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FULL/LONG TITLE OF THE STUDY

Service users' experiences of hospital-based NHS patient medicines helplines. A qualitative study.

SHORT STUDY TITLE / ACRONYM

Experiences of using NHS patient medicines helplines.

PROTOCOL VERSION NUMBER AND DATE

Version 1.4
01/07/2019

RESEARCH REFERENCE NUMBERS

IRAS Number:	233726
SPONSORS Number:	Not applicable.
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SIGNATURE PAGE

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

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

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

For and on behalf of the Study Sponsor:

Signature: ..... Date: 20/12/17

Name (please print): Jonathan Knight .....

Position: PVC - Research .....

Chief Investigator:

Signature: ..... Date: 20/12/2017

Name: (please print):

.....MATTHEW JONES…….....

LIST of CONTENTS

KEY STUDY CONTACTS

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Sponsor	The sponsor is the University of Bath. The contact on behalf of the sponsor is: Professor Jonathan Knight, pro-vc-research@bath.ac.uk, 01225 383162.
Joint-sponsor(s)/co-sponsor(s)	Not applicable
Funder(s)	Not applicable
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Committees	Not applicable

STUDY SUMMARY

Study Title	Service users' experiences of hospital-based NHS patient medicines helplines. A qualitative study.
Internal ref. no. (or short title)	Experiences of using NHS patient medicines helplines.
Study Design	This study will involve the use of qualitative semi-structured telephone interviews to explore individuals' experiences of using NHS patient medicines helpline services.
Study Participants	*Inclusion criteria of service users*: individuals who have contacted an NHS patient medicines helpline with the aim of seeking information and/or support regarding medicines (the contact can be via any means of communication other than face-to-face, such as telephone, email, or online webform); participants can include patients of the organisation which hosts the patient medicines helpline, and carers of such a patient (including parents of patients who are under 16 years old); aged 16 years and over; fluent in English; ability and willingness to provide informed consent; and ability, willingness, and availability to conduct a telephone interview within one month of having used an NHS Trust's patient medicines helpline service. *Exclusion criteria of service users*: If, in the pharmacy professional's judgement, taking part would likely cause distress to the service user; if a service user is known to be pursuing, or considering pursuing, a complaint against the Trust; inability to remember the helpline call (i.e., they cannot remember making the call, or cannot remember why they made the call); for service users who contact the service on behalf of a patient of the hospital, if the service user is

	considered to be a healthcare professional to the patient (based upon the information disclosed to the pharmacy professional during the helpline call).
Planned Size of Sample (if applicable)	A minimum of 30, with the final sample size based upon reaching thematic saturation.
Follow up duration (if applicable)	Not applicable. Participants will take part in one interview only.
Planned Study Period	01.01.2018 – 31.12.2019
Research Question/Aim(s)	Our aim is to conduct a qualitative research study to explore service users' experiences of using an NHS patient medicines helpline service. Research question: *What are service users' experiences of using a hospital-based NHS patient medicines helpline service?*

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. The PhD 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. Supervisory meetings are held once a month. The PhD student is responsible for all aspects of the study, with guidance from the supervisory team.

A Patient and Public Involvement group were asked to provide feedback on the study design, the participant information sheet, and the data collection tools for this study.

PROTOCOL CONTRIBUTORS

The sponsor/funder has no role or responsibility in the study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results. The sponsor has no control over the final decision regarding any of these aspects of the study.

The protocol was written by the Matt Williams, with feedback from the Key Protocol Contributors, outlined above.

A Patient and Public Involvement group were asked to provide feedback on the study design, the participant information sheet, and the data collection tools for this study.

KEY WORDS:

Patient medicines helplines
Medicines information
Drug information
Clinical pharmacy services
National Health Service
Medicines information-seeking

STUDY FLOW CHART

The research team will contact the Chief Pharmacist at NHS Trusts which operate a patient medicines helpline, with the aim of recruiting at least two Trusts to participate in this study. The research team will provide the study protocol, and visit NHS Trusts to discuss the research with pharmacy staff.

Once approval has been granted by the Health Research Authority and Research Ethics Committee, the research team will work with the participating NHS sites to set up the study.

Site activities:
Whenever the helpline team receives a call from a service user, the pharmacy professional will decide whether the caller meets the inclusion/exclusion criteria for the study. If the caller meets the inclusion/exclusion criteria, the pharmacy professional will ask the caller if they would like to receive an information leaflet about the study (a script has been written for this). If the caller agrees, the pharmacy professional will send the information leaflet to the caller after the call has ended. This process is to be repeated until at least 30 helpline callers have participated in the study, or until the study recruitment phase ends (the study recruitment phase lasts six months).

Helpline callers will contact the research team directly, if they are interested in taking part in the study. The research team will contact the potential participant via the telephone to answer any questions they have about the study. This will also provide another opportunity to check that the potential participant meets the inclusion/exclusion criteria for the study. For those who are eligible to participate, a convenient time will be arranged to conduct their first interview.

The research team will conduct the interview with the service user (to include verbal consent, audio-recorded, on a separate recording to the interview). This interview will be conducted within one month of the individuals' helpline contact. However, ideally interviews will be conducted as soon as possible after participants' helpline calls. This is to increase the chance that the caller will remember their experience of using the service, during their interview.

STUDY PROTOCOL

Service users' experiences of hospital-based NHS 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).

Since patient medicines helplines are used by patients and carers, and some services accept enquiries from members of the public (40), the term 'service users' will be used throughout this protocol to refer to anyone who uses a patient medicines helpline service. Relatedly, although the service is known as 'patient medicines helplines', a recent study found that some services also provide service users with the option of using other means of communication to acquire medicines information and support (e.g., web-form and email) (40). However, the term 'patient medicines helpline' will be used throughout this protocol to refer to any means of distance communication that a service user can use to acquire medicines information and support following hospital discharge.

The UK National Health Service is committed to providing evidence-based patient care (41). 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) (42-44). 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.

In 2014, UK national standards were developed to provide both "satisfactory" and "commendable" standards for setting up and operating a patient medicines helpline in the UK (43). Their aim is to ensure that all patient medicines helplines are providing a high-quality service to patients. The standards are set out in terms of helpline access, availability, promotion, use of standard operating procedures, level of information and professional support available, and quality and risk. Recent research has begun to examine whether patient medicines helplines in England are meeting these standards (40). Descriptive studies suggest that patient medicines helplines are operated in different ways across NHS Trusts (32, 40). For example, a survey conducted by Williams et al. (in preparation) examined how patient medicines helplines are operated at NHS Trusts in England. They found that helplines were available to patients up to four hours each weekday at 14% of NHS Trusts, and only 6% of NHS Trusts operate a patient medicines helpline which was available for extended hours (i.e., evenings, weekends) (40). Additionally, Williams et al. found 19% of NHS sites do not provide access to an out-of-hours answerphone for their patient medicines helpline, and contact with a pharmacy professional is not always available during advertised hours at 29% of NHS Trusts (40). These findings suggest that patients' experiences of contacting the medicines helpline at the Trust where they recently received care may not be as straightforward as calling the number and immediately

speaking to a pharmacy professional who can help them with their query. Research to date has not been conducted which asks patients to recount their experiences of using patient medicines helplines, in order to establish the impact of such variability in the operation of medicines helplines upon service users.

1.3 The importance of the patient experience and patient involvement in care

The aim of the UK National Health Service is to deliver high-quality care, and the patient experience is one of the three parts of the NHS definition of high-quality care, alongside clinical effectiveness and safety (45). This has been reflected by an increase in policies in recent years which emphasise that the NHS is committed to patient involvement in healthcare, and that services should be shaped around their needs (38, 41, 46). Ensuring that the patient experience of care is positive is one of five key domains within the NHS Outcomes Framework, which sets out national outcomes that the NHS should be aiming to improve (39). There is a growing recognition that patient experiences can be used to identify problems with healthcare delivery and to drive quality improvement initiatives (47-50). Patients' experiences as users of healthcare services can provide valuable insight into those aspects of services that work well, and those that do not. Listening to the experiences and perspectives of patients may therefore lead to more effective services, and ultimately, to improved patient outcomes.

1.4 Advantages of Qualitative Research

Many data collection tools have been developed and used to elicit patient experiences (51). Although, to meet the needs of a target-driven healthcare system there is currently a reliance on quantitative tools for eliciting patient experiences such as patient satisfaction surveys (51), the NHS Friends and Family Test (52), the NHS Inpatient Survey (53), and data from complaints, incidents and patient liaison services (54, 55). 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 (50, 56).

Compared to quantitative research, qualitative research places greater importance upon context, and individuals' insights, understandings, and meanings of their lived experiences (57). The use of qualitative data collection methods such as interviews and focus groups can explore the patient 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 (2015) 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. (58) 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. This is in accordance with healthcare quality improvement techniques, such as Experience-Based Co-Design, which recognise that eliciting and utilising the experiences of service users are vital for making

meaningful and lasting improvements (47).

1.5 Frameworks for designing and evaluating healthcare interventions

Frameworks have been developed for designing and evaluating healthcare interventions. The RE-AIM framework was first published in 1999 by Glasgow et al. (59). 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. (60) 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 x E. Glasgow et al. (59) expanded on this concept to develop RE-AIM, by adding three dimensions that apply to the settings in which research is conducted. These are *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 (61). Glasgow et al. emphasise the importance of focusing on all dimensions of the framework in order to fully evaluate the impact of an intervention (62, 63).

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 (62, 63). 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. For understanding service users' experiences and perceptions of using a healthcare service, 'efficacy'/'effectiveness' is the dimension of RE-AIM which is applicable.

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 (64, 65). Systematic reviews suggest that factors considered relevant to the acceptability of an intervention can be predictive of adherence (66-69). Perceived effectiveness and acceptability may also be considered to overlap. In their recently-developed framework of acceptability, Sekhon et al. (70) propose that perceived effectiveness is one of seven components which comprise the construct 'acceptability' (the others being attitude about the intervention, perceived burden of the intervention, whether the intervention fits with an individual's values, understanding of the intervention, costs associated with the intervention, and perceived efficacy to participate in the intervention).

Michie et al. (71) recently developed the APEASE framework for designing and evaluating interventions, which comprises six criteria, including both 'acceptability' and 'effectiveness'. The criteria are: affordability of the intervention (e.g., whether the intervention can be satisfactorily operated within an acceptable budget), practicability of the intervention (e.g., the extent that the intervention can be delivered as designed through the means intended to the target population), effectiveness and cost-effectiveness of the intervention (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 intervention (e.g., acceptable to those operating and using the intervention), side effects/safety of the intervention (e.g., whether there any unwanted side effects or unintended consequences of the intervention), and equity (e.g., whether the intervention can reduce or increase standards of living, wellbeing, and health between different sectors of society). Being a recently developed framework, only a few studies have been published which have used APEASE, primarily for choosing an

intervention (72-74).

As with the RE-AIM framework, several dimensions of the APEASE framework are not relevant regarding examining service users' experiences of an intervention or service. The 'affordability' and 'practicability' criteria pertain to the *development* of an intervention, rather than service users' views and experiences. The 'effectiveness/cost-effectiveness', 'acceptability', 'side effects/safety', and 'equity' criteria pertain to the *evaluation* of an intervention (72). Certain criteria, such as cost-effectiveness and equity, may be more suited to being examined using quantitative research methods (75, 76). The 'effectiveness' criterion is specified within the APEASE framework to pertain to effect sizes, which are attained using quantitative research methods. However, as described above in relation to RE-AIM, 'effectiveness' would also be suitable for evaluating interventions using qualitative research methods. For example, effectiveness could instead be examined by asking service users about their perceptions of the effectiveness of the service. Similarly, service users could be asked to describe their experiences of a service in terms of acceptability and perceived side effects/safety.

Therefore, the RE-AIM evaluation criterion 'effectiveness', and the APEASE evaluation criteria 'effectiveness', 'acceptability' and 'side effects/safety', could be used as a framework to develop a qualitative study which examines service users' experiences of patient medicines helplines.

1.6 Effectiveness of patient medicines helplines

Since the primary aim of patient medicines helpline services are to provide service users with information and support with their medicines (30), their effectiveness could be assessed in terms of whether or not they achieve this from the perspectives of the service user. Effectiveness could also be assessed in terms of whether or not the impact of the information/support upon the service user is perceived to be positive.

Service evaluation studies have sought to examine the proportion of service users who feel that they have a greater understanding of their medicines as a result of contacting a patient medicines helpline. Surveys of helpline users have found that between 62% and 82% of respondents reported that they had an improved understanding of their medicines following their helpline interaction (77-79). This suggests that between 18% and 38% of respondents either understood their medicines to the same level as before, or felt less of an understanding as a result of the helpline interaction. However, such findings are limited by being based upon single survey items. It could be that, despite efforts by the pharmacy team to provide clarification, some service users may remain feeling confused about aspects of their medication after contacting the helpline. There is an assumption that their knowledge gap is filled as a result of using the helpline service, and that service users understand the information and advice they receive. However, evidence is needed to ascertain this.

To date, no qualitative research has been published which explores service user experiences of contacting a medicines helpline. Such a design would be unique, and would be suited to explore patients' understanding and knowledge of the information or advice they have received. This is important, given that research shows that patients often lack knowledge of their medicines following hospital discharge (10, 13, 80) and that clinicians may overestimate patients' understanding of treatment consultations (81, 82). It is therefore feasible that patients may come away from the helpline interaction with ongoing knowledge gaps. Qualitative methods would be suitable for asking the question 'How do service users make sense of the information and advice provided by the pharmacist?'. Qualitative methods would also provide service users with an opportunity to describe any ongoing lack of understanding or confusion they may have regarding their medicines.

Service evaluation survey studies suggest that between 88% and 97% of service users reported following the advice they received (33, 35, 77, 79). However, one study reported that 96% of service

users in their survey reported following the advice either partially or fully (35). Combining the proportions for 'partial' and 'full' adherence to the advice given is limited in that there is no way of knowing what 'partially' following the advice entails, or whether this leads to harm. An assumption of medicines optimisation is that following the medication advice of a healthcare professional in full will be of benefit, whereas following the medication advice of a healthcare professional only partially may not be (2). Qualitative methods could explore how patients take their medicines, and why such choices are made. Qualitative methods could also provide important information and understanding regarding what it actually means to patients to follow the advice given - whether this translates to improved treatment adherence, and improved patient outcomes. To date, no published studies have explored the impact of patient medicines helplines with regards to medication adherence.

The aim of medicines optimisation is to make the most effective use of medicines so that they have the best possible outcome for patients (2, 83). Patient medicines helplines provide a method for pharmacists to optimise a patients' medicines, and research suggests that pharmacy professionals consider medicines optimisation to be a major benefit of providing patients with access to a medicines helpline (40). Service evaluation survey studies of patient medicines helpline users' experiences of the service suggest that between 42-47% of callers say that the medicines information they received from the helpline call resulted in an improvement in their condition (34, 77, 79) and 33% say that the information they received resulted in an improvement in their health (77). Qualitative methods could be used to add context to this, by exploring patients' views as to the reasons why health conditions do not improve for the majority of patients following calls to medicines helplines.

Service evaluation survey studies suggest that patients can feel reassured about their treatment as a result of contacting a hospital pharmacy team via the patient medicines helpline after discharge (30, 35, 77, 79, 84). For example, Badiani et al. (35) carried out a survey study which examined 100 patients' and carers' experiences of using a patient medicines helpline. They found that 45% of participants reported feeling reassured about their medicines or illness following the helpline call. However, data was collected by respondents ticking a box to say whether they felt reassured following the call, and the study did not examine the proportion of respondents who felt less reassured following the call. Other findings suggest that some patients can feel more anxious following the helpline call (33). Joseph et al. (33) conducted a survey which examined 58 patients' experiences of using a patient medicines helpline. They found that three quarters of the sample reported feeling less anxious about their medicines or health condition whereas one quarter reported feeling increased anxiety. However, the study by Joseph et al. is limited by a small sample size and being conducted at one hospital site, thereby raising a question mark over the generalisability of their findings. The study also did not seek to ascertain why some patients felt increased anxiety. Compared to survey methods, qualitative methods are better suited to uncover the reasons why some patients may feel increased anxiety following helpline calls.

1.7 Acceptability of patient medicines helplines

The APEASE 'Acceptability' criterion pertains to the extent to which an intervention/service is judged to be appropriate by relevant stakeholders, including service users and professionals involved (71). This is important since different stakeholders are likely to have a different view as to what constitutes an acceptable service. For example, for service users the acceptability of patient medicines helplines may be about how helpful the service is, whereas for pharmacy professionals, acceptability may be seen in terms of meeting standards (e.g., national standards recommend that patient medicines helplines meet certain criteria in terms of their access and availability (43)). This is in accordance with quality improvement initiatives which recommend seeking the views of both service users and service providers (47, 85). This could lead to recommendations for improvements which are of benefit to all stakeholders.

Service evaluation studies have been conducted which examine whether patient medicines helpline users perceive the service to be helpful (35, 77, 84). Although service users typically report finding patient medicines helplines helpful, some do not. For example, a survey study by Bramley et al. (77) found that 93% of 73 service users who contacted one of three Medicines Information Centres in London considered the advice they received to be helpful. NHS Benchmarking data for 2016 suggests that there were 17,297 calls per year to the patient medicines helplines of the 78 acute Trusts in their sample (86). If approximately 7% of callers do not find their experience helpful, then this amounts to approximately 1,211 calls to those Trusts that were not considered to be helpful. This unmet clinical need may result in additional and avoidable costs to healthcare providers if, for example, patients subsequently seek medicines-related support from their GP or if the patient is readmitted to hospital.

However, in a survey of service users experiences of patient medicines helplines conducted by Badiani et al. (35), 100% of their sample of 97 service users said that they found the advice helpful and would use the service again in future. This highlights an issue with basic survey tools for collecting data about patient experiences. Ticking a box in a survey to say that the service was helpful does not provide patients with an opportunity to say whether there were aspects of their helpline experience that could have been improved, even if their experience was generally positive. Additionally, the sample in the study by Badiani et al. (35) were recruited from one MI centre whereas the sample in the study by Bramley et al. (77) were recruited from three sites. This may also account for the difference in service users' ratings as to whether they found their experience helpful, and highlights the importance of collecting data from multiple sites to produce findings that can be considered to be more generalisable.

Relatedly, service evaluation studies have attempted to measure service user satisfaction with using medicines helplines (33-35, 77-79). This is important, since the ongoing measure of service user satisfaction of patient medicines helplines is one of the recommended standards within the national standards for operating a patient medicines helpline (43). Measuring service users' satisfaction with patient medicines helplines has ranged from having a single survey item asking respondents to rate their level of satisfaction on a scale from 'poor' to 'excellent' (34, 35), to asking specific questions on aspects of the helpline service deemed important to the investigators. These have included whether respondents felt understood, whether they felt reassured, whether they received an answer within an appropriate timeframe, and whether their problem had been resolved (35, 77-79, 84). Studies suggest that the majority of people who use patient medicines helplines are satisfied with the service and the information they received (33-35, 77-79).

Although quantitative studies have been useful for showing that patient medicines helplines are typically considered to be helpful and that patients are typically satisfied with the service, quantitative methods are not well suited to explore such findings in depth. Qualitative approaches would allow access to in-depth information regarding the helpfulness of patient medicines helplines and patient satisfaction with the service which are not captured by structured questionnaires (87). For example, qualitative research could explore what specifically it is about the helpline experience that patients found helpful and were satisfied with, whether there were any aspect that were unhelpful and led to feeling of dissatisfaction, why this was the case, and how the service could be improved. To date there are a lack of studies which have asked service users for their opinions as to whether any aspects of the patient medicines helpline service were unhelpful and why, and what aspects could be improved. Qualitative research could also help to understand the implications of patient satisfaction and dissatisfaction, by asking patients what impact, if any, a feeling of satisfaction or dissatisfaction with care had upon their actions following their helpline use. In this sense, acceptability of the service may influence perceived effectiveness of the service.

Recent developments within the NHS such as the Five Year Forward View (88, 89) and the Carter Report (90) recommend that NHS organisations collaborate by sharing services and resources to a

greater extent in the future. In a recent survey which asked Medicines Information Pharmacists and Chief Pharmacists at NHS Trusts throughout England to write their views as to the future of patient medicines helplines in a freetext box, 27% of 148 respondents wrote that patient medicines helplines would likely be operated either regionally or nationally in the future (40). Badiani et al. (2016) carried out a retrospective analysis of 200 calls received to one patient medicines helpline to ascertain the proportion of calls which required local knowledge in order to answer the query. They found that access to local knowledge was required in 74.5% of cases, and was deemed essential in 56.5% of cases (in 26.5% of cases, local knowledge was not required). The most commonly used local source was the patients' electronic medical records (72.5%, n=108), followed by contacting a healthcare professional involved in the patient's care (e.g., the discharging doctor or pharmacist; 34.2%, n=51). Badiani et al. conclude from this that the findings support the value of having a network of local medicines helplines, rather than a small number of centralised services. To date, no study has sought to elicit service users' views as to whether they value the helpline service being local and affiliated to the healthcare provider where they recently received their care, nor how they would feel about contacting a medicines helpline which is either regional or national instead. Qualitative methods would provide a useful means of exploring such views.

1.8 Perceived safety, side effects, and negative consequences of patient medicines helplines

The RE-AIM dimension 'effectiveness' emphasises the importance of evaluating not only the positive consequences of health interventions, but also their negative consequences. Within the APEASE framework, a similar emphasis can be seen within the 'side effects/safety' criterion (71). Part of this criterion is to establish whether there are any unwanted side effects or unintended consequences of the service. To date, no studies have examined whether service users have experienced any negative consequences of contacting a patient medicines helpline service, and qualitative methods would be appropriate for achieving this.

A perceived benefit of patient medicines helplines is that they can act as an early warning system or safety net, to highlight and rectify a proportion of the errors which occur in hospital pharmacy practice before they can potentially cause harm (91). Service evaluations of types of enquiries suggest that between 19-39% of patient medicines helpline calls are either regarding errors or that errors are revealed during the helpline interaction (30, 31, 35, 79, 84, 92). The main types of errors were having wrong or insufficient information supplied with the medication, and not receiving medications.

Errors may have more of an emotional impact for service users if there is also the potential for harm. Marvin et al. (31) found that, out of 500 calls to a patient medicines helpline, 48% were concerned with harm or judged to have the potential for harm, had professional information not been available. The potentially harmful situations were considered to be temporary, and none of these calls were regarding situations that were potentially lethal or likely to cause permanent harm. However, such findings highlight the benefit of providing patients with a means of communicating with a pharmacist regarding their medicines after receiving care. Although no patients were seriously harmed, patients may have been inconvenienced and/or unnecessarily worried as a consequence of errors made by hospital staff, particularly given that a large proportion of enquiries to patient medicines helplines are from the elderly (30). Such experiences may affect service users' attitudes, feelings and perceptions regarding healthcare services.

If a service user experiences a medicines-related error, qualitative methods would be useful to explore their experience of this in relation to their care and their healthcare organisation, particularly if the service user perceives that the error could have caused harm. Qualitative methods could also explore whether and in what ways the helpline service may have had an impact upon their experience of this issue, and whether it affected their perception of the organisation.

2 RATIONALE

Research suggests that many patients leave hospital with gaps in their knowledge about their 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. 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.

There is an assumption that patient medicines helplines meet service users' medicines information and support needs, although evidence is required to establish this. In order to ascertain what service users themselves think of medicines helplines, quantitative survey studies have been conducted. However, survey studies have several limitations. For example, surveys include questions that are important to the researcher, rather than allowing participants to provide information that is important to them. Relatedly, survey answer options do not allow participants to respond using their own words. The results of such studies suggest that patients typically consider medicines helplines to be useful, although quantitative surveys are not well suited to explore why and in what ways they are useful. Qualitative methods would be more appropriate to explore the experiences of service users in order to answer such questions.

In line with healthcare quality improvement approaches, services are likely to be improved by seeking to understand the experiences of service users. No qualitative studies have yet been conducted to examine service users' experiences of contacting a patient medicines helpline. Exploring and comparing the accounts of helpline callers in terms of acceptability, effectiveness and safety of the service may reveal whether patient medicines helplines do indeed meet service users' medicines information and support needs. Such a study may result in recommendations for the improvement of patient medicines helpline services.

3 THEORETICAL FRAMEWORK

The RE-AIM and APEASE frameworks, described above, have been used to inform the development of this qualitative study which examines individuals' experiences of using patient medicines helpline services.

Additionally, a model of medicines information-seeking behaviour has also been used to inform the development of this study. Several theoretical models of health information-seeking behaviour (HISB) have been developed which represent the hypothesised underlying factors that influence information-seeking, and the processes involved (93-95). The Comprehensive Model of Information-Seeking (CMIS; (96)) is the only HISB model which has been modified specifically for the context of medicines information seeking behaviour (MISB; (97)). The modified CMIS is also novel in that it aims to address the issue lacking in other models by attempting to explain why certain sources of support are sought and others not, rather than whether information-seeking will or will not happen. Figure 1 shows the modified CMIS (from here referred to as the medicines information-seeking behaviour model, or MISB model).

The original CMIS highlights the importance of antecedents for explaining why individuals seek information, and considers how information source characteristics might influence and shape information-seeking behaviour (96-98). However, in the MISB model, the focus is upon the factors that determine the selection of specific sources of information. Therefore, in the MISB model, under 'Information Seeking Actions' the outcome changes from simply seeking information to the use of specific information sources.

A second modification of the model is the context of information-seeking. Whereas the

conceptualisation and initial application of the CMIS was disease-specific (e.g., cancer), for the MISB model this is not the case. The focus is instead upon information-seeking about prescribed medicines, and so does not refer to a specific disease or even a specific type of medicine. This shift in context has resulted in the modification of some of the model variables in the 'antecedent' section of the original model. For example, 'Direct experience', which referred to having experience of a particular disease, has changed to the number of prescription medicines taken. This is important, since research has found that several medicines-related issues are associated with the number of prescribed medicines that a patient takes. For example, associations have been found between the number of prescribed medicines taken and inappropriate prescribing (99, 100), prescribing errors (101, 102), adverse drug reactions (100, 103), drug-drug interactions (104, 105), lack of patients' knowledge of their prescribed medicines (106, 107), and patients' suboptimal adherence to their prescribed medicines (100, 108). Evidence also suggests that hospital readmission is positively associated with, and predicted by, the number of medicines a patient is prescribed (109, 110).

The current study concerns individuals who have already chosen to seek medicines information, and have already chosen the means of attaining this information. However, both the CMIS and the model of MISB could be used to inform qualitative studies which seek to examine service users' experiences of contacting a patient medicines helpline service. For example, participants could be asked why they chose to seek medicines information via the patient medicines helpline instead of an alternative source. Specific probes could focus upon reasons pertaining to the individual, and reasons pertaining to characteristics of the sources, to reflect these two aspects of the MISB model. An example of this could be to ask patients whether the number of medicines they take, and the complexity of their medicines regimen, impacted their decision to contact the helpline service rather than speak to their GP.

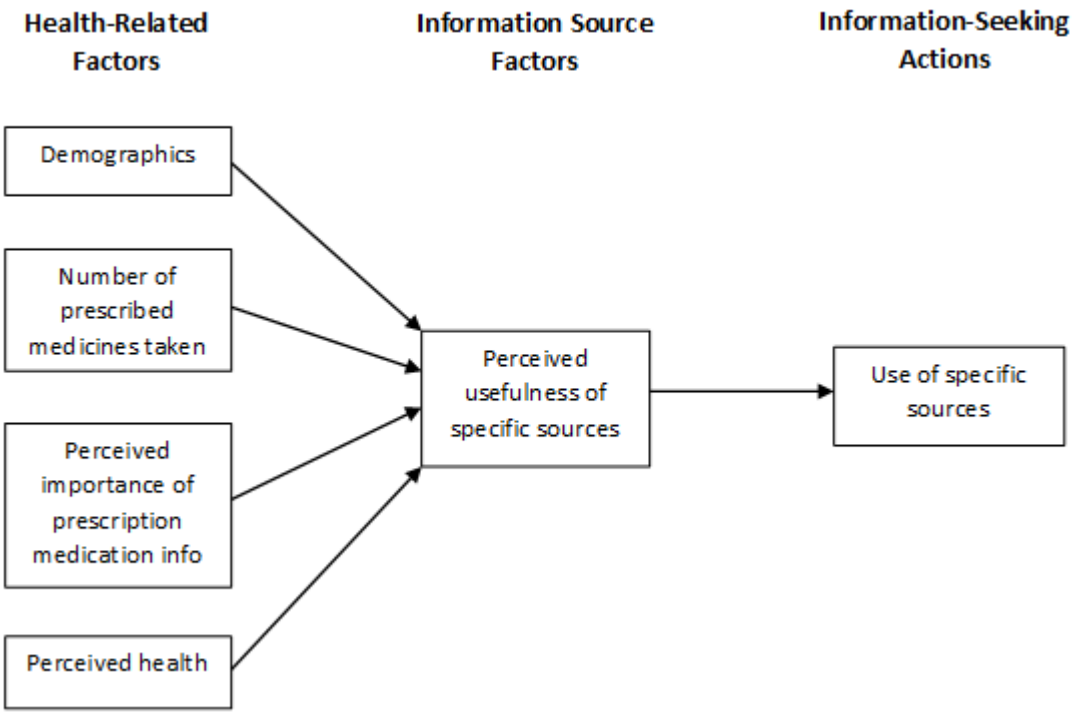

Figure 1 The modified Comprehensive Model of Information Seeking (Delorme et al. (97)).

4 RESEARCH QUESTION/AIM(S)

4.1 Objectives

Our aim is to conduct a qualitative research study to explore service users' experiences of patient medicines helpline services.

Research question: *What are service users' experiences of using a hospital-based NHS patient medicines helpline service?*

4.2 Outcome

An outcome of this study will be recommendations for improving patient medicines helpline services so that they better meet the needs of service users.

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 service users' experiences of using NHS patient medicines helpline services.

Both face-to-face and telephone interviews have strengths and limitations. Telephone interviews were chosen for this study, since telephone interviews are more cost- and time-effective than face-to-face interviews, enabling potential participants to be recruited from NHS Trusts throughout the UK rather than local to the University of Bath. The study is being conducted as part of a PhD project, and so there are financial and time constraints. Travelling to and from sites which may be over an hour away from the University in order to conduct at least 30 interviews does not seem cost- and time-effective compared to conducting the interviews via telephone. Telephone interviews also provide flexibility for the participants (e.g., it is easier to schedule a telephone call to fit in with people's busy lives, including evenings and weekends, and it is easier for participants to re-schedule if necessary). Additionally, there is currently a lack of evidence that telephone interviews produce lower quality data compared to face-to-face interviews within qualitative research (111).

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 (112) and British Psychological Society (113). Consent forms will not be used, since service user consent will be obtained verbally, over the telephone.

The information sheet was developed with the involvement of two relevant groups:
1. People who have recently been discharged from hospital, or carers of people who have recently been discharged from hospital (see section 8.6 Patient and Public Involvement).
2. Pharmacy professionals with expertise in Medicines Information and operating a patient medicines

helpline.

5.2.2 Questionnaire pertaining to the helpline call and participants' background

In order to add context to the semi-structured interviews, the following background data will be collected directly prior to the telephone interviews using data collection forms (one for participants who are patients, and another for participants who are carers):

Patients: Name of the NHS Trust which provides the patient medicines helpline service which they used; date they contacted the patient medicines helpline service; whether or not they had previously used the helpline service; patient type (i.e., whether they were an inpatient or an outpatient); approximate number of prescribed medicines currently taken (participants will be provided with the answer options of 0-1, 2-4, 5-9, and 10 or more).

Carers: Name of the NHS Trust which provides the patient medicines helpline service which they used; date they contacted the patient medicines helpline service; whether or not they had previously used the helpline service; relationship to patient.

The following background information will not be asked of carers: name of all medications currently prescribed; current morbidities. This was discussed amongst the research team, and it was decided that collecting information about the patient via the carer, would be unethical unless the patient also provides their consent.

5.2.3 Interview schedule

Two interview schedules have been developed:

Interview Schedule 1 has been developed for the purpose of interviewing helpline service users who are patients rather than carers, with the interview taking place within one month of their helpline contact. The aim of Interview Schedule 1 is to understand patients' experiences and perceptions of the patient medicines helpline service.

Interview Schedule 2 has been developed for the purpose of interviewing helpline service users who are carers rather than patients, with the interview taking place within one month of their helpline contact. The aim of Interview Schedule 2 is to understand carers' experiences and perceptions of the patient medicines helpline service.

The two interviews will be semi-structured. Both interview schedules primarily consist of open-ended questions, and were developed in accordance with established conventions for semi-structured interviewing (e.g., (114-116)). The interview schedules will not be treated as fixed; they 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 (57). The interview schedules will serve as flexible guides which do not rigidly dictate the direction of the interview, allowing participants the maximum opportunity to recount their experiences, including aspects of the 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.

Two interviews schedules were developed in order to collect slightly different data from patients and carers. For the carer interview, the patient whom the carer cares for has not consented to participate in this study, nor have they consented for their medication and health-related information to be disclosed. Although the main topics for the two interviews are the same, the use of probes has been restricted for certain questions in the carer interview schedule (e.g., the question about the impact that the use of the helpline service has had). For carers, there is no need to probe for information regarding the patient's medication use and health status, since the emphasis of their interview is upon whether or not, as a carer, their needs were met when using the helpline service.

The development of the interview schedules were informed by the following sources: relevant research, including a systematic review of the impact of patients medicines helplines (44), and a survey study of how patient medicines helplines are currently operated in England (40); UK national standards for operating a patient medicines helpline (43); the RE-AIM and APEASE criteria for evaluating interventions (71); the Sekhon et al. framework of the acceptability of healthcare interventions (70); and the Delorme et al. model of medicines information-seeking behaviour (97). Table 1 outlines the topics for the interviews.

The interview schedules were developed with the involvement of two relevant groups:
1. People who have recently been discharged from hospital, or carers of people who have recently been discharged from hospital (see section 8.6 Patient and Public Involvement).
2. Pharmacy professionals with expertise in Medicines Information and operating a patient medicines helpline.
Individuals who helped develop the data collection tools will be excluded from participating in the actual study.

Table 1. Topics for the interviews with service users

Topics for interviews with service users
1. Why the patient/carer contacted the helpline service, including what their question or concern was, the perceived seriousness of the issue, whether they considered any other sources of medicines information, and their decision-making process for choosing to use the helpline service.
2. What the patient/carer found helpful and unhelpful about their experience of contacting the medicines helpline service.
3. What impact the patient's/carer's use of the service has had (e.g., Was the advice followed? If so, what were the outcomes of this? If the advice was not followed, what were the reasons for this?).
4. Whether there were any self-perceived negative consequences of using the helpline service.
5. How the patient/carer feels about the medicines now, compared to before the helpline contact.
6. How the patient/carer feels about the hospital and NHS Trust now, compared to before the helpline contact.
7. What the patient/carer would have done had the helpline service not been available, or if the helpline service was not local, and why.
8. Whether the patient/carer sought any other sources of medicines-related information or support following their use of the helpline service, and if so, why.

5.2.4 Demographics questionnaire

The following demographic data will be collected directly after the semi-structured interviews using a data collection form: Age; gender; ethnicity; occupational status; current occupation (if applicable); highest educational qualification attained. We will also ask participants for their email address or postal address, for the purpose of sending them their £10 voucher for taking part in the study.

5.2.5 Call log

Sites will be asked to keep a log of calls received during the recruitment period. An excel document has been created for this purpose. The data to be logged will be anonymous, and will comprise the following: Date and time of the call; caller ID number; whether or not the caller was told about the study; if the caller was not told about the study, the reason why not (e.g., not meeting the eligibility criteria); if the caller was told about the study, whether or not they agreed to receive the information sheet; whether the information sheet has been sent. The caller ID number will be the unique ID number allocated to enquirers in MiDatabank, the national system which is used to record, manage and store enquiries used by MI teams in the UK. This number will be used so that pharmacy professionals can keep track of who calls and whether or not they have been sent an information sheet, while ensuring that the call log is anonymous to the research team.

5.3 Procedure

Data collection will take place within one month of service users' contact with a medicines helpline service. However, ideally data will be collected as soon as possible after the helpline contact. This is to increase the chance that the caller will remember their experience of using the service, during their interview. Data collection will occur at one time-point, over the telephone, and will involve the consent process, answering background information questions pertaining to the helpline call, participating in a semi-structured interview, and answering demographic questions. Overall, the entire telephone call will last approximately 20-30 minutes.

5.3.1 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.

In order to establish that the individual has capacity to participate in the study, prior to consent, they will be asked to briefly describe what the study involves, based upon the information they have received about the study. If they are unable to accurately describe what the study entails, they will be informed that they unfortunately do not meet the criteria for participating in the study, and thanked for their interest. Individuals who are able to accurately describe what the study entails will be asked to consent to participate as long as they meet all of the study inclusion/exclusion criteria, as outlined in Section 7.1).

The British Psychological Society (BPS) propose that "The way in which consent is sought from people to participate in or otherwise contribute data for research should be appropriate to the research topic and design" ((113), pg 15). The BPS state that consent via verbal recording is acceptable, provided there is an explicit statement confirming that the participant has received information about the research and the information has been understood (113). This research study is considered to be low risk, since the aim is to examine service users' experiences of using a medicines helpline service. For such a study design, it would be advantageous to collect data as soon as possible after the helpline contact has taken place, to facilitate the recounting of participants' experiences. Additionally, data will be collected via telephone interview rather than face-to-face. Collecting written consent will likely increase the number of days between the helpline contact and the interview, compared to a verbal recording of consent. Therefore, a verbal recording of consent is deemed to be appropriate for this low risk, telephone interview study.

A script has been developed to facilitate the telephone call with service users, and to ensure that the information which participants receive at the start of the call is standardised. At the start of the telephone call, the participant will be asked if they agree for the call to be audio-recorded. Consent to take part in the study will involve MW reading out all consent statements in the consent form over the telephone and asking the participant if they agree to each statement. The consent statements have been informed by the consent preparation guidance of the Health Research Authority (112), and the University of Bath Research Ethics Approval Committee for Health (117). The statements are:

1) Please could you confirm that you have received information about the 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, without your medical care or legal rights being affected?
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 understand that if you disclose any thoughts or actions of harm to yourself during this interview, that it is our duty to inform the Pharmacy team at the NHS Trust where you received care, so that they can inform your GP?
6) Do you agree to take part in the study?

The consent process will take approximately 5 minutes. 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. Prior to the interview, participants will also be made aware that the research is independent of the hospital at which they were admitted, thereby encouraging participants to disclose their experiences of the helpline service, whether positive or negative.

5.3.2 Collecting background information pertaining to the helpline call and participants' background

Following consent, service users will be asked to answer questions pertaining to the background of the helpline call, in order to add context to the sample in the study write-up (see Section 5.2.2 for information about what data will be collected). This process will take approximately 5 minutes.

5.3.3 Semi-structured interview

Following the collection of background information, once the participant is happy to proceed, the interview will be conducted. The interview will involve the use of Interview Schedule 1 or Interview Schedule 2, depending on whether the service user is a patient or carer, respectively (see Section 5.2.3 for information about the interview schedules). The interview will take approximately 20-30 minutes.

Once the interview has been completed, the participant will be thanked for their time and will be asked if they would like to receive a copy of the findings once they become available. If so, their preferred method of contact will be kept in an excel file, separate from the data for the study, on the University of Bath secure server in a folder which is only accessible to the research team.

5.3.4 Collecting demographic information

Following the interview, service users will be asked to answer demographic questions, in order to add context to the sample in the study write-up (see Section 5.2.2 for information about what data will be collected). This process will take approximately 5 minutes.

5.3.5 Piloting the procedure

A pilot study will be conducted in order to test whether the above study procedure is realistic and workable (e.g., whether the recruitment process is effective; whether interviewing service users up to one month after they contacted the helpline causes any confusion or issues remembering the helpline call; establishing the approximate length of time that interviews take; and whether the interview schedules are likely to provide us with the data to answer our research question). The pilot study will involve collecting data for the first three participants at one of the NHS sites. Following the pilot, discussions will be held within the research team, and between the research team and the NHS site, in order to decide whether any changes to the procedure need to be made. If changes need to be made to the main study in order to improve its procedure, relevant amendments with regulatory bodies will be sought, if required (e.g., HRA, or Research Ethics Committee). Although conducting a pilot study is recommended, it is also acknowledged that pilot work does not guarantee that the main study will be problem-free (118). However, a pilot study is useful for increasing the likelihood of developing a design and procedure which will provide data that can answer our research questions (118, 119).

5.3.6 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' (120, 121). Thematic analysis is widely used, and there is no single agreed method for conducting it (57). The thematic analysis procedure we will use for the analysis of data for this study will be Braun and Clarke's inductive reflexive thematic analysis (57, 120, 122). The procedure by Braun and Clarke was chosen because it is a flexible analysis which can be applied across a range of theoretical and epistemological approaches, whilst also providing a detailed account as to how the analysis can be conducted (120). Since thematic analysis is a method rather than methodology, it can be used irrespective of the ontological, epistemological, and theoretical frameworks of the research.

The analysis will involve the following stages, as outlined by Braun and Clarke (57, 120):
1. *Familiarisation with the data.* This will involve repeatedly reading through the transcript for each interview separately and making notes of things that are of interest. Part of this process will involve transcribing the data verbatim, which will also aid familiarisation. Transcription will be conducted by MW. It will include all verbal utterances, and will exclude non-verbal utterances.
2. *Generating initial codes*. Next, the data will be coded, in accordance with the research questions for this study. 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. Coding for this study is likely to include a combination of inductive and deductive coding. This will ensure that codes are both data-driven, and also influenced by previous theory and literature (e.g., the APEASE criteria, the Delorme et al. Model of Medicines Information-Seeking Behaviour; and Will's proposed list of benefits of patient medicines helplines; (71, 91, 97)). Coding will be conducted using NVivo, in order for data to be organised and located in one place. Once all interviews have been coded, all interviews will once again be re-read to ensure that the codes satisfactorily capture the data. This process will be conducted by MW, and will be reviewed by MJ, AJ, and JS to ensure that there is agreement among the research group. Any disagreements will be resolved through discussion.
3. *Developing themes*. Whereas codes capture one idea or instance of interest, a theme will collate ideas and instances of interest in to a meaningful central organising concept (57). This will be achieved by reviewing the codes for all of the interviews in order to identify overlap. Themes can be organised in to a structure, such as overarching themes and sub-themes, depending on what makes sense in order to best capture the codes. Once the candidate thematic structure has been developed, the collated data relating to each code will be reviewed to ensure that the theme also satisfactorily captures the data. Developing the candidate thematic structure for approximately 35 interviews will be a flexible process, whereby themes can be renamed or let go, and the structure can be re-shaped, as a result of re-reading the codes and underlying text for all cases and also re-reading the interview transcripts. Visual mapping will be used throughout this process, in order to visually capture the candidate thematic structures which are developed (57). The process of identifying themes and developing a thematic structure will be conducted by MW, and will be reviewed by MJ, AJ, and JS to ensure that there is agreement among the research group. Any disagreements will be resolved through discussion.
4. *Reviewing themes*. This stage involves the refinement of the candidate themes. First, the coded data extracts will be reviewed for each theme, to ensure that they form a coherent pattern. If not, the theme will need to be reworked (e.g., renamed, or separated in to two or more themes). Second, the validity of the themes will be considered in relation to the whole data set. This will involve re-reading the entire data set to ensure that they are represented by the thematic structure. If not, new themes may be developed. If new themes are developed, coding across the data set will take place for these new themes. The result of this stage is to have a final set of themes, with an understanding of how they relate to each other, and the overall story they tell about the data. The process of reviewing

themes will be conducted by MW, and will be reviewed by MJ, AJ, and JS to ensure that there is agreement among the research group. Any disagreements will be resolved through discussion.
5. *Defining and naming themes*. A brief definition will be written for each theme in order to state what the theme is about, in relation to the thematic structure. Theme definitions should be a couple of sentences long. The theme definitions will be written by MW, although any disagreements as to the definitions will be resolved through discussion among the researchers.
5. *Writing the analysis*. In thematic analysis, writing the analysis constitutes an essential part of the actual analysis. This stage involves moulding the analysis to ensure that the interpretation makes sense and is grounded in appropriate examples. Rather than being purely descriptive, the write-up will tell the reader what is interesting about the data, and why, in relation to the research questions. The write-up will primarily be conducted by MW, with input from MJ, AJ, and JS to ensure that there is final agreement among the research group.

5.3.7 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 (120, 123-125). Sources included Braun & Clarke's 15-point checklist of criteria for good thematic analysis (57), Elliott et al.'s guidelines for the publication of qualitative research (124), and Santiago-Delefosse et al.'s 12 essential criteria for conducting qualitative research (125). 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, themes and interpretations 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

The aim of this study is to examine individuals' experiences of using NHS patient medicines helpline services. Therefore, recruitment sites will be NHS Trusts which operate a patient medicines helpline service.

The study will be multicentre, since participants will be patients and carers who are recruited from at least two NHS Trusts. Sites will be involved in the recruitment of participants. At the end of helpline calls, the pharmacy professional who dealt with the enquiry will ask the caller whether they would be interested in receiving information about the study. If so, the pharmacy professional will send an invite letter and Participant Information Sheet to the caller. This will happen for all callers who meet the study inclusion/exclusion criteria, detailed in Section 7.1. Therefore, the pharmacy professional will ascertain whether or not each caller meets the study inclusion/exclusion criteria in order to know whether or not to ask the caller about the study. This recruitment phase of the study will last for 6 months.

There are no different types of activities being undertaken at each site. All other activities will be performed by the research team at the University of Bath (i.e., potential participants will contact the research team directly, and consent and data collection will be conducted via the telephone from the University of Bath). Therefore, the research team will only get to find out about potential participants if they decide to contact the research team. No patient information will be passed from the participating NHS sites to the research team.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

7.1.1 Inclusion criteria of NHS sites

An NHS Trust within the UK; currently operating a patient medicines helpline service. A patient medicines helpline is defined as a telephone line, provided or commissioned by an NHS Trust, to enable patients and/or their carers to contact a pharmacy professional for medicines-related information and advice. It is advertised as being available for this purpose, and it is specifically for medicines-related information and advice, and not for general clinical advice.

7.1.2 Exclusion criteria of NHS sites

Not currently operating a patient medicines helpline service.

7.1.3 Inclusion criteria of service users

Individuals who have contacted a patient medicines helpline with the aim of seeking information and/or support regarding medicines (the contact can be via any means of communication other than face-to-face, such as telephone, email, or online webform); participants can include patients of the organisation which hosts the patient medicines helpline, and carers of such a patient (including parents of patients who are under 16 years old); aged 16 years and over; fluent in English; ability and willingness to provide informed consent; and ability, willingness, and availability to conduct a telephone interview within 1 month of having used an NHS Trust's patient medicines helpline service.

Research suggests that approximately 70% of calls to patient medicines helplines are from patients and 30% of calls are from carers (30). Therefore, both patients and carers will be invited to participate in this study.

7.1.4 Exclusion criteria of service users

If, in the pharmacy professional's judgement, taking part would likely cause distress to the service user; if a service user is known to be pursuing, or considering pursuing, a complaint against the Trust; if a service user cannot remember the helpline call (i.e., they cannot remember making the call, or cannot remember why they made the call); for service users who contact the service on behalf of a patient of the hospital, if the service user is considered to be a healthcare professional to the patient (based upon the information disclosed to the pharmacy professional during the helpline call).

7.2 Sampling

7.2.1 Size of sample

For qualitative research which aims to identify patterns across data, a sample size of between 15-30 interviews may be considered typical (57). This study involves interviewing service users in order to explore their experiences of using patient medicines helplines. In order to attain a sample size that provides adequate data to sufficiently answer our research question, we used similar previous studies to estimate an initial sample size, and we will collect additional data if we feel that thematic saturation has not been reached with this number. Thematic saturation will be the point at which the researchers of this study agree that it seems likely that no new themes will be identified through the collection and analysis of additional data (126). However, we acknowledge that the concept of data saturation has been questioned as a means of identifying the appropriate number of participants to include (127). For example, it has been suggested that data may never truly saturated, since there could always be potential themes to be identified (128).

In order to establish an initial sample size, we conducted a scoping exercise to find qualitative studies of people's experiences of using helpline services. This involved searching Scopus for suitable studies using the terms 'helpline* AND qualitative AND interview*', and 'hotline* AND qualitative AND interview*'. Six articles were considered to be suitable. The average sample size of the six studies was 32 (129-134) (the median was used, since one of the five studies had a particularly large sample size). Therefore, we will aim to initially conduct 30 interviews, and then analyse the data for these interviews. If the research team perceives that saturation has been achieved, no more data will be collected. However, if the research team perceives that saturation has not yet been achieved, we will then continue collecting and analysing interviews, making changes to the existing themes. Data collection will stop at the point when the analysis of the most recent three interviews have resulted in no changes being made to the themes, nor the meanings associated with the themes.

It is acknowledge that saturation is likely to be influenced by a number of factors, such as study design, epistemological stance, characteristics of the study sample, analytical approach, resources, and experience, and that it is difficult to estimate the number of participants that will be required (127, 135, 136). It is also recognised that it is typical for authors to justify the cessation of qualitative data collection with the term 'saturation' without providing evidence as to how saturation is actually achieved (135, 137, 138). We will endeavour to be transparent in the assessment of saturation, based upon the approaches used by Guest et al. (126), Francis et al. (137), and Hennink et al. (135). This will involve documenting the progression of theme development by counting the number of themes developed in each interview, identifying when new themes are developed, and when changes are made to existing themes. It will also involve documenting examples of the meanings pertaining to the theme, using quotes from the interview transcripts.

Although we aim to collect data until we feel that we have reached thematic saturation, we also recognise that this may not be feasible due to resource limitations. Therefore, we will stop collecting data irrespective of whether saturation has been reached, after six months of recruitment and data collection at

the NHS sites. It is estimated that a sample of at least 30 cases should be achievable within this time frame. A sample of 30 was chosen based upon the number of participants we feel it is achievable to recruit within six months, considering that the average acute NHS Trust receives 5 calls per week to their medicines helpline (40). The response rates of the studies sourced during the scoping exercise, described above, were used to calculate this. However, in order to provide a conservative estimate, we calculated this based upon the lowest response rate out of the included studies (37%; (129)).

7.2.2 Sampling technique

The sample will be purposive. Participants will be individuals who have used an NHS patient medicines helpline service. This is because the aim of the study is to understand individuals' experiences of using an NHS patient medicines helpline service.

7.3 Recruitment

7.3.1 Sample identification

Participants will be individuals who have used an NHS patient medicines helpline service.
The study will be multicentre, since participants will be patients and carers who are recruited from at least two NHS Trusts.

Prior to submitting the application for Heath Research Authority approval, NHS Trusts will be contacted to ascertain whether they have the potential to participate in this study. The Chief Pharmacist or Head of Pharmacy Services at NHS Trusts in England will be contacted via email in order to send them an information sheet about the study, and to invite them to consider taking part. We will endeavour to be pragmatic in our approach to recruit NHS Trusts. The first Trusts to be contacted to see if they would be interested in participating will be Trusts which our research team know have an interest in medicines information research, and Trusts within the Bath and Bristol areas. This will be followed by Trusts in the areas beyond Bath and Bristol, until at least two Trusts agree to take part. The email to Chief Pharmacists or Head of Pharmacy Services will be followed up with a telephone call approximately one week later, if there has been no reply.

Those NHS Trusts which express an interest will be sent the study protocol. MW and MJ will also visit sites which express an interest in taking part in order to discuss the research with the Chief Pharmacist/Head of Pharmacy Services and pharmacy professionals who run the patient medicines helpline.

Once the application for Health Research Authority has been made, and the Approval Letter has been issued, participating NHS Trusts will be contacted to put the local arrangements in place to deliver the study. This will involve sending the local document package to the Medicines Information team and the research management team of the NHS Trusts (see Appendix 1 for a list of the relevant documents).

Sites will be involved in the recruitment of participants. At the end of helpline calls, the pharmacy professional who dealt with the enquiry will ask the caller whether they would be interested in receiving information about the study. If so, the pharmacy professional will send an invite letter and Participant Information Sheet to the caller. The letter and information sheet will be sent by the NHS Trust, and the letter will be printed on NHS Trust headed paper. This will happen for all callers who meet the study inclusion/exclusion criteria, detailed in Section 7.1. Therefore, the pharmacy professional will ascertain whether or not each caller meets the study inclusion/exclusion criteria in order to know whether or not to ask the caller about the study.

The research team at the University of Bath will not have access to any patient information. The

Participant Information Sheet informs potential participants to contact the research team if they would like to participate, or if they have any questions about the study. The research team will only hear about the individual if the individual contacts the research team to express an interest in taking part in the study. The Participant Information Sheet also informs potential participants that the telephone interview should ideally be conducted as soon as possible after their contact with the helpline service (and within one month). This is to attempt to minimise memory errors of their accounts of their experiences.

Research suggests that approximately 70% of calls to patient medicines helplines are from patients and 30% of calls are from carers (30). Therefore, both patients and carers will be invited to participate in this study. However, we will not strategically select individuals to ensure that the sample consists of both patients and carers. All individuals who express an interest in participating, and who meet the study inclusion/exclusion criteria, will be invited to participate. MW will liaise with participating sites to ensure that recruitment stops once 30 participants have been interviewed (or until data saturation has been reached, if this has not occurred by the 30th interview). This will reduce the likelihood that helpline callers will be sent information about the study when the recruitment phase has ended.

Participants will not be recruited by any other methods (e.g., publicity, posters, leaflets, adverts or websites).

Potential participants will have been informed via the Participant Information Sheet, and again prior to the interview, that the consent process will take place verbally, over the telephone. For individuals who agree to participate, a convenient time will be arranged for their interview (see section 5.3.1 for details about the procedure for conducting the interviews).

As a 'thank you' for their time, participants will be offered a £10 shopping voucher for taking part in the study (either Amazon or Love2Shop). Participants will be informed of this in the participant information sheet. The voucher can be posted or emailed to them once they have taken part in the study. This amount was selected as a small, non-coercive expression of thanks. All data will be collected over the telephone, and the telephone call will be paid for by the research team. Therefore, there will not be a need to reimburse participants for any expenses.

NHS Trusts who participate in the study will be asked to keep track of the number of enquiries they receive during the recruitment period, including how many were invited to receive the study information sheet, how many were not, and the reason why not. This information will be used to establish the proportion of helpline callers who decide to participate in the study, from each of the sites. It will also be useful to see whether the proportion of callers invited compared to those not invited, is similar across the participating sites. This data will be anonymous - sites will not be asked to provide the research team with any patient information.

7.3.2 Consent

The consent process is described in detail in Section 5.3.1, above.

8 ETHICAL AND REGULATORY CONSIDERATIONS

8.1 Assessment and management of risk, and other ethical considerations

The research involves working with NHS patients. However, it can be considered low risk since it does not involve an intervention of any kind. 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 a participant decides to take part, they will be informed in the Participant Information Sheet and during the consent process that they can change their mind at any time by letting one of the research team know. They will also be informed that they do not need to provide a reason for withdrawing from the study. If they withdraw from the study, we will endeavour to exclude their data from the analysis. However, this may not be possible, since participants' contact details will be destroyed at the end of the project. Their interview data will be linked to their contact details via a unique identification number. This means that, once all contact details have been destroyed, it will no longer be possible for their data to be identified in order to exclude it from the analysis. Participants will be informed of this in the Participant Information Sheet.

It is anticipated that interview telephone call will last approximately 20-30 minutes (1-2 minutes for consent, 1-2 minutes for collecting information pertaining to the helpline call, 15-25 minutes for the semi-structured interview, and 1 minute to collect demographic information). Therefore, the study does not involve prolonged or repetitive testing.

We acknowledge that the design of the study, where pharmacy professionals who operate the helpline service will judge whether or not a potential participant meets the study inclusion/exclusion criteria, may cause selection bias. However, this was discussed among the research team, and it was agreed that it would not be ethical to send invitations to callers where this might cause distress. In addition, discussion with potential research sites has made it clear that they would not participate in a study without these exclusion criteria. Therefore, our research question can only be investigated in this way.

Research suggests that 30% of callers to patient medicines helpline services are from carers of patients. We will therefore include both patients and carers of patients who have use a patient medicines helpline service, if they decide to participate in the study. When carers participate in the study, the issue arises as to whether or not the patient they care for also needs to consent if they have capacity, since the carer may disclose information about the patient during the interview. However, the aim of the study is to explore whether the helpline caller's needs were met when they used the helpline service. When interviewing patients, we will collect background information about them, such as demographics, number of prescribed medicines, and morbidities. We will not ask carers for such information about the patient they care for. Therefore, regarding carers, the focus of the interview is upon them and whether, as a helpline caller, their needs were met. The interview schedule for carers is therefore different to the interview schedule for patients. Interviews with carers will be about their experiences of calling the helpline service, and will not directly ask them questions about the patient they care for. However, if during an interview with a carer they do provide information about the patient they care for, this information will be anonymised at the point of transcription.

Since the research will involve interviewing patients about their experiences of using NHS services as a result of potentially serious and life-threatening illness, they may disclose feelings of distress. If this happens, participants will be reassured that there are support services both within the NHS and external to the NHS which are available for them to discuss their situation with and seek support. A list of contact details for such support services has been created so that the interviewer can have this at hand during the interviews.

The consent process will inform participants that if they disclose any thoughts of a suicidal nature or disclose any thoughts of risk of harm to themselves, we will ask the Medicines Information Manager or Chief Pharmacist of the NHS Trust to contact the participants' GP to inform them of this, since the

hospital will be able to access their GP details. Since this statement is in the consent process, it is therefore the participants' choice as to whether or not they wish to continue and participate in the study. The participant will also be strongly advised at the end of the interview to speak to their GP or call NHS 111 as soon as possible, to let their GP know how they are feeling so that they can manage their care in this respect. If a study participant is actively threatening harm to themselves when contacted, they will be kept on the phone and explained that it is the study protocol that we will endeavour to contact the emergency services for them. We will ask them for their current location, and a nominated person will be asked to contact the emergency services on behalf of the interviewer, so that the interviewer can remain on the phone with the participant. The nominated person will be either one of the three study supervisors or another member of the University of Bath (either a postgraduate researcher or faculty member of staff) who will be 'on call' for each interview, in case such a situation arises (this will be arranged prior to every interview, to ensure that there is always someone 'on call' for the duration of the interview). The interviewer will conduct the interview using a land line at the University of Bath, and will use his mobile phone to get in touch with the nominated person to inform them that their support is needed.

If potential malpractice is reported by a participant during the study, the researcher (MW), who is a PhD student and does not have expertise in Pharmacy Practice, will discuss this with the supervisory 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 respond to the identification of malpractice and/or unsafe medicine-related misunderstandings by contacting the Medicines Information Manager or the Chief Pharmacist or Head of Pharmacy of the NHS Trust.

The situation may arise where the patients who are being interviewed may ask the interviewer (MW) for information and advice about their medicines. The interviewer will make it clear that he is not a trained pharmacy professional and does not have the expertise to answer their question, advising them to re-contact the patient medicines helpline or speak with their GP instead.

The situation may also arise where the participant asks for support with dissatisfaction about the NHS Trust or the helpline service. Such participants will be given the contact number for the Patient Advice Liaison Service for their NHS Trust, since this service functions to deal with patient complaints.

The interviews will involve service users describing their understanding of the information and advice provided by the pharmacy professional who dealt with their helpline enquiry. This has ethical implications, since the service user may have misunderstood the information and advice they received, and experience harm or may not receive the full benefit of their medicines as a consequence. However, the PhD researcher (MW) is not a pharmacy professional and therefore does not have the expertise to necessarily notice if a piece of information sounds unusual or potentially harmful (additionally, the pharmacists' account of the helpline call will not be collected for this study, in order to check the service user's account to it). It is also aimed that the analysis will take place once all 30 interviews have been completed, in collaboration with MJ and JS who have expertise within pharmacy practice. At this point, if MJ and JS notice anything which seems odd or potentially harmful, they will decide what action should be taken. However, prior to analysis, if a piece of information is identified by MW which seems odd or potentially harmful, MW will discuss the case with MJ and/or JS. MJ and JS will then decide, based upon the perceived seriousness of it, the appropriate course of action.

The situation may arise where a potential participant is contacted via the telephone for the purpose of being interviewed and it becomes apparent that they do not have capacity at that time to take part in the study. For example, the individual may appear to be intoxicated or may appear to have difficulty remembering their contact with the helpline service. In line with guidelines by the British Psychological

Society and Health Research Authority, potential participants will only be allowed to take part in the study if they have capacity to make the informed decision to consent (113, 139), and if they seem able to meet the requirements of the study (i.e., being able to recount their experiences of using a patient medicines helpline). Otherwise, the individual will be explained that they do not meet our inclusion criteria for participating in the study, they will be thanked for their time and the call will be ended.

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

This study involves interviewing patients and carers about their experiences of using an NHS service (patient medicines helplines). Therefore, before the start of the study, a favourable opinion will be sought from an NHS REC for the study protocol and all other study documents (e.g., data collection tools).

Any substantial amendments will not be implemented unless the amendment has been reviewed by NHS REC.

All correspondence with the REC will be retained.

The Chief Investigator will be responsible for producing an annual report, and will notify the REC of the end of the study. An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination. Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

8.3 Regulatory Review & Compliance

Before participating sites can inform patients and carers about the study, 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 as well as the study delivery team) 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

If a substantial amendment is to be made regarding the REC application or the supporting documents, the Chief Investigator will submit a Notice of Substantial Amendment form, along with the relevant supporting documentation and the study protocol, to the REC for consideration. The documents will be clearly marked to highlight what changes are being made. This will be generated by IRAS and submitted to the REC electronically. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It will be the Chief Investigator's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC. Any uncertainty as to whether an amendment is substantial or not will require advice being sought from the REC office or the HRA Queries Line.

Amendments will be notified to the participating organisations (R&D office and local research team) so that they can assess whether the amendment affects the NHS permission for that site. Some amendments that may be considered to be non-substantial for the purposes of REC will still be notified to

NHS R&D (e.g. a change to the funding arrangements). Therefore, participating organisations will be notified of all substantial and non-substantial amendments.

The protocol amendment history will be tracked in Appendix 2 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 members of the public (see PPI, below).

8.6 Patient & Public Involvement

8.6.1 The importance of patient and public involvement in research

The National Institute for Health Research INVOLVE website and the Health Research Authority website define patient and public involvement in research (PPIR) as research that is carried out 'with' or 'by' patients and/or members of the public rather than 'to', 'about' or 'for' them (140, 141). PPIR is considered to be important because it results in service user empowerment and feeling valued, and it can offer unique and invaluable insights and expertise into the prioritisation, design, implementation and evaluation of research, making it more effective and credible (142-145). PPIR typically involves individuals who are similar to the sample who will be researched, who inform the study design and the development of study materials prior to data collection. This is considered important, in order to develop user-relevant and user-friendly materials such as information sheets and interview schedules (142). PPIR is also useful for developing processes for obtaining consent that are acceptable to potential participants, checking that relevant outcomes are being used, and for gauging the likelihood of people participating in the study, given the risks and ethical considerations involved (146). PPIR is well-established as public policy in the UK, and the importance of PPIR mirrors the importance of patient and public involvement (PPI) in developing and evaluating services within the National Health Service (145, 147, 148).

8.6.2 How patient and public involvement will be used in this study

The study design, procedure, and all data collection tools and the information sheet have been reviewed by a group of people who have recently been discharged from hospital, or carers of people who have recently been discharged from hospital (n = 6, all aged 18 years and over). Some of the participants had recent experience of contacting a patient medicines helpline service. This was conducted in order to provide a check that the design, procedure, and materials are suitable to meet our aims, and also that the study materials are easily understandable. An invitation leaflet was developed to inform members of the public what their involvement would be if they decide to take part. In accordance with the National Institute for Health Research INVOLVE website (149, 150), members of the public were clearly informed as to what their involvement would be and what they would be paid. We aimed to ensure that the people who took part were representative of the types of people who contact patient medicines helplines. In order to achieve this, we endeavoured to recruit both patients and carers, whilst aiming to ensure that the demographics of people were representative of the demographics of callers to patient medicines helplines as established in published service evaluation studies, (e.g., almost 50% of callers are aged 65 years and above, and just over half of callers are female (30, 33, 34)). We also aimed to recruit people

with varying levels of experience of being involved in PPIR. People were recruited from an advert placed on the People in Research website (151), and from a medicines information team at an NHS Trust who sent the information leaflet to helpline callers who agreed to receive it.

Members of the public who decided to take part were sent a pack which contained the following: instructions on what we would like them to do, a summary of the study, the participant information sheet, and the interview schedule. They were offered to be sent the pack via email or in the post. The instructions asked them to read through the documents, and then comment on them by writing on them. For the information sheet and interview schedule, they were asked to comment upon them in terms of clarity and accessibility. For the interview schedule they were also be asked to comment upon whether they feel that the questions are suitable for meeting our study aims, whether any questions should be amended/removed/added, and also whether the order of questions makes sense. It was envisaged that this process would take approximately 1 hour. Next, the PPIR participants were contacted via telephone in order to discuss their comments (conducted by MW). This this aspect of the work took approximately 20 minutes. Following the telephone discussion, the PPIR participants were asked to send the documents back, along with their comments, in a pre-paid envelope which was included in their pack. In accordance with typical payments used by INVOLVE for conducting this type of work for this duration of time, people who take part in PPIR were paid £25 each (150, 152). Payment was in the form of a voucher (either Amazon or Love2Shop; (153, 154)) which was posted or emailed to participants once their involvement was complete. Since their involvement did not involve travelling, there was no additional payment for expenses.

Research suggests that PPIR is often not well reported in research articles (155). For example, Mathie et al. conducted a UK scoping study to establish the proportion of a selection of studies which had evidence of PPIR (155). They found that 51% of studies had some evidence of PPIR, and that the extent of this varied widely. Therefore we will ensure that any future publication of this study clearly states the full extent of PPIR, including aspects of the study which does not include PPIR (i.e., PPIR will not involve the collection nor analysis of data for this study).

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 forms which will be used to record participants' demographics and 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 secure managed 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.

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, and they will receive a voucher for taking part. 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 and the voucher has been sent. Participants 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 (156).

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 researcher and the PhD supervisory team

will have access to the full dataset. These individuals are:

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 researcher's CV
First academic supervisor's CV (also the Chief Investigator).
Second academic supervisor's CV.
Third academic supervisor's CV.
Participant Information Sheet (and stamped envelopes)
Poster for pharmacy teams to help recruit participants
Call log, for keeping a log of helpline callers during the recruitment period
IRAS form
Statement of Activity
Schedule of Events

11.2 Appendix 2 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	1.1	21/3/2018	MW	Change of Chief Investigator from Matthew Williams to Dr Matthew Jones. Additional statement added to consent statements about dealing with disclosures of suicidal thoughts/thoughts of harm. Clarifying that contact details will be retained for the purpose of sending participants their voucher and the results of the study once they become available, and then contact details will be destroyed. Change of participants' minimum age to be eligible to participate, from 18 to 16. Clarifying the exclusion criteria so that healthcare professionals are excluded but carers are not. Added a statement about providing contact details for PALS to participants if they request a contact for who they can complain to if they are dissatisfied with the NHS Trust. Change to background information collected from patients (no longer asking them to list their medicines, and will instead ask for an approximate number.

2	1.2	08/08/18	MW	The length of time to conduct interviews has changed from '30-45 minutes' to '20-30 minutes'. This was based upon the time taken to collect data for the first few participants. The end date for the study has been changed from 31/12/18 to 31/07/19. This will enable current PICs to be involved in the study for six months, and provides the opportunity to potentially involve additional sites as PICs over the next few months if we feel that this would be necessary to meet our recruitment target.
3	1.3	13/03/2019	MW	Amend the end date for the study from 31/07/19 to 31/12/19.
4	1.4	01/07/2019	MW	Change analysis from framework analysis to inductive reflexive thematic analysis.