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FULL/LONG TITLE OF THE STUDY

Pharmacy professionals' perceptions of patient medicines helplines. A qualitative study.

SHORT STUDY TITLE

Pharmacists' perceptions of patient medicines helplines.

PROTOCOL VERSION NUMBER AND DATE

Version 1.4
01/07/2019

RESEARCH REFERENCE NUMBERS

IRAS Number: 234481

SPONSORS Number: Not applicable

FUNDERS Number: Not applicable

SIGNATURE PAGE

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

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

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

For and on behalf of the Study Sponsor:

Signature:

Name (please print): Jonathan Knight

Position: PVC - Research

Date: 20/12/17

Chief Investigator:

Signature:

Name: (please print):
........................MATTHEW JONES…….............................

Date:
20/12/2017

Pharmacists' perceptions of patient medicines helplines

LIST of CONTENTS

KEY STUDY CONTACTS

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Joint-sponsor(s)/co-sponsor(s)	Not applicable
Funder(s)	Not applicable
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Committees	Not applicable

STUDY SUMMARY

Study Title	Pharmacy professionals' perceptions of patient medicines helplines. A qualitative study.
Internal ref. no. (or short title)	Pharmacists' perceptions of patient medicines helplines
Study Design	This study will involve the use of qualitative semi-structured telephone interviews to explore pharmacy professionals' experiences and perceptions of NHS patient medicines helpline services.
Study Participants	*Inclusion criteria of pharmacy professionals*: either a Chief Pharmacist at an NHS Trust within England which operates a patient medicines helpline service, or a Pharmacy professional (including pharmacy technicians) who operates a patient medicines helpline service at their NHS Trust within England; registered with the General Pharmaceutical Council (GPhC); fluent in English; ability and willingness to provide informed consent; and ability, willingness, and availability to conduct a 25 minute telephone interview. *Exclusion criteria of pharmacy professionals*: Not willing to be audio-recorded for the telephone interview.
Planned Size of Sample (if applicable)	Approximately 35.
Follow up duration (if applicable)	Not applicable
Planned Study Period	01/01/2018 – 31/12/2018

Research Question	What are pharmacy professionals' perceptions of NHS patient medicines helpline services?

FUNDING AND SUPPORT IN KIND

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON FINANCIALSUPPORT GIVEN**
University of Bath	This study is being conducted as part of a PhD which is being funded by the University of Bath.

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor indemnifies the management, design, and conduct of this study. The sponsor will determine if any requested changes to the study documents are non-substantial or substantial amendments.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

The study is being conducted as part of a PhD. The supervisory team for the PhD comprises three researchers with expertise in Pharmacy Practice and qualitative research (including the Chief Investigator of this study). Supervisory meetings are held once a month. The Chief Investigator is responsible for all aspects of the study, with guidance from the supervisory team.

A Patient and Public Involvement Group will not be used for this study, since the study is examining pharmacy professionals' experiences and perceptions of an NHS service. Instead, a group of pharmacy professionals were asked to provide feedback on the study design and the data collection tool.

PROTOCOL CONTRIBUTORS

The protocol was written by the Study Co-ordinator, with feedback from the Key Protocol Contributors, outlined above.

A Patient and Public Involvement Group will not be used for this study, since the study is examining pharmacy professionals' experiences and perceptions of an NHS service. Instead, a group of pharmacy professionals were asked to provide feedback on the study design and the data collection tools.
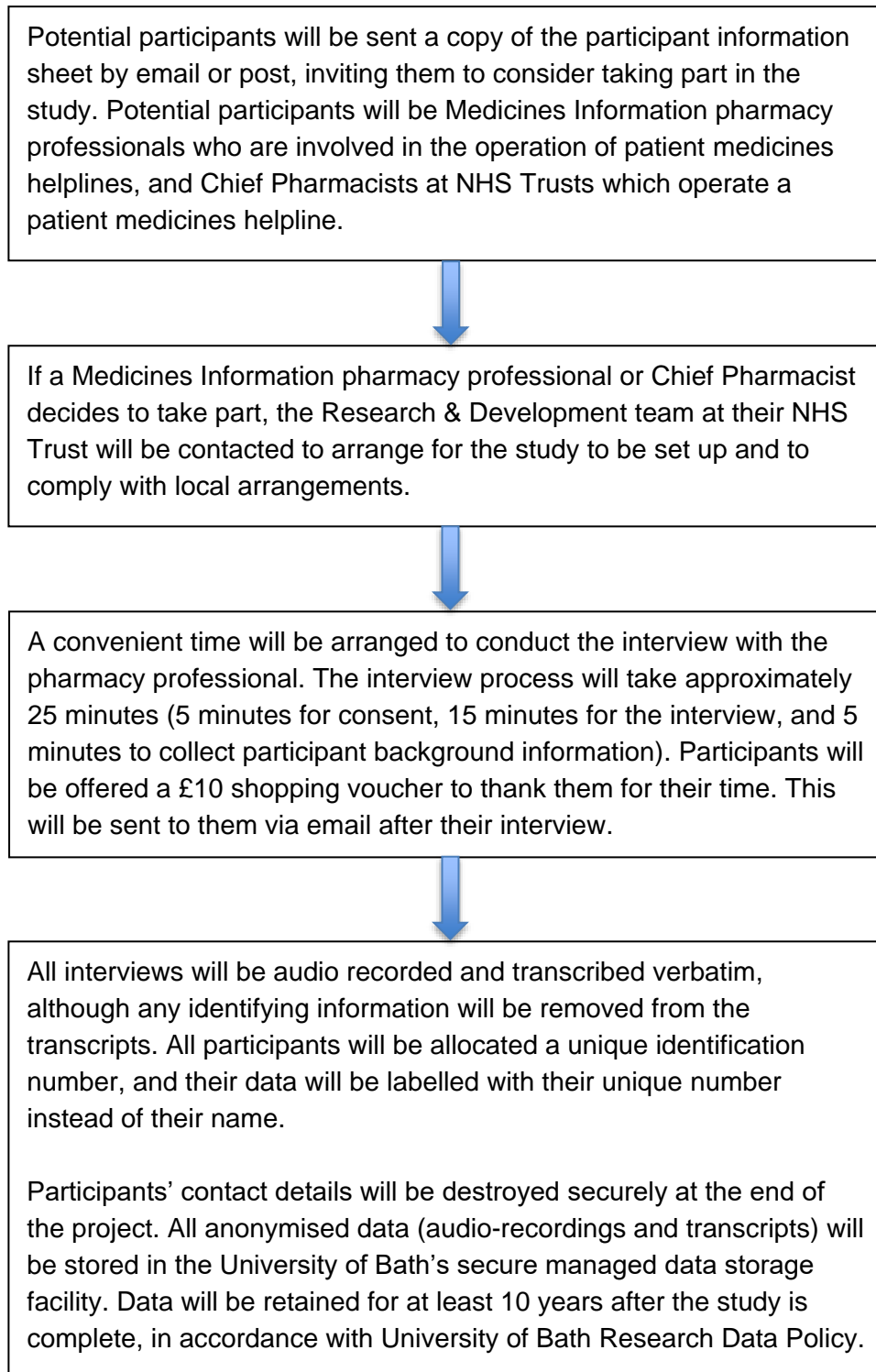
KEY WORDS:

Patient medicines helplines
Medicines information

Drug information
Clinical pharmacy services
National Health Service
Qualitative

STUDY FLOW CHART

Potential participants will be sent a copy of the participant information sheet by email or post, inviting them to consider taking part in the study. Potential participants will be Medicines Information pharmacy professionals who are involved in the operation of patient medicines helplines, and Chief Pharmacists at NHS Trusts which operate a patient medicines helpline.

If a Medicines Information pharmacy professional or Chief Pharmacist decides to take part, the Research & Development team at their NHS Trust will be contacted to arrange for the study to be set up and to comply with local arrangements.

A convenient time will be arranged to conduct the interview with the pharmacy professional. The interview process will take approximately 25 minutes (5 minutes for consent, 15 minutes for the interview, and 5 minutes to collect participant background information). Participants will be offered a £10 shopping voucher to thank them for their time. This will be sent to them via email after their interview.

All interviews will be audio recorded and transcribed verbatim, although any identifying information will be removed from the transcripts. All participants will be allocated a unique identification number, and their data will be labelled with their unique number instead of their name.

Participants' contact details will be destroyed securely at the end of the project. All anonymised data (audio-recordings and transcripts) will be stored in the University of Bath's secure managed data storage facility. Data will be retained for at least 10 years after the study is complete, in accordance with University of Bath Research Data Policy.

STUDY PROTOCOL

Pharmacy professionals' perceptions of patient medicines helplines. A qualitative study.

1   BACKGROUND

1.1 Medicines information and support needs following hospital discharge

Patients often experience changes to their medicines regimen while they are in hospital, and it is healthcare policy and procedure in the UK to ensure that patients' medicines are managed optimally after discharge from secondary care (1, 2). However, a growing body of evidence highlights that patients in the UK often lack knowledge of their medications following discharge from hospital (3-5). For example, Holloway et al. carried out an interview study with patients on five wards of a teaching hospital in Glasgow on the morning of their discharge (3). It was found that 60% of patients could not name at least one of their medicines, only 25% knew the prescribed dose of at least one of their medicines, and 30% did not know when or how to take at least one of their medicines. A growing body of evidence also highlights that discharged patients in the UK often report not being able to recall receiving important information about their medications (3, 6-9). For example, results from the 2015 national NHS Adult Inpatient Survey found that 18% of patients felt that they were not given clear written or printed information about their medicines, and 44% did not recall receiving any information from staff about side effects to look out for when they returned home (6). Such findings from the UK correspond with findings from international studies which also suggest that patients often lack medicines-related knowledge following discharge, particularly around side effects (10-14), and that patients often report not being able to recall receiving important medicines-related information (15-19).

As well as often requiring information about medicines, research suggest that a substantial proportion of patients who have been discharged from hospital subsequently experience medicines-related problems, both in the UK (20-23) and internationally (24-26). For example, Marvin et al. (20) carried out a survey which involved providing telephone follow-up calls to 27 patients three weeks following discharge for a short-stay admission from a hospital in London. It was found that 44% of the patients in the study experienced medicines-related problems, mainly around side effects and administration. However, the study by Marvin et al. is limited by its small sample size, and there is a question mark over the generalisability of the findings since participants were recruited from only one NHS Trust. Lee et al. (21) subsequently conducted a study which involved interviewing 96 patients after being discharged from one of six acute hospitals in the North-West of England. It was found that 36% of patients experienced problems with their medication following discharge, mainly around side effects (63%). Also, 31% reported that they had needed help with their medicines, and 26% had actually sought or been given help following discharge, mostly from GPs.

Hospital-based patient medicines helpline services provide patients with a means of accessing medicines-related information and support following hospital discharge.

1.2 Patient medicines helplines

In the UK, a network of local and regional medicines information services, collectively known as UKMi, are based in the pharmacy departments of many hospitals (27). The initial aim of medicines information services was to provide medicines-related information and advice to healthcare staff regarding pharmacotherapy for their patients. However, in response to evidence that patients often have unmet needs regarding their medications following hospital discharge, in 1992 the first medicines helpline for patients was established at an NHS Trust in the UK (28, 29). This service enabled patients to speak to a pharmacy professional with questions or concerns regarding their medicines. Since then,

patient medicines helplines have become available to patients and their carers at many hospitals throughout the UK. In 2014 it was found that approximately 55% of MI Centres now provide patient medicines helplines (30). Although there are ten regional MI Centres within England, these provide medicines information for healthcare professionals rather than patients. Therefore, patient medicines helplines are typically a local service, provided by NHS Trusts for their patients and carers only. Service evaluation studies suggest that calls received by patient medicines helplines are predominantly about adverse effects, administration and dosage, and interactions (30-34), and that calls can avoid harm (31) and highlight errors (30, 31, 35). Providing a patient medicines helpline service also accords with healthcare policy recommendations regarding the importance of giving patients the opportunity to seek information about their care and to be involved in decisions about their care (36-39).

The UK National Health Service is committed to providing evidence-based patient care (40). However, so far only a paucity of descriptive data exists to attempt to answer whether patient medicines helplines are effective at delivering on what their proponents suggest are advantages of operating a helpline. Such advantages include improving patient adherence, reducing patient harm, highlighting errors so that staff can learn from them, reducing patients' avoidable use of other healthcare services (e.g., GP visits, Accident & Emergency visits, and hospital readmissions), and improving the patient experience of healthcare services (e.g., patient satisfaction with care) (41-43). It is therefore hypothesised that patient medicines helplines can be beneficial not only for service users, but also healthcare organisations in terms of learning from patient experiences (e.g., using information about errors to improve healthcare services) and reducing the burden on other services. However, further research is needed to ascertain whether these are indeed outcomes from patient medicines helplines. It is also currently unknown whether there are any negative outcomes from patient medicines helplines. Adding to the limited evidence which is currently available may help to improve patient medicines helplines so that they better meet the needs of service users, increase the opportunity for healthcare organisations to learn from errors, and reduce the burden on other healthcare services.

1.3 Advantages of Qualitative Research

Although quantitative studies are primarily used to establish whether or not healthcare services are effective, qualitative research can be important in understanding *why* healthcare services are effective or not, and *how* services can be improved (44, 45).

Compared to quantitative research, qualitative research places greater importance upon context, and individuals' insights, understandings, and meanings of their lived experiences (46). The use of qualitative data collection methods such as interviews and focus groups can explore experience to a greater depth and with less constraint than traditional quantitative methods, generating richer data and a more thorough understanding of individuals' experiences. For example, Rutter, Fitzpatrick and Rutter (47) conducted interviews with doctors and dentists working in primary care in England and Wales who contacted a medicines information centre. The study helped to understanding how the medicines advice which the doctors and dentists received influenced their decision making and patient care. Similarly, Cook et al. (48) carried out focus groups with NHS Direct users and non-users to uncover a range of barriers and facilitators that impacted upon the uptake of the service. Within health services research, qualitative studies can therefore be used to make recommendations for improving services to better meet the needs of its users.

Typically, three types of study design have been used in order to collect data about patient medicines helplines: cross-sectional surveys of service user experiences (33-35), cross-sectional surveys to ascertain how many helplines exist and how they are being operated (30, 32), and retrospective or prospective analyses of types of enquiries received to specific helplines (30, 31, 33-35). Although useful, the findings from such quantitative studies lack detail about individualised experiences, since

the data collection tools used are not well suited to explore in depth the experiences of service users and staff who use or operate helplines. Qualitative research can expand upon, and add context to, the findings from studies that have used such quantitative methods of data collection.

1.4 The use of qualitative research to understand pharmacists' perceptions of patient medicines helpline services.

Qualitative methods could expand upon previous research conducted by Williams et al. which used an online survey to examine Chief Pharmacists' and Medicines Information Pharmacists' perceptions as to the benefits of patient medicines helplines (49). For this study, the survey was completed by 66 Chief Pharmacists and 87 Medicines Information Pharmacists at NHS Trusts in England which operate a patient medicines helpline. Major perceived benefits were avoiding patient harm, identifying errors, improving medication adherence, supporting patient discharge, providing assurance that patients can access professional help from home, improving the patient experience, and optimising medicines. However, a limitation of this study is that it does not seek to explore limitations of the helpline service, and perceived ways that the service could be improved. Additionally, the survey study did not provide pharmacy professionals with the opportunity to describe in detail their perceptions of patient medicines helpline services.

Qualitative studies of service providers' perceptions as to the benefits and limitations of healthcare services have been conducted for the purpose of producing recommendations for service improvement. For example, Dhillon et al. conducted interviews with twenty four general practitioners regarding their perceptions of the benefits and limitations of home medicines reviews (50). Benefits included polypharmacy reduction, and education for both the clinician and patient. Limitations included the length of time to conduct the review, and having to complete a lot of paperwork. Suggestions for service improvement included using a standardised report template, creating a more streamlined and clear process, and taking in to consideration the patient's preference regarding who conducts the review. Such a study design could also be useful regarding understanding pharmacy professionals' perceptions of patient medicines helpline services.

2   RATIONALE

Research suggests that recently discharged hospital patients often lack important information about their prescribed medicines. Patient medicines helplines have been set up at many hospital Pharmacy Services at NHS Trusts in the UK, with the aim of providing an information and advice service to recently discharged hospital patients who have questions or concerns about their prescribed medicines. Patients can also call if there is an error with their medicines. Studies suggest that between 19-39% of helpline calls avoid harm to patients. Therefore, medicines helplines provide several benefits. However, studies also suggest that patient medicines helplines are not as widely used as they could be. On average, acute Trusts receive 8 calls per week, and only 52% of Trusts in England currently provide the service. Providing a patient medicines helpline service accords with healthcare policy recommendations regarding the importance of giving patients the opportunity to seek information about their care.

Recently, a survey study was carried out to examine how patient medicines helplines are operated, and what pharmacists think are their benefits (49). However, survey studies have limitations. For example, surveys include questions and answer options that are important to the researcher, rather than allowing participants to provide information that is important to them. We would like to know more about the benefits of medicines helplines, and the ways that they could be improved. Establishing this may help to increase the availability and use of NHS medicines helplines. To achieve this, qualitative methods would be more appropriate.

In line with healthcare quality improvement approaches, services are likely to be improved by seeking to understand the perceptions of service providers. No qualitative studies have yet been conducted to examine pharmacy professionals' perceptions of operating a patient medicines helpline. Such a study may result in recommendations for the improvement of patient medicines helpline services.

The questions which pharmacy professionals will be asked for this study are considered important in order to understand their experiences and perceptions of patient medicines helplines. A group of pharmacy professionals with expertise in operating patient medicines helplines were consulted and asked to provide feedback upon these questions. This provided an opportunity to check that the questions are worth asking and appropriate for meeting our research aims, and to ascertain whether they had suggestions for any additional questions.

Exploring patients' and carers' experiences of using healthcare services is also considered important for improving services (51). However, the focus of this particular study is upon pharmacy professionals' experiences and perceptions, therefore service users will not be sought as participants in this study. However, a study which explores patients' and carers' experiences of using patient medicines helplines is being planned by our research group, and will be conducted separately to the present study.

3   THEORETICAL FRAMEWORK

Frameworks have been developed for designing and evaluating healthcare interventions. The RE-AIM framework was first published in 1999 by Glasgow et al. (52). Being 18 years old, RE-AIM is a well-established framework for evaluating the impact of health interventions. RE-AIM is based upon the work of Abrams et al. (53) who defined the impact of an intervention as the product of a programme's reach (the percentage of the population receiving the intervention) and its efficacy (assessment of both positive and negative consequences of an intervention): $I = R \times E$. Glasgow et al. (52) expand on this concept to develop RE-AIM, by adding three dimensions that apply to the settings in which research is conducted: Adoption (the proportion and representativeness of settings that adopt an intervention), Implementation (the extent to which an intervention is delivered as intended), and Maintenance (the extent to which an intervention becomes a relatively stable, enduring part of the behavioural repertoire of an individual/organisation). Additionally, Glasgow et al. suggest that 'efficacy' could be replaced with 'effectiveness', depending on the stage of research and/or the intervention being investigated, in order to assess its impact in terms of actual changes in real-life conditions (54). Glasgow et al. emphasise the importance of focusing on all dimensions of the framework in order to fully evaluate the impact of an intervention (55, 56).

Although originally the focus of RE-AIM was upon assessing the impact of an intervention using quantitative data, the framework has been expanded to emphasise the importance of qualitative data to understand the framework's different dimensions (55, 56). For example, Kessler et al. propose that the use of qualitative measures/data are important for understanding the outcomes of an intervention, as part of the RE-AIM 'efficacy/effectiveness' dimension.

A limitation of the RE-AIM framework is that it does not include a dimension to capture stakeholders' views as to the acceptability of an intervention. Within qualitative health research, capturing relevant individuals' experiences and perceptions as to both the effectiveness and acceptability of interventions is considered important (57, 58). Michie et al. (59) recently developed the APEASE framework for designing and evaluating interventions, which comprises six criteria, including 'acceptability'. The criteria are: affordability of the service (e.g., whether the service can be satisfactorily operated within an acceptable budget), practicability of the service (e.g., the extent that the service can be delivered as designed through the means intended to the target population), effectiveness and cost-effectiveness of the service (e.g., the effect size of the intervention in relation to the desired objectives in a real world

context, and the ratio of effect to cost), acceptability of the service (e.g., acceptable to those operating and using the service), side effects/safety of the service (e.g., whether there any unwanted side effects or unintended consequences of the service), and equity (e.g., whether the service can reduce or increase standards of living, wellbeing, and health between different sectors of society). Studies have begun to use the APEASE criteria, primarily for choosing and evaluating interventions (60-62).

The RE-AIM and APEASE evaluation criteria will be used to inform the development of questions for this qualitative study which examines pharmacy professionals' perceptions and experiences of patient medicines helplines.

4 RESEARCH QUESTION/AIM(S)

4.1 Objectives

The aim of the study is to explore pharmacy professionals' perceptions of the benefits of patient medicines helplines, their limitations, and ways that they can be improved. Through learning about pharmacy professionals' experiences and perceptions of medicines helpline services, we aim to make suggestions to improve how helplines are operated so that they better meet the needs of service users and providers. This accords with the NHS agenda of seeking service providers' views and experiences to improve service quality.

Our research question is: *What are pharmacy professionals' perceptions of NHS patient medicines helpline services?*

4.2 Outcomes

Potential outcomes of this study are:
- An understanding of pharmacy professionals' perceived benefits of patient medicines helplines.
- An understanding of pharmacy professionals' perceived limitations of patient medicines helplines.
- An understanding of how patient medicines helpline services could be improved.
- An understanding of pharmacy professionals' perceptions of the future direction of patient medicines helpline services within the NHS.

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

5.1 Design

This study will involve the use of qualitative semi-structured telephone interviews to explore pharmacy professionals' experiences and perceptions of NHS patient medicines helpline services.

Telephone interviews were chosen since they provide flexibility both for the research team and the participants. Additionally, they are more cost- and time-effective than face-to-face interviews, enabling pharmacy professionals throughout England to be more easily interviewed.

5.2 Materials

5.2.1 Participant information sheet

A participant information sheet has been developed, in accordance with guidance from the Health Research Authority (63) and British Psychological Society (64).

5.2.2 Participants' background information

The following background data will be collected during the telephone interviews, using a data collection form: Age; gender; ethnicity; job title; number of years employed as a pharmacy professional; number of years' experience of operating or providing a patient medicines helpline. Participants' email addresses will also be collected for the purpose of sending them their voucher for taking part in the study. Their email address will be on a separate page to the rest of their data, will be stored in a separate folder to all of their other data, and will be destroyed (shredded) as soon as the voucher has been sent.

5.2.3 Interview schedule

An interview schedule has been developed, for the purpose of interviewing pharmacy professionals regarding their experiences and opinions of their patient medicines helpline service.

The interviews will be semi-structured. The interview schedule primarily consists of open-ended questions, and were developed in accordance with established conventions for semi-structured interviewing (e.g., (65-67)). The interview schedule will not be treated as fixed; it may evolve during the data collection process in order to increase the opportunity to collect rich data. This is a common approach for semi-structured interviewing (46). The interview schedule will serve as a flexible guide which does not rigidly dictate the direction of the interview. This will allow participants the opportunity to talk about aspects of their helpline service which are important to them. Planned and spontaneous prompts will also be used to encourage participants to describe their experiences in greater depth.

The topics to be explored in the interview have been derived from the following sources: relevant research, including a systematic review of the benefits of providing patients with a medicines helpline (43), and a survey of pharmacy professionals' perceptions as to the benefits and future directions of patient medicines helplines (49); UK national standards for operating a patient medicines helpline (42); the APEASE criteria for designing and evaluating interventions (59); and the RE-AIM framework for evaluating the impact of interventions (52). Table 1 outlines the topics for the interviews.

The interview schedule has been developed with the involvement of Medicines Information Pharmacists with expertise in operating patient medicines helplines. Individuals who helped developed the data collection tools will be excluded from participating in the actual study.

Table 1. Main topics for interviews with pharmacy professionals

Topics
1. Why the patient medicines helpline service was set up, including pharmacy professionals' perceptions as to their purpose.
2. Perceived benefits of operating a patient medicines helpline service.
3. Perceived challenges of operating a patient medicines helpline service.
4. Perceptions as to whether and in what ways the patient medicines helpline service meets service users' needs.
5. Perceptions as to whether and in what ways the patient medicines helpline service is cost-effective.
6. Perceptions as to whether and in what ways any aspects of the patient medicines helpline service could be improved.
7. What procedures are in place when an enquiry reveals that there has been a medicines-related error.
8. Perceptions as to how patient medicines helpline services may develop in the future.
9. Perceptions as to how regional services would compare to local services.

5.3 Procedure

5.3.1 Interviews

The interview with pharmacy professionals will take place at a time which is convenient for them. A script has been developed to facilitate the interview telephone call, and to ensure that the information which participants receive at the start of the call is standardised.

At the start of the interview telephone call, the participant will be asked if they agree for the call to be audio-recorded. The audio recording for the consent process will be separate from the recording for the interview, to ensure that the interview recording, including the file name, can be anonymised. The consent process will take approximately 5 minutes. Section 7.3.2 details the consent process. Once the participant is happy to proceed, the interview will be conducted, using the interview schedule (see Table 1 for the main topics which are included in the interview schedule). The interview will take approximately 15 minutes.

Following the interview, participants will be asked to answer questions pertaining to their background. Once the interview has been completed, the participant will be thanked for their time. They will also be asked if they would like to receive the results of the study once they become available. Collecting participants' background information will take approximately 5 minutes.

Overall, the data collection process will take approximately 25 minutes per participant.

5.3.2 Analysis

Thematic analysis is a method of analysing qualitative data which results in the identification of patterns in the data that can be referred to as 'themes' (68, 69). Thematic analysis is widely used, and there is no single agreed method for conducting it (46). Grounded theory and IPA are types of thematic analysis, although they may be better thought of as methodologies rather than methods. As such, researchers who use these approaches may be considered to be conducting a 'grounded theory study' or an 'IPA study', since the approaches govern the entire study rather than just data analysis. Grounded theory provides a framework for developing theory which is grounded in data that has been systematically collected and analysed. Grounded theory is not considered to be a suitable analytic technique for the present study, since our aim is not to generate theory. IPA provides a theoretically-informed framework for conducting research which specifies several important aspects, such as what the ontological and epistemological underpinnings of the research are, what theoretical framework should inform the research, what types of research questions can be asked, what sampling strategy should be used, and how the analysis should be conducted (70). IPA's interpretative and phenomenological stance makes it more suitably applied to explore the lived experiences of a small set of cases about a unique and highly emotive phenomenon. Examples include 'South African women's experiences of breast cancer' (71), and 'mother's accounts of their stillbirth experiences' (72).

The thematic analysis procedure that was developed by Braun and Clarke (46, 68), and framework analysis, are other types of thematic analysis. Both can be considered to be methods rather than methodologies. As such, they can both be used irrespective of the ontological, epistemological, and theoretical frameworks of the research. Being methods rather than methodologies, they should be chosen if they provide a best fit with the specific aims of a research project. Both approaches can be used to interpret a phenomenon of interest, and are considered appropriate for use in qualitative healthcare research (46, 69, 73). Neither approach explicitly generates or develops theory, although this is a possibility (68, 74). Although there are important differences in how framework analysis and thematic analysis are conducted, their outputs can be similar in that they can both result in the identification of patterns in the data that can be referred to as 'themes' (68, 69). The flexibility of both of these approaches, and the potentially similar outputs they can produce, would make them suitable for the current study.

Framework analysis will be used for this study. Framework analysis is a pragmatic, rigorous and transparent technique used to order data to facilitate interpretation (75, 76). Within framework analysis, the analytical processes of data management and interpretation occur sequentially rather than concurrently. The approach advocates distinct stages of organising, describing, and interpreting data (74). This ensures that there is a systematic path, whereby there is transparency as to how the building blocks of the analysis were developed (74). The aim of data management within Framework Analysis is to make data accessible and to reduce its volume. It does this by taking a case- and theme-based approach, rather than focusing on one or the other. This is what primarily differentiates framework analysis from thematic analysis. With a case- and theme-based approach, data is organised in a matrix so that cases (e.g., participants) are represented in rows, and themes are represented in columns. Advantages of this it to ensure that data from each case is well represented within each theme, and vice versa, and to also provide transparency throughout this process. This overcomes a proposed limitation of thematic analysis, which suggests that published findings can sometimes lack transparency as to how themes were developed (73).

Being a flexible approach, Framework Analysis can be used for deductive, inductive, or combined qualitative analysis (69). A combined approach could be useful for the present study, whereby codes will be developed from the data with the option to also develop codes which are influenced by previous theory and literature (e.g., the RE-AIM and APEASE frameworks to evaluate healthcare interventions, the Sekhon et al. framework for the acceptability of healthcare interventions, the Delorme et al. model of medicines information-seeking behaviour, and Wills' proposed benefits of patient medicines helplines; (59, 77-79)).

Framework analysis is also particularly useful for analysing data comprising of groups (69). This will be beneficial for the present study, which will involve analysing the data both within and across cases, and to compare the results for different types of pharmacy professional (i.e., those who answer helpline enquiries, compared to Chief Pharmacists). The data will not be analysed separately for different types of pharmacy professional, although we would like to be able to compare the findings at the interpretative stage for these groupings. Framework Analysis will be useful for this, since the framework matrix will enable us to more easily move through the whole data set compared to analyses which do not use a framework matrix to organise the data (e.g., Braun and Clarke's Thematic Analysis; (68)). The framework matrix can be sorted to more easily view those cases which are of relevance regarding the above comparisons.

The analysis will involve the following stages, as outlined by Richie and Spencer, and Gale et al. (69, 74). The first five stages detail the process of data management. The final stage pertains to data interpretation. Throughout the process of analysis, it is recommended that all members of the team who are involved in the analysis keep a reflective diary, where they record notes, thoughts, and impressions of the data (69). The diary is particularly helpful for use during the final, interpretative stage of the analysis.

1. *Transcription of interview data*. Conduct a verbatim transcription of each interview, with large margins and adequate line spacing for later coding and note-making. All verbal utterances will be transcribed, whereas non-verbal utterances will not. Transcription will be conducted by MW, since transcription is considered an opportunity to become immersed in the data (69).

2. *Familiarisation with the interview data*. This will involve re-listening to the audio-recording of each interview, and/or reading each interview. Notes, thoughts or impressions of things that are relevant to the research question will be made down one side of the margin on the transcript printout. This process will be conducted by MW.

3. *Coding*. Coding is a data reduction technique, where repeating instances of interesting aspects of the data are recorded. A code is a word or brief phrase that captures the essence of the instances of interest in the data. This stage involves carefully reading each transcript, line by line, and using a label to describe each line. Codes can refer to anything of interest (e.g., emotions, values, behaviours, incidents). Codes can also be developed based upon existing literature and theory. Each line may produce more than one code. Codes can also be developed based upon multiple lines of text. The aim of coding is to classify all of the data so that different parts of the data set can be systematically compared. At least two researchers within the group should code the first few interviews separately. For the present study, the first few interviews will be coded by at least two member of the research team. Also, the first few interviews to be coded will include at least one interview from each of the two recruitment sites, and at least one interview of a pharmacy professional who answers helpline enquiries and at least one interview of a Chief Pharmacist. This will ensure that the different types of participants are represented in the initial coding process, which will be an important grounding for the subsequent coding and analysis stages.

4. *Developing a working analytical framework*. After coding the first few interviews, the research team will meet to compare codes. The research team will agree on a set of codes to be used for all other interviews. At this stage, codes can be grouped together to form themes. Codes can form the subthemes within the superordinate themes. The agreed set of themes/subthemes forms the analytical framework. The themes/subthemes can be numbered, to help differentiate them. An accompanying note can also be written for each of the themes, to clarify its meaning. This stage is an iterative process, to be repeated for the next few transcripts, and then the next, until no new themes/subthemes are developed. There can also be an 'other' subtheme within each theme, so that potentially important data is not ignored and can be recoded at a later time. Although the first few interviews will be separately coded by two members of the research team, subsequent coding will be conducted by MW, and discussed within the team. This

stage is useful for establishing whether data saturation has been reached. For the present study, if new themes/subthemes are being developed in the 30th interview, we will know that data saturation has not yet been reached and that additional data will need to be collected. If so, data will continue to be collected and the first 4 stages of Framework Analysis will be repeated until no new themes/codes are developed within at least three interviews.

5. *Applying the analytical framework*. The analytical framework is used to index all transcripts with the themes/subthemes. We will use NVivo for this stage, in order to store and organise the data so that it is easily retrievable. NVivo a computer software package for organising and analysing qualitative data (80). Therefore, it will be possible within NVivo to index each transcript and to also view the indexed sections under each code/theme. It may be that some new themes/subthemes are developed during this stage. The analytical framework becomes final after all transcripts have been indexed. If new themes/subthemes are developed, it is important to ensure that all previously indexed transcripts are re-indexed to include the new themes/subthemes. This stage will be conducted by MW, with discussion amongst the research team.

6. *Charting data into the framework matrix*. At this stage, a matrix is generated, for inputting the data. This can be conducted in an Excel spreadsheet or in Nvivo (version 9 onwards). For consistency, we will use NVivo, since the previous stage will also be conducted using NVivo. Charting is the process of summarising the data by theme/subtheme, from each transcript. Within the matrix, themes/subthemes are columns and interviews are rows. The charting process will involve reducing the data, whilst ensuring that the meaning is retained. Quotes should be used to illustrate the themes/subthemes. This stage will be conducted by MW, with discussion amongst the research team.

7. *Interpreting the data*. This involves developing a more analytic set of categories from the data, ensuring that variations within each theme are identified. During this stage, the data within each theme is re-read in order to search for 'elements' and underlying dimensions which account for the variability within the theme. This involves grouping together responses which are regarding the same element (i.e., the same thoughts, perceptions, behaviours), and categorising these as an underlying dimension. This is important for exploring variation within each theme/subtheme. Patterns can then be identified between the categories. The categories can also be used to compare accounts of different groups within the sample. Links can also be made to existing knowledge or theory, if applicable. This stage will be conducted by MW, with discussion amongst the research team.

5.3.3 Validity

Guidelines for enhancing the validity and trustworthiness of qualitative research were consulted during the planning of the study, and will be used throughout the data collection, analysis, and write-up stages (68, 81-83). Sources included Elliott et al.'s guidelines for the publication of qualitative research (82), and Santiago-Delefosse et al.'s 12 essential criteria for conducting qualitative research (83). The following examples are methods which will be implemented to enhance the validity of this study: situating the sample, to ensure that readers are provided with enough information about participants and their situations to judge whether the findings are potentially transferable to other similar individuals and settings; use of a reflective diary, to evidence that the researchers are positioned as active in the research process, and to be transparent as to how their perspectives may have influenced the findings; a 'paper trail' approach, in order to show transparency regarding how the study was conducted so that readers can judge its rigour; credibility checks, where each stage of the analysis is checked amongst the research team to verify that the identified codes and themes are appropriate; and grounding in examples, to allow readers to appraise the fit between the data and the researchers' understanding of them.

6   STUDY SETTING

Settings will be NHS Trusts in England which operate a patient medicines helpline service. Medicines Information Pharmacists who are involved in the operation of a patient medicines helpline, and Chief Pharmacists at NHS Trusts which operate a helpline, will be interviewed for this study.

Participants will be contacted by email, or by post if their email address is unknown, to invite them to consider taking part in the study. Email addresses for Medicines Information Pharmacists will be sourced using the UK Medicines Information (UKMI) website, or using NHS Trust websites. The UKMI website contains a public-access directory of the contact details of hospital-based medicines information teams within the UK. Chief Pharmacists' email addresses will be sourced from NHS Trust web pages, if available. If email addresses are not available, MI teams and Chief Pharmacists will be contacted by post. Therefore, the study does not require the co-operation of a gatekeeper for initial access to participants. When potential participants are contacted about the study, they will be sent the study Participant Information Sheet so that they can choose to read what the study is about, and what it involves. The Participant Information Sheet has been developed in accordance with guidance from the Health Research Authority.

Only Medicines Information pharmacy professionals and Chief Pharmacists at NHS Trusts which operate a patient medicines helpline will be contacted, since the study is aiming to understand pharmacy professionals' experiences and perceptions of patient medicines helpline services. Such sites will be appropriate for addressing the research question.

Since participants will be employed by NHS Trusts within England, the study will be multicentre. There will not be any site specific requirements to run the study (therefore, there will be no different types of activity being undertaken at each site). Sites will need to consider whether pharmacy professionals will be able to take approximately 25 minutes to participate in the study. It is likely that, at an NHS Trust, no more than two pharmacy professionals will participate in this study (i.e., a Medicines Information pharmacy professional, and the Chief Pharmacist). Participants will be offered a £10 voucher (Amazon) to thank them for their time. This amount was selected as a small, non-coercive, expression of thanks.

7   SAMPLE AND RECRUITMENT

7.1   Eligibility Criteria

7.1.1   Inclusion criteria

Inclusion criteria of pharmacy professionals: either a Chief Pharmacist at an NHS Trust within England which operates a patient medicines helpline service, or a Pharmacy professional (including pharmacy technicians) who operates a patient medicines helpline service at their NHS Trust within England; registered with the General Pharmaceutical Council (GPhC); fluent in English; ability and willingness to provide informed consent; and ability, willingness, and availability to conduct a 25 minute telephone interview.

Pharmacy professionals who operate patient medicines helplines will be included, since they see first-hand the benefits and potential limitations of the service. Chief Pharmacists will be included, since they may be better placed to provide a perspective as to how medicines helplines are beneficial within the wider organisation. We will aim to recruit an equal number of Medicines Information pharmacists and Chief Pharmacists.

7.1.2   Exclusion criteria

Exclusion criteria of pharmacy professionals: Not willing to be audio-recorded for the telephone interview.

7.2   Sampling

7.2.1   Size of sample

This study involves interviewing pharmacy professionals regarding their experiences and opinions of patient medicines helpline services. In order to attain a sample size that is likely to provide adequate data to sufficiently answer our research question, we will use published similar studies to estimate a sample size.

To estimate a sample size, we conducted a scoping exercise to find qualitative studies of healthcare staff's perceptions of healthcare services. This involved searching Scopus for suitable studies using the terms 'qualitative AND service*' in the article title, and 'healthcare AND (staff OR nurse* OR clinician* OR practitioner* OR pharmacist* OR doctor*)' in the abstract, title or keywords. Eight studies were considered to be suitable. The mean sample size of the eight studies was 20.4 (84-91). Therefore, we will aim to conduct up to approximately 35 interviews. This number is typical of qualitative research that aims to identify patterns across data, since a sample size of approximately 30 is considered typical (46).

7.2.2   Sampling technique

The sample will be purposive. Participants will be Medicines Information pharmacy professionals who are involved in the operation of hospital-based NHS patient medicines helplines, and Chief Pharmacists at NHS Trusts which operate patient medicines helplines. This is because the aim of the study is to understand pharmacy professionals' experiences and perceptions of patient medicines helplines, and these two groups of pharmacy professionals will have this expertise.

7.3   Recruitment

7.3.1 Sample identification

This study does not require the co-operation of a gatekeeper for initial access to participants. Medicines Information Pharmacists who are involved in the operation of a hospital-based NHS patient medicines helpline service, and Chief Pharmacists at NHS Trusts which operate a patient medicines helpline service, will be interviewed for this study.

Potential participants will be contacted by email, or by post if their email address is unknown, to invite them to consider taking part in the study. Email addresses for Medicines Information Pharmacists will be sourced using the UK Medicines Information (UKMI) website, or using NHS Trust websites. The UKMI website contains a public-access directory of the contact details of most hospital-based medicines information teams within the UK. Chief Pharmacists' email addresses will be sources from NHS Trust web pages, if available. If email addresses are not available for any MI teams and Chief Pharmacists, they will be contacted by post via their NHS Trust.

The recruitment email or postal pack will contain the Participant Information Sheet. Pharmacy professionals who are interested in taking part will be asked to contact the research team. Those which do not reply within two weeks will be resent the email or postal pack. Individuals who express an interest

in participating will be contacted by telephone to discuss the research and to see if they have any questions about the study. If they are happy to proceed, a time will be arranged for the interview.

Participants will be offered a £10 Amazon shopping voucher for taking part in the study. This amount was selected as a small, non-coercive, expression of thanks.

7.3.2 Consent

Prior to participating in the study, all participants must consent to taking part. Since data will be collected via the telephone, consent will also be obtained verbally, over the telephone. A verbal recording of consent is deemed to be appropriate by the British Psychological Society for low risk, telephone interview studies (64). The consent process has been informed by the Health Research Authority consent preparation guidance (63).

A script has been developed to facilitate the interview telephone call with pharmacy professionals, and to ensure that the information which participants receive at the start of the call, including the consent process, is standardised. At the start of the interview telephone call, the participant will be asked if they agree for the call to be audio-recorded. They will be informed that this will involve both the consent process, and the actual interview, being separately recorded. The audio recording for the consent process will be separate from the recording for the interview, to ensure that the interview recording, including the file name, can be anonymised. Study participants will be NHS staff; therefore participants will not be vulnerable or unable to give informed consent. However, prior to participating in the study, participants will be asked to describe what the study is about and what it involves for them, as an assessment of their capacity to give consent.

Consent to take part in the study will involve MW reading out all consent statements over the telephone and asking the participant if they agree to each statement. The consent statements are:
1) Please could you confirm that you have received information about this study, that you have had the opportunity to consider the information, ask questions about the study, and have had these answered satisfactorily?
2) Do you understand that your participation is voluntary and that you are free to withdraw from the study at any time without giving a reason?
3) Do you understand that your anonymised data may be retained for at least 10 years in accordance with the University of Bath Research Data Policy, and that it may be shared and used to support other research in the future?
4) Do you understand that parts of your interview may be used verbatim in future publications or presentations and that such quotes will be anonymised (i.e., they will not mention you personally)?
5) Do you agree to take part in the study?

8   ETHICAL AND REGULATORY CONSIDERATIONS

8.1   Assessment and management of risk

The study is considered to be low risk. The study involves conducting one interview which lasts approximately 25 minutes with NHS staff (pharmacy professionals) regarding their experiences and opinions of an NHS service (patient medicines helplines). The study does not involve NHS patients. The study does not involve drugs, placebos or other substances being administered to participants, nor will the study involve invasive, intrusive, or potentially harmful procedures of any kind. Blood or tissue samples will not be obtained from participants. Study participants will not be vulnerable or unable to give informed consent (e.g., children, or people with learning disabilities). The study is not likely to induce psychological stress or anxiety, or cause harm or negative consequences beyond that

experienced in the participants' everyday lives.

If potential malpractice is reported by a participant during the study, the main researcher, who is a PhD student and does not have expertise in Pharmacy Practice, will discuss this with the supervisor team, two of whom are registered pharmacists with experience of practice in a variety of settings, including medicines information. The supervisory team includes the Chief Investigator, Dr Matthew Jones. The supervisory team will advise the PhD researcher how to respond to the identification of malpractice.

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

This study involves recruiting and collecting data from NHS Staff, and does not involve recruiting and collecting data from NHS patients. Therefore, the study does not need NHS REC approval.

However, prior to study commencement, a favourable opinion will be sought from the University of Bath Research Ethics Approval Committee for Health (REACH) for the study protocol and all other study documents (e.g., data collection tools).

8.3 Regulatory Review & Compliance

Before participants are recruited into the study from a particular site, the Chief Investigator will ensure that appropriate approvals from participating organisations are in place. Specific arrangements on how to gain approval from participating organisations are in place and comply with the relevant guidance.

For any amendment to the study, the Chief Investigator, in agreement with the sponsor, will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator will work with sites (R&D departments at NHS sites) so they can put the necessary arrangements in place to implement the amendment to confirm their support for the study as amended.

8.4 Amendments

In accordance with Health Research Authority guidance on how to submit amendments for studies which do not require REC review, any amendments will be submitted by email to hra.amendments@nhs.net using the HRA amendment form *(92)*. The HRA will then categorise the amendment and provide this information within 5 days. The amendment and the categorisations information will then be sent by the Chief Investigator to participating NHS organisations (i.e., their Research & Development office).

The protocol amendment history will be tracked in Appendix 3 of the protocol. All previous versions will be listed here, along with details of changes made. The most recent protocol version can be identified on page ii of the protocol, under the heading *'Protocol Version Number and Date'.*

8.5 Peer review

This study protocol has been reviewed by all members of the research team (one PhD student, and three PhD supervisors with expertise in qualitative research and/or pharmacy practice research). The study has also been reviewed by two members of the Health and Clinical Research Group within the Department of Pharmacy & Pharmacology, University of Bath, who are external to the research. The

study protocol has been reviewed by one Medicines Information Pharmacist who is external to the research team/organisation. The study design and study documents (participant information sheet and interview schedule) have been reviewed by three Medicines Information Pharmacists, who are also external to the research team/organisation.

8.6 Patient & Public Involvement

A Patient and Public Involvement Group will not be used for this study, since the study is examining pharmacy professionals' experiences and perceptions of an NHS service. Instead, a group of pharmacy professionals with expertise of operating a patient medicines helpline service were asked to provide feedback on the study design and the data collection tool.

8.7 Protocol compliance

Accidental protocol deviations can happen at any time. They must be adequately documented and reported to the Chief Investigator and Sponsor immediately. Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

8.8 Data protection and patient confidentiality

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

All data which we will collect from our participants will be stored securely and confidentially (by 'data', we mean the recording of participants' consenting to take part, the recording of their interviews, and a form which will be used to record participants' background information such as their age and gender). Identifiable data will not be shared outside of the research team.

All interviews will be audio-recorded and transcribed word for word. The consent process will also be recorded, although this will be recorded separately to the participants' interview. Once an interview has been conducted, the consent recording and the interview recording will immediately be uploaded to the University of Bath data storage facility, in a protected folder which is only accessible by the research team. The recordings will then be deleted from the recording device. Consent recordings will be retained for at least 10 years following completion of the study, in accordance with the University of Bath Research Data Policy (83).

All participants will be allocated a unique identification number, and their data will be labelled with their unique number instead of their name. A spreadsheet (Excel document) which links participants' unique ID number and their name will be kept separate from their study data. This will be stored on a password-protected University of Bath secure server which is only accessible by the research team.

All personally identifiable information will be removed during transcription (e.g., names, places of work). This will ensure that the data is anonymous.

Identifiable data will not be shared outside of the research team, and the data custodian will be the Chief Investigator. Data will be stored and archived in the University of Bath's secure managed data storage facility. Data will be stored on campus. Paper copies of data will be locked in a filing cabinet which is only accessible to the research team. Electronic data will be stored on a password-protected University of Bath server, which is also only accessible to the research team.

Participants' contact details will be stored separately from their interview data, and contact details will be destroyed securely at the end of the project. Electronic documents will be deleted, and paper documents will be shredded. However, at the end of the interview, participants will be given the option of receiving the results of the study once they become available. If they agree to this, they will be made aware that this will involve the research team retaining their preferred contact details until the results have been disseminated. They will also be informed that, as per the study period, their contact details will be kept securely at the University of Bath, and will only be accessible to the research team.

With participants' consent, anonymous data will be archived in the University of Bath Research Data Archive and a data access statement will be made available in the publication of the study. For any participants who do not consent to their anonymised data being archived for the purpose of data access, their data will not be included, and the remaining archived data will clearly state that the full dataset was not archived for this reason. Archived data will be retained for at least 10 years, in accordance with the University of Bath Research Data Policy (93).

8.9   Indemnity

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

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

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

8.10   Access to the final study dataset

The study is being conducted as part of a PhD. The PhD student and the PhD supervisory team will have access to the full dataset. These individuals are:

Mr Matt Williams
Dr Matthew Jones (Chief Investigator)
Dr Abbie Jordan
Dr Jenny Scott

The study does not involve site investigators. Therefore, disclosing any restrictions in access for study investigators is not applicable.

Secondary analysis can only be undertaken with the consent of participants. As part of the consent process, participants will be asked to consent to their anonymised data being made available to be shared with researchers at the end of the study, including the potential for the data to be re-analysed. A data access statement will be included in the publication of the study. For any participants who do not consent to their anonymised data being archived for the purpose of data access, their data will not be included, and the remaining archived data will clearly state that the full dataset was not archived for

this reason.

9 DISSEMINIATION POLICY

9.1 Dissemination policy

The data arising from the study will be owned by the University of Bath. On completion of the study, the data will be analysed and a final study report prepared (the full study report will form part of the PhD thesis). The anonymised data (anonymised interview transcripts, and the thematically analysed data) will be archived in the University of Bath Research Data Archive. A data access statement will be included in the publication of the study. The final study report and the publication of the study will be made available on Opus, the University of Bath's online publications store. The publication of the study will acknowledge that the study was conducted as part of a PhD programme, which was funded by the University of Bath.

All participants who take part in the study will be asked if they would like to receive the publication of the study, when it becomes available. Those participants who express a desire to see the publication will be sent a copy via email or post (whichever they prefer).

9.2 Authorship eligibility guidelines and any intended use of professional writers

The following individuals will be granted authorship on the final study report:

Matthew Williams, Department of Pharmacy & Pharmacology, University of Bath.
Dr Matthew Jones, Department of Pharmacy & Pharmacology, University of Bath.
Dr Abbie Jordan, Department of Psychology, University of Bath.
Dr Jenny Scott, Department of Pharmacy & Pharmacology, University of Bath.

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11.   APPENDICIES

11.1   Appendix 1- Required documentation

PhD student's CV
First academic supervisor's CV (also the Chief Investigator)
Second academic supervisor's CV
Third academic supervisor's CV
Participant Information Sheet
IRAS form
Statement of Activity
Schedule of Events

11.2   Appendix 2 – Schedule of Procedures

Sites will not be required to complete any tasks for this study. Therefore, a Schedule of Procedures has not been included. However, sites will need to consider whether pharmacy professionals who would like to participate in the study will be able to take approximately 25 minutes to complete the study (5 minutes to consent the participant in to the study; 15 minutes for interviewing the participant; 5 minutes to collect the participant's background information). All data will be collected over the telephone.

11.3   Appendix 3 – Protocol Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	1.1	19/03/2018	Matt Williams	Email addresses will be collected from participants for the purpose of emailing them their voucher. We have clarified that the consent recordings will be retained for at least 10 years once the study has been completed, in line with University of Bath policies (instead of stating that they will be destroyed once the study has been completed).
2	1.2	29/05/2018	Matt Williams	Change the number of participants from 20 to between 20-30.
3	1.3	11/10/2018	Matt Williams	Change the number of participants from 20-30 to 35.
4	1.4	01/07/2019	Matt Williams	Change analysis from Thematic Analysis to Framework Analysis.