HRA Protocol Compliance Declaration:

This protocol has regard for the HRA guidance

# FULL/LONG TITLE OF THE STUDY

Antibiotic prescribing for asthma exacerbations in primary care: exploring prescribing decisions and optimising intervention materials to improve antibiotic use in asthma.

**SHORT STUDY TITLE / ACRONYM**

**Appropriate Antimicrobial Use for Asthma Exacerbation (PAUSE)**

**PROTOCOL VERSION NUMBER AND DATE**

**V 1.0 21/01/2025**

# RESEARCH REFERENCE NUMBERS

|  |  |
| --- | --- |
| **IRAS Number:** | 349059 |
| **SPONSORS Number:** | 93950 |
| **FUNDERS Number:** | Not applicable |

# SIGNATURE PAGE

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

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

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

|  |  |  |
| --- | --- | --- |
| **For and on behalf of the Study Sponsor:** | | |
| Signature:  ...................................................................................................... |  | Date: ....../....../...... |
| Name (please print):  ...................................................................................................... |  |  |
| Position: ...................................................................................................... |  |  |
| **Chief Investigator:** | | |
| Signature: ...................................................................................................... |  | Date: ....../....../...... |
| Name: (please print):  ...................................................................................................... |  |  |

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# KEY STUDY CONTACTS

|  |  |
| --- | --- |
| Chief Investigator | Professor Nick Francis  Head of School  Primary Care Research Centre  University of Southampton  [nick.francis@soton.ac.uk](mailto:nick.francis@soton.ac.uk) |
| Sponsor | University of Southampton |
| Funder(s) | Southampton Biomedical Research Centre (BRC)  Asthma & Lung UK |
| Key Protocol Contributors | Nour Odeh  Postgraduate Researcher  Primary Care Research Centre  [N.odeh@soton.ac.uk](mailto:N.odeh@soton.ac.uk)  Professor Kay Wang  Primary Care Research Centre  University of Southampton  [kay.wang@soton.ac.uk](mailto:kay.wang@soton.ac.uk)  Dr Kate Lippiett  Nursing, Midwifery and Health  University of Southampton  [K.A.Lippiett@soton.ac.uk](mailto:K.A.Lippiett@soton.ac.uk)  Dr Ingrid Muller  Primary Care Research Centre  University of Southampton  [I.Muller@soton.ac.uk](mailto:I.Muller@soton.ac.uk) |

# STUDY SUMMARY

|  |  |
| --- | --- |
| Study Title | Antibiotic prescribing for asthma exacerbations in primary care: exploring prescribing decisions and optimising intervention materials to improve antibiotic use in asthma. |
| Internal ref. no. (or short title) | **Appropriate Antimicrobial Use for Asthma Exacerbation (PAUSE)** |
| Study Design | Phase 1  Qualitative interviews with people aged 18 and above with asthma  Qualitative interviews with parents/carers of children with asthma  Qualitative interviews with primary care health professionals  Phase 2  Think-aloud interviews with primary care health professionals, people with asthma and parents/carers of children and young adults with asthma to optimise intervention materials. |
| Study Participants | Phase 1 Semi-structured interviews  8-10 Adults with asthma aged ≥18 years  8-10 Parents/carers of children and young adults with asthma  15-20 primary care health professionals  Phase 2 Think aloud interviews  10-15 primary care health professionals  5-10 Adults with asthma  5-10 Parents/ carers of children with asthma |
| Planned Size of Sample (if applicable) | Phase 1- Maximum 40  Phase 2- Maximum 35 |
| Study Setting | Primary care |
| Planned Study Period | Jan 2025 – Mar 2026 |
| Research Question/Aim(s) | To explore the perspectives of primary care professionals involved in the management of asthma, people with asthma, and their parents/carers on factors influencing the use of antibiotics in the management of acute respiratory symptoms. To develop an intervention to support the management of acute respiratory symptoms in people with asthma. |

# FUNDING AND SUPPORT IN KIND

|  |  |
| --- | --- |
| **FUNDER(S)** | **FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN** |
| **Southampton Biomedical Research Centre** | **Research funds** |
| **Asthma & Lung UK** | **Salary grant** |
|  |  |

# ROLE OF STUDY SPONSOR AND FUNDER

The University of Southampton will act as the sponsor and sees its responsibilities as follows:

The UoS as Research Sponsor will:

1. Assess the adequateness of any independent expert review.
2. Ensure that the Chief Investigators have the necessary expertise, experience and qualifications to conduct the study.
3. Provide the necessary insurance to cover the Chief Investigator and research team.
4. Determine the arrangements for monitoring research studies.
5. Provide advice and guidance on study management, conduct and applicable legislation, guidelines and policies.
6. Determine the acceptability of the archive arrangements proposed by the Chief Investigator.

# ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT GROUPS & INDIVIDUALS

* Study Management Group

The role of the Study management Group is to provide oversight of the conduct of the programme. This includes oversight of the practical aspects of the study as well as ensuring that the study continues to be run in a way which is both safe for the patients and provides appropriate safety and efficacy data to the sponsor.

Specific responsibilities of the Management Group include, but are not limited to, the following:

• to provide overall supervision of the study

• to take steps to reduce deviations from the protocol to a minimum

• periodic review of the progress of the study unblinded manner

The Study Management Group will have ultimate responsibility for the study. The Group will consist of the principal investigator of the study and all protocol contributors.

**PROTOCOL CONTRIBUTORS**

The protocol was designed and written by the research team including the patient and public group involved in the project.

|  |  |
| --- | --- |
| KEY WORDS: |  |
|  | Asthma, primary care, antibiotics, antimicrobials, chest infection, pneumonia |

# STUDY FLOW CHART

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Years | 2025 | | | | 2026 |
| Quarter | 1 | 2 | 3 | 4 | 1 |
| Study months | 4-6 | 7-9 | 10-12 | 13-15 | 15-18 |
| Qualitative interviews study with primary care professionals and people with asthma |  |  |  |  |  |
| Develop prototype intervention for user feedback |  |  |  |  |  |
| Carry out ‘think aloud’ study of prototype intervention content with primary care professionals and people with asthma |  |  |  |  |  |
| Modify intervention content and format based on feedback |  |  |  |  |  |
| Finalise intervention for feasibility study and rigorous testing of final versions |  |  |  |  |  |

# STUDY PROTOCOL

Antibiotic prescribing for asthma exacerbations in primary care: exploring prescribing decisions and optimising intervention materials to improve antibiotic use in asthma.

## BACKGROUND

Asthma is a chronic inflammatory condition of the airways, impacting an estimated 262 million individuals globally in 2019 and resulting in around 45,500 deaths(1). This disease is marked by an overactive response to a variety of triggers. Clinically, asthma is identified by a history of respiratory symptoms including breathlessness, wheezing, chest tightness, and coughing(2).

The intensity of asthma symptoms and the extent of airflow obstruction can fluctuate over time and vary in severity among patients. Depending on the condition's severity, people with asthma may experience acute asthma exacerbations (AAE) - periods when symptoms worsen significantly, potentially leading to serious health outcomes if not properly managed. The causes of asthma exacerbations are likely diverse, with a minority being triggered by bacterial infections of the respiratory tract (3).

International guidelines for managing asthma exacerbations, such as those from the Global Initiative for Asthma (GINA), the British Thoracic Society (BTS), the European Respiratory Society (ERS), and the American Thoracic Society (ATS), generally recommend against the use of antibiotics for asthma exacerbations, due to the inflammatory nature of the condition, unless there is clear clinical or test evidence indicating a bacterial infection.

There is insufficient and inconsistent evidence to recommend antibiotics use for AAEs. A 2018 Cochrane review that included six randomised control trials found limited evidence of symptom improvement and peak expiratory flow rate between the two groups (4). Despite the current guidelines and insufficient evidence to recommend antibiotic use for AAEs, recent research indicates that antibiotics are frequently prescribed for AAEs even when there is no clear indication for their use.(7) Widespread use of antibiotics contributes to the development of antimicrobial resistance (AMR), a situation where microbes, like bacteria, become resistant to the drugs designed to eliminate them (8) . AMR is a critical global health threat with potentially severe consequences if not addressed (9).

It is usually not possible to distinguish between an infective exacerbation of asthma and chest infections in the primary care setting. Viral and bacterial respiratory tract infection commonly trigger the inflammation and bronchospasm characteristic of asthma. It has been established that in primary care settings, antibiotics are prescribed to around 80% of people with asthma who present with suspected lower respiratory tract infection(4). This discrepancy between current guidelines and evidence on unnecessary antibiotic prescribing in AAEs highlights the need to better understand antibiotic prescribing behaviour for AAEs and develop an intervention to support more targeted use of antibiotics in people with asthma in primary care setting.

This study aims to develop a behavioural intervention to reduce unnecessary antibiotic use for people with asthma in primary care. As it is often not possible to differentiate between an AAE and chest infection, the intervention will target both. The study will be conducted in two phases.

Phase 1 involves qualitative interviews with primary care health professionals, people aged 18 or older with asthma, and parents/carers of children and young people with asthma. These interviews will explore healthcare professionals' experiences and reasons for antibiotic prescribing, adherence to guidelines, and strategies to reduce inappropriate use. Patients and parents/carers will discuss their knowledge, treatment experiences, and beliefs about antibiotics use for AAEs. Insights from these interviews will guide the intervention's development.

Phase 2 uses think-aloud interviews to refine the intervention, gathering feedback from primary care professionals and patients on its content, design and usability. Participants will be recruited from primary care centres and professional networks, ensuring diversity in age, gender, ethnicity, and profession.

The study's goal is to support appropriate antibiotic use, aligning with guidelines to combat antimicrobial resistance.

## 2 THEORETICAL FRAMEWORKS

We will draw on the extended Common-Sense Model and the Social Cognitive Theory model to design interview guides and interpret findings in qualitative studies with young people and healthcare professionals; and to provide a framework for intervention planning and development (Phase 1).

The extended Common-Sense Model (CSM), which includes the Necessity-Concerns framework, is highly relevant to theorising the beliefs of patients concerning symptoms and treatment (10). We will supplement this with the self-efficacy construct from Social Cognitive Theory (SCT)(11), as increasing self-efficacy is likely to be a key aspect of an effective intervention for healthcare professionals.

Intervention development will follow the Person-Based Approach(12) and

associated Theoretical Domains Framework to identify likely influences on behaviour not covered

by core theoretical models.

## 3 RESEARCH AIM AND OBJECTIVES

Aim

To develop a behavioural evidence-based intervention that reduces unnecessary use of antibiotics for acute respiratory symptoms in people with asthma in primary care settings.

Objectives

* To explore the views and experiences of primary care professionals involved in the management of asthma on factors influencing antibiotic use in acute respiratory symptoms in people with asthma.
* To explore the views and experiences of people with asthma and parents/carers of children and young adults on factors influencing antibiotic use for acute respiratory symptoms in primary care
* Develop a behavioural intervention to support the reduction of unnecessary use of antibiotics for AAEs in primary care.
* Optimise intervention development using think-aloud interviews with primary healthcare professionals, people with asthma and their parents/carers.

## 4 STUDY DESIGN

**4.1 Study Design**

Phase 1: Qualitative interview study:

Qualitative interviews with primary care professionals managing asthma and people aged 18 or older with asthma and parents/carers of children and young people with asthma to inform the development of the interventions.

Semi-structured qualitative interviews with primary care professionals involved in the management of asthma to explore topics including:

* Views and experiences of managing asthma exacerbation and prescribing antibiotics.
* Views and experiences on antibiotic prescribing decisions for AAE and factors that influence the decisions.
* Confidence and understanding of evidence-based recommendations.
* Beliefs about the consequences of overuse of antibiotics for asthma exacerbation in primary care.
* Strategies to decrease unnecessary antibiotic prescribing for asthma exacerbation.
* Barriers and facilitators to implementation of evidence-based interventions which support a reduction in antibiotic prescribing for asthma exacerbations in primary care.

Semi-structured qualitative interviews with people with asthma and parents/carers of children and young adults with asthma to explore topics including:

* views and experiences of managing asthma exacerbation and treatment options.
* Current sources of information, view and experiences of self-managing asthma exacerbation.
* Care expectations when seeking help for an asthma exacerbation and the use of antibiotics.
* Beliefs about the need and risks of antibiotics for asthma exacerbation.
* Barriers and facilitators to implementation of evidence-based interventions which support a reduction in antibiotic prescribing for asthma exacerbations in primary care.

The semi-structured interviews will be transcribed verbatim. Qualitative data management and analysis software (NVivo) will be used to code and organise the data. The findings of the interviews will provide us with the information required to design a behavioural intervention for primary care professionals and/or people with asthma and parents/carers. The intervention is aimed at reducing unnecessary use of antibiotics.

Phase 2: Think-aloud interviews for intervention optimisation:

The intervention will be refined and optimised through a series of 10-15 think-aloud interviews with primary care health professionals, alongside 5-10 think-aloud interviews involving individuals with asthma and 5-10 think-aloud interviews with parents/carers of children and young adults with asthma. This methodology will be employed to gather detailed insights into participants' perspectives on the draft intervention materials. By encouraging participants to verbalize their thoughts while engaging with the content, this technique allows for a deep exploration of their experiences, helping to identify areas for improvement in terms of usability, accessibility, and overall relevance. Feedback gathered during these interviews will inform an iterative development process, ensuring the intervention is continually adapted to meet the needs and expectations of users.

**4.2 Interview Conduct**

Interviews will be carried out either face-to-face or remotely via videoconferencing or telephone. Face-to-face interviews will be held in participants’ homes or public places. If interview is held in a public place, measures will be taken to maintain participants’ privacy and ensure the conversation could not be overheard. Interviews will be semi-structured following an interview topic guide and will take between 30 to 60 minutes. The interview topic guide has been developed with the support of PPIE members and could be adapted during the course study to enhance the quality, relevance, and depth of the data and facilitate more detailed and accurate responses.

Audio recordings will be professionally transcribed, de-identified, and checked. Transcripts will be assigned pseudonymised identifiers and imported into NVivo for data handling.

All those participating in an interview will be offered a £20 voucher.

**4.3 Data Analysis**

Phase 1- Qualitative Interviews

Transcripts will be analysed using Reflexive Inductive Thematic Analysis (13). The findings will then be used to inform the intervention development.

Phase 2- Think Aloud Interviews

Transcripts will be analysed using Reflexive Inductive Thematic Analysis (13). The findings will then be used to refine and adapt the intervention.

**4.4 Data storage**

All electronic data will be stored on a secure server until the transcription for the interviews in both phase 1 and phase 2 of the studies has been completed. Once these has been carried out and unique identifiers has been assigned then the digital recordings will be destroyed.

Identifiable data will be pseudonymised and the identification key will be stored in a different file, separate from the data. Participant data will be kept accurate and up-to-date and will not be held longer than the agreed duration by the sponsor, which is 15 years.

## 5 STUDY SAMPLE

5.1 Eligibility Criteria

Cohort 1: People with asthma:

**Inclusion criteria:**

* Age ≥18
* Experience of asthma exacerbation and/or lower respiratory tract infection (excluding pneumonia) in the last 2 years.
* Prescription of corticosteroid-containing inhaler in the last 6 months.

**Exclusion criteria:**

* Unable to understand and communicate in English
* Unable to complete study procedures
* Do not have the capacity to consent in accordance with Mental Capacity Act 2005

Cohort 2: Parents/carers of children and young adults with asthma

**Inclusion criteria:**

* Age ≥18
* Cares for a person with asthma (≤18 years , has experienced asthma exacerbation and/or lower respiratory tract infection (excluding pneumonia) in the last 2 years and has been prescribed a corticosteroid-containing inhaler in the last 6 months).

**Exclusion criteria:**

* Unable to understand and communicate in English
* Unable to complete study procedures
* Do not have the capacity to consent in accordance with Mental Capacity Act 2005

Cohort 3: Primary care professionals:

**Inclusion criteria:**

* Primary care-based health professional responsible for or involved in making antibiotic prescribing decisions.

**Exclusion criteria:**

* Unable to understand and communicate in English

**5.2** **Sample Size**

We anticipate the following approximate numbers will provide sufficient information power (14) to guide intervention development:

Phase 1 - Qualitative Interviews

* 8-10 Adults with asthma aged ≥18 years
* 8-10 parents/carers of children and young adults with asthma.
* 15-20 primary care professionals

Phase 2 – Think-aloud interviews

* 10-15 think-aloud interviews with primary care professionals
* 5-10 think-aloud interviews with adults with asthma
* 5-10 think-aloud interviews with parents/carers of children and young adults with asthma.

**5.3**  **Sampling technique**

Adults with asthma and parents/carers of children and young adults with asthma will be sampled purposively to include a range of age, gender, ethnicity and deprivation status.

Primary care professionals will also be sampled purposively to include a range of age, gender, ethnicity, and profession.

Sampling will be completed after potential participants complete the reply form and provided the required demographic information. If they are not selected for the interview, they will be informed via email and their data will be deleted.

## 6 RECRUITMENT

Cohort 1 – People with asthma and parents/carers of children and young adults with asthma

Recruitment of this cohort will be done primarily in primary care centres through South Central Research Delivery Network (RDN). Agreement will be completed with primary care centres to be used as PIC sites. Database searches will identify people with asthma who have had antibiotics prescribed for them in the last two years for asthma exacerbation or chest infection. Invitations will then be sent through SMS text, email, postal mailout or opportunistic recruitment by participating practices, offering participation in either the qualitative interview study and/or think-aloud interview. Primary care professionals will be asked to screen the lists to exclude individuals who have opted out of research or individuals, based on the principal investigator, will not be suitable to participate in the study.

Potential participants (or their parents/carers) will either be sent: 1) a SMS text message to

their registered mobile number with a link to the study pack; 2) an email to their registered email address with the study pack; or 3) a postal mail out pack including an information sheet and details of how to contact the study team. The study pack will include participant information sheet which include information on eligibility and interview process and information on how to express interest in taking part in a qualitative interview and/or (at a later date) think-aloud interview.

Participants may also be recruited opportunistically during consultations. In this case, the GP will provide a person with asthma (or their parents/carers) a study pack containing the enclosures listed above.

Once potential participants have read the information sheet and are interested in participating, they will be asked to complete a paper or online form leaving their contact details. They will be contacted by the research team to discuss the study further and to invite them to an interview at a time, mode (videoconferencing, telephone or face-to-face) and location convenient to them, if they are still keen to participate. If following the discussion with the study team, the potential participant no longer wants to participate, their contact details will be deleted.

If keen to participate, written consent will be obtained and sent through SafeSend (University of Southampton secure portal to send sensitive documents) to the study team before commencing the interview. If the interview is taking place by telephone or by videoconferencing, then participants will be asked to complete online consent prior to the interview taking place. If this hasn't been done prior to the arranged interview, then the consent will be sought verbally at the start of the interview and recorded. Specific consent for audio recording of the interview will also be sought.

Cohort 2 – Primary Care Health professionals

Primary care professionals will be invited to participate in qualitative interviews through NIHR Research Delivery Networks, relevant national groups, contacts, and professional lists. We will seek to interview primary care professionals (e.g. GPs, Advanced Nurse Practitioners, Clinical pharmacists).

Invitations will include an online link to express interest in participating. They study team will then send potential participants the study pack and contact them by phone or email to arrange an interview. Interviews will take place by telephone, videoconferencing (e.g. Teams) or face-to-face, according to participant preference, at a time, mode and location workplace premises) convenient to them.

Informed consent will be sought prior to the start of all interviews. If the interview is taking place by telephone or by videoconferencing, then participants will be asked to complete online consent prior to the interview taking place. If this hasn't been done prior to the arranged interview, then the consent will be sought verbally at the start of the interview and recorded. Specific consent for audio recording of the interview will also be sought.

## 7 CONSENT

All potential participants will have received the study pack, including participant information and a copy of the informed consent form, and will have enough time (min 48 hours) to review the paperwork before participating in the study. Potential participants will have the chance to ask questions to the study team prior to their participation via email or phone.

The study team will send a maximum of two reminders prior to the interview to remind participants of the upcoming interview and to clarify any outstanding questions.

participants will be informed from the start of contact with the research team that they will be able to provide their consent via two options: a) a written consent form sent via SafeSend prior to an interview or b) a verbal consent taken on the day and recorded prior to and separate from the interview. If anyone is not willing to provide their consent to taking part in the study, interested individuals will be thanked for their interest and time but their participation will not be able to progress further, and their information will be deleted.

Specific consent for recording of the interview will also be sought, but if this is declined, the interviewer will proceed and take detailed notes.

## 8 ETHICAL AND REGULATORY CONSIDERATIONS

**8.1** **Assessment and management of risk**

There is no anticipated risk associated with this study. The interviewers will follow the University of Southampton and Primary Care Department policies. Lone working policy will be followed when visiting participants in their homes.

All participants will be made aware that they can withdraw from the study at any time. While it is expected that in the majority of the cases, the interview will not cause undue stress, emotional responses may be elicited, particularly if participants have had distressing experience with asthma exacerbation. Thus, the researcher will offer participants to pause and reflect. The participants will be offered to decline to answer the question that triggered the emotional distress or ask to stop the interview if they do not wish to continue. The participants will also be signposted to the appropriate support should they feel distressed during or following the interview. A full risk assessment will be reviewed by the sponsor prior to commencement of the study.

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

The research activities outlined within this protocol will be reviewed by the Health Research Authority (HRA) and the National Research Ethics Service (NRES) and no work will start until full approval is given by the HRA and a favourable opinion is gained from NRES. All relevant documents will be reviewed and agreed and any future amendments to any of the documents or the protocol will be submitted to these bodies prior to any implementation of those changes, if they are deemed to be substantial by the sponsor (University of Southampton).

* Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site.
* All correspondence with the Research Ethics Committee (REC) and Health Research Authority (HRA) will be retained.
* It is the Chief Investigator’s responsibility to produce the annual reports as required.
* The Chief Investigator will notify the REC of the end of the study. This is when data collection is complete with no further data are collected from participants, and all qualitative interviews have been conducted.
* 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.

**Regulatory Review & Compliance**

No sites will commence recruitment until full HRA approval has been received and each site has been assessed for capability and compliance.

Amendments

If the sponsor or sponsor’s representative wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor must submit a valid notice of amendment to the REC and HRA for consideration. The REC will provide a response regarding the amendment within 35 days of receipt of the notice. It is the sponsor’s responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

**8.3**  **Peer review**

The peer review of the study will be instigated and approved by the sponsor. The study protocol was reviewed by an independent researcher with expertise in qualitative research to assess the chosen qualitative methodological approach for its suitability in addressing the research question. Another independent researcher with clinical background and expertise in managing asthma in primary care will also review the study protocol.

**8.4**  **Patient & Public Involvement**

Patient and Public Involvement is incorporated in this project throughout the research process and will adhere to UK Standards of Public Involvement.

Study Design and Planning: The group will provide insights to researchers during the study design phase to ensure the research is relevant and addresses public concerns and interests. They will also assist in the review and development of study documentation to ensure it is clear, comprehensive and accessible to a lay audience.

Enhancing Study Acceptability: The group will offer perspectives that help ensure the study design and documentation are acceptable to the general public and ensure the study respects ethical standards from a public point of view.

Communication and dissemination: The group will develop strategies for effective communication of study progress and results to the public and to establish channels for ongoing feedback between researchers and the public to foster transparency and trust.

**8.5** **Protocol compliance**

* Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms 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.

### 

**8.6** **Data protection and patient confidentiality**

All investigators and study site staff will 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.

The means whereby personal information is collected, kept secure, and maintained. In general, this involves:

• The creation of coded, depersonalised data where the participant’s identifying information is replaced by an unrelated sequence of characters.

• Secure maintenance of the data and the linking code in separate locations using encrypted digital files within password protected folders and storage media.

• Limiting access to the minimum number of individuals necessary for quality control, audit, and analysis

• The confidentiality of data will be preserved when the data are transmitted to sponsors and coinvestigators

• The custodian of the data is the University of Southampton.

**8.7 Indemnity**

The protocol has been reviewed and approved by the Research Governance office and insurance office and the Chief Investigator is an employee of the University of Southampton.

1. The University of Southampton has arrangements that will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor for harm to participants arising from the management of the research.

2. The University of Southampton has arrangements that will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor or employer for harm to participants arising from the design of the research.

3. The GP surgeries will have arrangements in place for insurance and/or indemnity to meet the potential legal liability of investigators/collaborators as long as their activities are within their normal course of duties.

**8.8** **Access to the final study dataset**

* The CI, Co-investigators and Research Fellows employed to collect data and build the intervention will have access to the final data.
* The qualitative work is aimed at developing an intervention therefore it is not intended that the dataset will be used for secondary analysis, but the anonymised dataset will be made available upon reasonable request as required.

## 9 DISSEMINIATION POLICY

On completion of the study, the data will be analysed and tabulated for publication and for a Final Study Report will be completed, which will be publicly available.

We do not foresee any commercially exploitable results from this study; rather the aim is to better inform NHS best practice and decision making.

Participants will be notified of the outcome of the study.

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## 11. APPENDICIES

**11.1** **Appendix 1\_ Study Documentation**

**Participant information sheet for health professionals**

**Participant information sheet for people with asthma**

**Phase 1 and 2 consent form**

**Qualitative interview guide\_ Primary care professionals**

**Qualitative interview guide \_ People with asthma**

**Think aloud guide**

**11.2 Appendix 2 – Amendment History**

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| --- | --- | --- | --- | --- |
| **Amendment No.** | **Protocol version no.** | **Date issued** | **Author(s) of changes** | **Details of changes made** |
|  |  |  |  |  |