunteer cohort pharmacists, will be arranged with the Clinical Commissioning Group (CCG) team operating in the study area.

This phase will address primary and secondary objectives P3, S5 and S8.

Phase 5: Wider stakeholder workshop: interactive feedback session

This final phase involves an interactive workshop session to present the headline findings of the whole study to the wider stakeholder community. These stakeholders will help the research team to reflect upon and formalise how the emergency supply service could form an integral and coordinated component of established health and social care pathways; wider implications for policy and practice; how to tackle challenges and barriers.

This final phase addresses primary objective P4.

This phase of the study has been included to ensure a comprehensive overview of the study.

METHOD

Phase 1: Clinical audit of emergency supply of prescribed medicines

The aim of this phase is to complete a clinical audit of all patient requests for the emergency supply of prescribed medicines. The audit will be undertaken by community pharmacists in the NW over two 4-week data collection periods. Community pharmacists from a cohort who through the Research Ready project have been selected by the North West Primary Care Pharmacy Research Group and North West Primary Care Research Network (PCRN) to prepare themselves and their practice setting for undertaking research will be eligible for participation.

Recruitment of participants

Community pharmacists will be recruited via the North West PCRN and a weighted snowballing technique will ensure that a diverse sample of pharmacies is obtained, with regard to contract type and location/setting. This sampling technique will ensure (as far as is possible) that independent/small/large/national chain pharmacies with a variety of opening hours at various locations in the North West will be incorporated into the study. Ensuring that the resulting community pharmacist who are involved in the study are diverse in experience, gender, length of time since first registered, pharmacy location, prescription volume and pharmacy type. A minimum of 10 pharmacies will be recruited to the study to ensure that a minimum of 500 emergency supply requests are recorded within the clinical audit.

Each community pharmacist will be sent a letter (and information pack) inviting them to take part in the study (Phase 1: Invitation letter: version 1, 1st October 2012), informing them of this phase, as well as further phases of the project and potential levels of participation within the other phases. The information pack will contain a study information leaflet and consent form (Phase 1: Study information leaflet: version 1, 1st October 2012). The RA will then telephone each pharmacist to see if they would like to take part in the study or if they have any questions and/or concerns regarding taking part. Those who agree to take part in the audit will be asked to sign a consent form (Phase 1: Informed consent form, version 1, 1st October 2012) to indicate they understand the nature and requirements of the audit, and specifically that patient details will be anonymised. In addition, their possible involvement in the later phases of the study will be reviewed (see overview of study above).

The RA will then visit each community pharmacist who has agreed to take part in phase 1, explain what that phase involves and what data are required to be collected. Aspects regarding the robustness and validity of the data will be explained as will the need for maintaining confidentiality and assuring anonymity of patient details.

In order to ensure that at least ten pharmacists complete both data collection periods of this phase, up to twenty community pharmacists will be recruited.

Data collection

A minimum of 500 requests will be recorded, from a minimum of 10 pharmacies, over two 4-week periods. These periods of time have been selected to include at least one Bank Holiday in which, anecdotally, patient requests for the emergency supply of medicines increase. All requests will be logged (Phase 1: data capture form: version 1, 1st October 2012) and any request for multiple medicines from a patient will be linked within the database.

During the main data collection periods the community pharmacists will be contacted (either by telephone or in person) on a weekly basis by the RA to facilitate their engagement, and as an opportunity to discuss any issues that arise. This has been shown by previous research studies to be a valuable activity to facilitate high quality data collection. Each community pharmacist will populate a pre-designed spreadsheet with the data they have collected, and will forward this to the RA on a weekly basis. This will facilitate central quality assurance of the data, with the RA being able to intervene if any fields are consistently missed and to give feedback if necessary to the participating pharmacists. These spreadsheets will be collated into a large single database, with each pharmacist being identifiable by a unique coded reference.

Data capture form

The Emergency supply data capture form (Phase 1: data capture form: version 1, 1st October 2012) will quantify the number and types of emergency supply undertaken and will gather the following data:

- Demographic details: patient age, gender, residential status and location (including partial postcode that can be mapped to the MOSAIC UK consumer classification system);
- Medication(s) requested, therapeutic class, dose prescribed, and length of treatment supplied;
- Reason for request for emergency supply and the action taken by the pharmacist.

These data, in the main, relate to the information that pharmacists are required to obtain from a patient when supplying an emergency supply of prescription only medicines under the regulations of the Medicines Act. No patient-identifiable information will be collected during the course of this phase of the study.

In addition, community pharmacists will record any related issues or dilemmas that arise at the time of the supply, including a rating of the level of complexity in resolving them. To facilitate this aspect, the recruited community pharmacists will be provided with a short in-house training session (undertaken by members of the research team) to facilitate and structure the consistent recording of their thought processes at the time of the emergency supply. To identify the various levels of concern or dilemma inherent in each emergency supply, the pharmacist will be asked to rate each supply. To standardise this process, the pharmacists will devise a shared coding framework during the course of the training session.

Data analysis

Statistical analysis, using SPSS software will be undertaken by the RA, of the quantitative data collated from the clinical audit of emergency supply conducted. This will involve descriptive and, where appropriate, comparative statistics to identify trends in the emergency supply of medicines. Comparative analyses, where valid, may explore any association between frequency and characteristics of requests with pharmacy or pharmacist variables, such as ownership or location.

Phase 2: Interviews with service providers

The aim of this phase is to review the incidence of dilemmas and concerns that have arisen in the emergency supply of medicines, principally to determine if and how these were resolved. This phase involves semi-structured telephone interviews with community pharmacists including those involved in phase 1.

Interviewers and participants

Up to three volunteer pharmacists, recruited by the RA, will receive training in qualitative telephone interviewing skills. Each will then be asked to recruit and interview at least two other pharmacists, the intention being to interview all pharmacists involved in the Phase 1 clinical audit. These interviews will be recorded and conducted in the month following the first 4-week period of data collection and each will be no more than 20 minutes in duration.

Recruitment of participants

The RA will send out an information pack explaining this phase of the study to all community pharmacists involved in Phase 1. Each pack will contain a copy of the study information sheet (Phase 2: participant information leaflet: version 1, 1st October 2012), two copies of the informed consent form (Phase 2: informed consent form – pharmacist: version 1, 1st October 2012) and a reply paid envelope. Those pharmacists who are willing to be interviewed will return a completed copy of the informed consent form to the RA; the other copy will remain with the pharmacist. Once the completed consent form is received the RA will contact a pharmacist interviewer to initiate arrangements to complete the interview. Those pharmacists who wished to be interviewed will be given at least 24 hours to reflect on their decision. Pharmacists who indicate they are not willing to be interviewed will not be contacted further.

A follow up telephone call will be made to those pharmacists who have not forward a reply within 5 days of the initial posting.

It is anticipated that each pharmacist will interview three, but no more than five, other pharmacists during this phase. The interviewer will thank those pharmacists who do not wish to be interviewed them for their time.

Development of the interview schedule

Due to the lack of published research and the time to be spent interviewing each patient (no more than fifteen minutes) the interview schedule (Phase 2: interview schedule: version 1, 1st October 2012) is based on the objectives of this phase as noted above. One interviewer will pilot the interview schedule with no more than two pharmacists. Once transcribed, the RA will discuss the findings with the Research team to ensure that the relevant information is being collected and the procedures are pertinent. Any minor alterations will be made to the interview schedule at this stage. Major alterations to the interview schedule will only be undertaken after consultation with the relevant NHS ethics committee and before any further data collection takes place.

Data collection

It is proposed to undertake the data collection over a period of five to six weeks once the first data collection period of Phase 1 has been completed.

Each interview will begin with the pharmacist outlining the aim of the study and asking the potential interviewee if they still agree that the interview can be audio recorded. If the interviewee does not agree, the pharmacist will thank the interviewee for considering taking part in the study and destroy the two copies of the signed informed consent form. For those interviewees who remain willing to continue with the interview the pharmacist will first, thank them for agreeing to take part. Secondly, remind them that they can withdraw from the interview at any time before commencing with the interview (Phase 2: interview schedule: version 1, 1st October 2012). At the end of the interview, the pharmacist will thank the interviewee for their time and ask if they have any questions they wish to raise regarding the content and process of the interview.

Each interviewer will use a series of prompts to encourage the interviewee to fully describe their experiences and concerns. In addition, some personal details of the interviewee will be collected, for example gender, age, when registered, place of work. The interview will be

informed by the ratings of the complexity of resolution made by the interviewee pharmacists during the course of Phase 1.

Transcription and analysis of the data

Each telephone interview will be professionally transcribed, the interviewer and interviewee being identified only by their unique coded reference. The study will aim for theoretical saturation, anticipating that after 25-30 cases no new themes will emerge.

The transcripts will be thematically analysed by the RA for trends and emergent patterns, using a constant comparison approach from Grounded Theory[9&10]. This will be linked to the pharmacists' shared coding framework generated in Phase 1. In addition, thematic analysis of the transcribed data undertaken by the RA will examine common and contrasting perceptions of the emergency supply process. This will further describe the frequency and characteristics of a range of emergency supplies through participants' description of the context of the issues and dilemmas. Members of the project team, in conjunction with the RA, will review the emergent themes and underlying quotations to ensure robustness and transparency regarding coding and reconstruction.

Feedback to the interviewers

The project team will review any issues that arise from undertaking the interview or from the recorded data and, if appropriate, additional support will be provided. The RA will review the first recorded interview or transcript from each pharmacist to perform quality assurance. The RA will provide feedback to each interviewer. This feedback will focus on enhancing their interview technique: for example, where additional prompting or enquiries into generalisation would enhance their abilities.

Phase 3: Follow-up interviews with service users

The aim of the follow-up interview with patients, which will be no longer than 15 minutes, will be to determine their views and experiences of the service (including how they knew it existed), as well as the impact it had on the continuity of their medicines supply, and resulting adherence. These recorded telephone interviews will be undertaken by the RA to ensure they are no conflicts for the pharmacist providing the service.

Participant criteria

Pharmacy users (16 years of age or older) who have requested an emergency supply of prescribed medicine from community pharmacists recruited to Phase 1 will be asked to take part in this phase. This recruitment will occur outside of the two Phase 1 data collection periods. Individuals under 16 years of age or those who refuse consent for participation will be excluded.

Recruitment of participants

Individuals who request an emergency supply of prescribed medication from pharmacists involved in the study will be recruited following provision of the service. Pharmacists will either hand or send them an invitation letter and information sheet (Phase 3: Invitation letter version 1, 1st October 2012; participant information sheet, version 1, 1st October 2012). These will invite them to participate in the follow-up interviews about the service and include a consent form and request their telephone contact details (Phase 3: informed consent form version 1, 1st October 2012). The signed consent form will be returned to the RA in a Freepost envelope. Once the signed informed consent forms are received, the RA will contact each patient to determine a mutually convenient time to undertake the recorded telephone interview. At the time of the telephone interview, they will be asked to reaffirm verbally their consent to take part in the interview and to be recorded.

Each pharmacist will recruit up to ten patients to be interviewed. These ten patients will not be part of the Phase 1 cohort of patients. Pharmacists will be asked to give or send information

and consent documents to 30 consecutive emergency supply patients, in order to achieve a response from 10.

Interview schedule

Due to the lack of published research and the time to be spent interviewing each patient (no more than fifteen minutes) the interview schedule (Phase 3: interview schedule: version 1, 1st October 2012) is based on the objectives of this phase as noted above. The RA will pilot the interview schedule with no more than two patients. Once transcribed, the RA will discuss the findings with the Research team to ensure that the relevant information is being collected and the procedures are pertinent. Any minor alterations will be made to the interview schedule at this stage. Major alterations to the interview schedule will only be undertaken after consultation with the relevant NHS ethics committee and before any further data collection takes place.

Procedure

It is proposed to undertake the data collection over a period of twelve to thirteen weeks once the data collection period of Phase 2 has been completed.

Each interview will begin with the RA outlining the aim of the study and asking the potential interviewee (patient) if they still agree that the interview can be audio recorded. If the patient does not agree, the RA will offer to take written notes of the interview. If this is still not agreeable the RA will thank them for considering taking part in the study and destroy the two copies of the signed informed consent form. For those patients who remain willing to continue with the interview the RA will first, thank them for agreeing to take part. Secondly, remind them that they can withdraw from the interview at any time before commencing with the interview (Phase 3: interview schedule: version 1, 1st October 2012). At the end of the interview, the RA will thank the patient for their time and ask if they have any questions they wish to raise regarding the content and process of the interview.

The RA will use a series of prompts to encourage the interviewee to fully describe their experiences and concerns. In addition, some personal details of the interviewee will be collected, for example gender, age and diagnosed medical conditions.

Data collection and analysis

The recorded interviews will be professionally transcribed. The patient and recruiting pharmacist (who were involved in the emergency supply) will be only identified by a unique reference code. The transcribed data will be thematically analysed by the RA for emergent themes and compared to those from Phase 2 to highlight commonality and diversity.

Phase 4: Interactive feedback: interim study findings to local GP teams & CCG

Phase 4 involves the community pharmacists from Phase 1 presenting the interim study findings to their local general practice team. The aim, utilising focus group methodology, is to obtain the views of the local general practice team regarding the emergency supply service and its impact on the medical practice workflow and patient wellbeing.

The RA, in conjunction with the research team, will undertake the triangulation of the findings from the previous phases. A short PowerPoint presentation will be generated that overviews the study and the salient findings, with a set of notes to prompt the main points for each slide.

Participants

Each of the selected pharmacists in the North West 'Research Ready' scheme is paired with a local GP practice that is research-active, and this should facilitate the participation of such practices in this activity. Pharmacists will engage with the practice at the beginning of the study. From the outset of the project, contact will also be established by the project team with the CCG team to facilitate their engagement in later stakeholder aspects.

Training session

A half-day training session will be provided to community pharmacists from Phase one recruited to take part in this phase, which will outline the salient points of the study and discuss how this would be relevant to general practice staff. An opportunity to role-play presenting the salient findings of the study would be provided to enable and enhance facilitator skills.

Recruitment, data collection and analysis

Prior to the interactive feedback session with the practice teams/CCG to discuss interim findings, a letter will be sent to each practice explaining the purpose of the study and specific details about the phase (Phase 4: Invitation letter, version 1, 1st October 2012; Phase 4: participant information sheet, version 1, 1st October 2012). This will be followed up with a telephone call from the pharmacist to determine a mutually convenient time for the meeting. At the meeting, attendees will be asked to sign a consent form to permit the group discussion to be recorded (Phase 4: consent form, version 1, 1st October 2012).

At the start of the meeting, a community pharmacist will give an overview and the salient findings of the study. A recorded discussion (Phase 4: discussion guide, v1 1st October 2012) will then take place regarding participants' opinions and experiences of the Emergency Supply activity undertaken by community pharmacists and how this has impacted on patient care and on the activities within the practice. The RA will be present at the meeting to take field notes and provide support to the pharmacist (facilitator). The recorded focus group will be professionally transcribed.

The practice staff and the community pharmacist will be only identified by a unique reference code. The transcribed data will be thematically analysed by the RA for emergent themes and compared to those from Phase 3 to highlight commonality and diversity.

Phase 5: Wider stakeholder workshop: interactive feedback session

The aim of this final phase of the study is to reflect upon and formalise how the emergency supply service could form an integral and coordinated component of established health and social care pathways; wider implications for policy and practice; and how to tackle challenges and barriers.

Participants

It is anticipated that the participants would include representatives from, for example, Department of Health (DH), CCGs, Strategic Health Authority (SHA), Royal Pharmaceutical Society (RPS), Pharmaceutical Service Negotiating Committee (PSNC), National Pharmaceutical Association (NPA), and out-of hours services providers.

Data collection and analysis

During this phase, participants will undertake group work, facilitated by the project team and the participating community pharmacists. They may, for example, wish to reflect upon the lack of advertising of this service. Data collection proformas will be collected from each group as part of the data for the study. The data will be analysed by the RA for emergent themes. The participants in this phase will be only identified by a unique reference code.

ETHICAL CONSIDERATIONS

Ethical approval for this project will be sought from NHS and/or Liverpool John Moores University Research Ethics Committees as required. Appropriate procedures to ensure good ethical practice will be adhered to throughout the duration of the research.

Confidentiality & Anonymity

All information given to the research team will remain confidential and anonymous. During the transcribing of the recorded interview any identifier details (for example names, addresses and/or description of places) will be removed.

All signed informed consent forms, recorded personal details and transcripts will be kept in a secure filing cabinet in the research office within the School of Pharmacy and Biomolecular Sciences, Liverpool John Moores University. This cabinet will be locked whenever Dr Charles Morecroft and the RA are not present. All electronic files relating to this study will be password protected, such that only Dr Charles Morecroft and the RA will have access. All data relating to the study will be destroyed ten years after the study has been completed. Personal data will be securely destroyed as soon as the study analysis has been completed.

Any identifying features or quotations taken from the transcripts when used in the reporting and disseminating of this study will be anonymised.

Management and supervision of the study

The day-to-day management regarding the research activities of the community pharmacists involved in the study will be undertaken by the RA. However, the overall supervision of the study will be undertaken by the Chief Investigator (Dr Charles Morecroft) to which the RA, all members of the research team, participating community pharmacists and participants will report any concerns they may have regarding the research process and content. Any major concerns regarding the research process and content will be relayed to both the Research Governance and the relevant ethics committees by the Chief Investigator. If interviewees and pharmacists prefer to inform their concerns directly, the information leaflet, which is given to all participants involved in the study, will have the details of the complaints procedure.

In the unlikely event that the collection of issues or dilemmas causes distress, Dr Charles Morecroft has the necessary skills for supporting pharmacists. Similarly, should any inappropriate practice be identified, this will be reviewed by the research team and an appropriate course of action will be undertaken that is compliant with the General Pharmaceutical Council's current Code of Ethics for pharmacists.

Personal Safety

The majority of interviews will be undertaken by telephone at little risk to the interviewer. If an interviewee requested a face-to-face interview this would be conducted at the University or in a convenient private space within a convenient community pharmacy involved with the study. The RA will be reminded of the School of Pharmacy and Biomolecular Sciences, Liverpool John Moores University's safety procedures regarding research and undertaking meetings off-campus.

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