Protocol Version 0.2, 3rd[th] February 2025

FULL TITLE
Missed opportunities for improving outcomes in Chronic Obstructive Pulmonary Diseases in underserved populations

SHORT TITLE: COPD underdiagnosis

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STUDY SUMMARY:

IRAS: 331290

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Full title	Missed opportunities for improving outcomes in Chronic Obstructive Pulmonary Disease in underserved populations
Health condition studied	Chronic Obstructive Pulmonary Disease (COPD)
Study type	Mixed methods explanatory sequential study design consisting of two phases quantitative followed by qualitative
Participants	• Work package 1 (WP1): quantitative modelling of publicly available data to estimate the magnitude of underdiagnosis of COPD in General Practice in England • Work package 2 (WP2): Cross-sectional prevalence survey randomly sampling 4,761 people from two primary care networks in deprived areas, offering a breathing assessment (est. 30% uptake with a 7% prevalence) creating a cohort of 100 patients with COPD. • Work package 3/4 (WP3/4) Semi-structured interviews with health professionals (10-15) and people living with COPD (15-25) purposively sampled informed by findings from WP1-2. • Work package 5 (WP5): Co-design workshops will be held with representation from key stakeholders (patients, health professionals, managers, integrated care boards) to develop interventions for improving diagnosis and care for people living with COPD.
Study duration/ length	60 months (5 years)
Start date	1 December 2024
End date	1 December 2029
Key study milestones	• Project set-up: study months -2 to 5 (October 2024 to April 2025) • Quantitative modelling study (WP1): study months 0 to 24 (December 2024- December 2025) • Cross-sectional prevalence survey (WP2): study months 10 to 50 (September 2025- December 2028) • Qualitative studies (WP3/4): study months 22 to 48 (September 2026-December 2028) • Co-design workshops and Stakeholder dissemination event (WP5): sudy months 48 to 60 (December 2028 – December 2029
Funder	NIHR Advanced fellowship NIHR303606
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KEY WORDS:

Chronic Obstructive Pulmonary Disease
Non-communicable Chronic Respiratory Diseases
Underserved populations
Mixed methods
Minoritised ethnic groups
Co-design
Prevalence survey
Breathlessness

LIST OF ABBREVIATIONS:

COPD	Chronic Obstructive Pulmonary Disease
DECRN	Deep End Clinical Research Network
PCN	Primary Care Network
GOLD	Global Initiative for Obstructive Lung Disease
QOF	Quality and outcomes framework
SSC	Study Steering Committee

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1 INTRODUCTION

1.1. Brief Overview

Chronic Obstructive Pulmonary Disease (COPD) is a preventable and treatable chronic lung disease affecting three million people in the UK and is associated with a substantial healthcare burden. COPD is commoner in deprived communities and associated with risk factors such as smoking, air pollution and poor housing. People living with COPD in the most deprived areas are up to ten times more likely to have poor outcomes compared to those in the least deprived areas, with increased morbidity and mortality.

Some ethnic minority groups are at higher risk of developing COPD as they are more likely to smoke and live in the most income-deprived neighbourhoods. They are also more likely to have COPD unrelated to smoking, and those that are first generation immigrants are likely to have alternative risk factors. Despite this, the proportion of ethnic minorities diagnosed with COPD appear lower than expected with little research conducted in this area.

The aims of this work are**:**

To determine the burden of disease caused by COPD in underserved populations and why it may be under-estimated.

To explore barriers and enablers of primary care interventions (vaccination, pulmonary rehabilitation, and treatment of tobacco dependency) for people diagnosed with COPD in under-served populations.

The associated research questions are:

To what extent is COPD under-detected in under-served (socioeconomically deprived and/or ethnic minority) populations, and what are the main reasons for this?

Why do primary care interventions (vaccination, pulmonary rehabilitation, and treatment of tobacco dependency) for supporting people with COPD fail to reach underserved populations?

1.2 Summary of methods

This is a mixed methods, explanatory sequential design consisting of two distinct phases: quantitative followed by qualitative. There are five work packages (WP); **WP1-2** Quantitative phase, **WP3-4** Qualitative phase and **WP5** Interpretation of results and intervention co-development.

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WP1: This will provide an estimation of the number of patients with undiagnosed COPD in underserved populations nationally using publicly available data. This will be compared with prospectively collected data from **WP2.**

WP2: The prevalence of COPD in underserved primary care populations will be established in people from underserved communities registered in two primary care networks.

WP3: An understanding of barriers and facilitators to recognising COPD in underserved populations will be generated through a semi-structured interviews, informed by **WP1-2**.

WP4: An understanding of how COPD and key primary care interventions (vaccination, pulmonary rehabilitation, and treatment of tobacco dependency) are perceived by underserved populations will be generated through the semi-structured interviews, leveraging the cohort established in **WP2**.

WP5: Findings from **WP1-4** will be integrated and interventions co-developed to improve recognition and management of people with COPD in underserved populations.

1.3 Main benefits of research

Recognising underserved people with COPD and intervening early could reduce the burden of this condition on both patients and the health system. Primary care-based interventions, improve health, reduce exacerbations and are the most cost-effective for COPD. This study provides valuable information from voices seldom heard allowing co-development of fit for purpose interventions. Findings will be disseminated through publication, social media, community groups and existing stakeholder networks.

1.4 Study flow chart

See Figure 1

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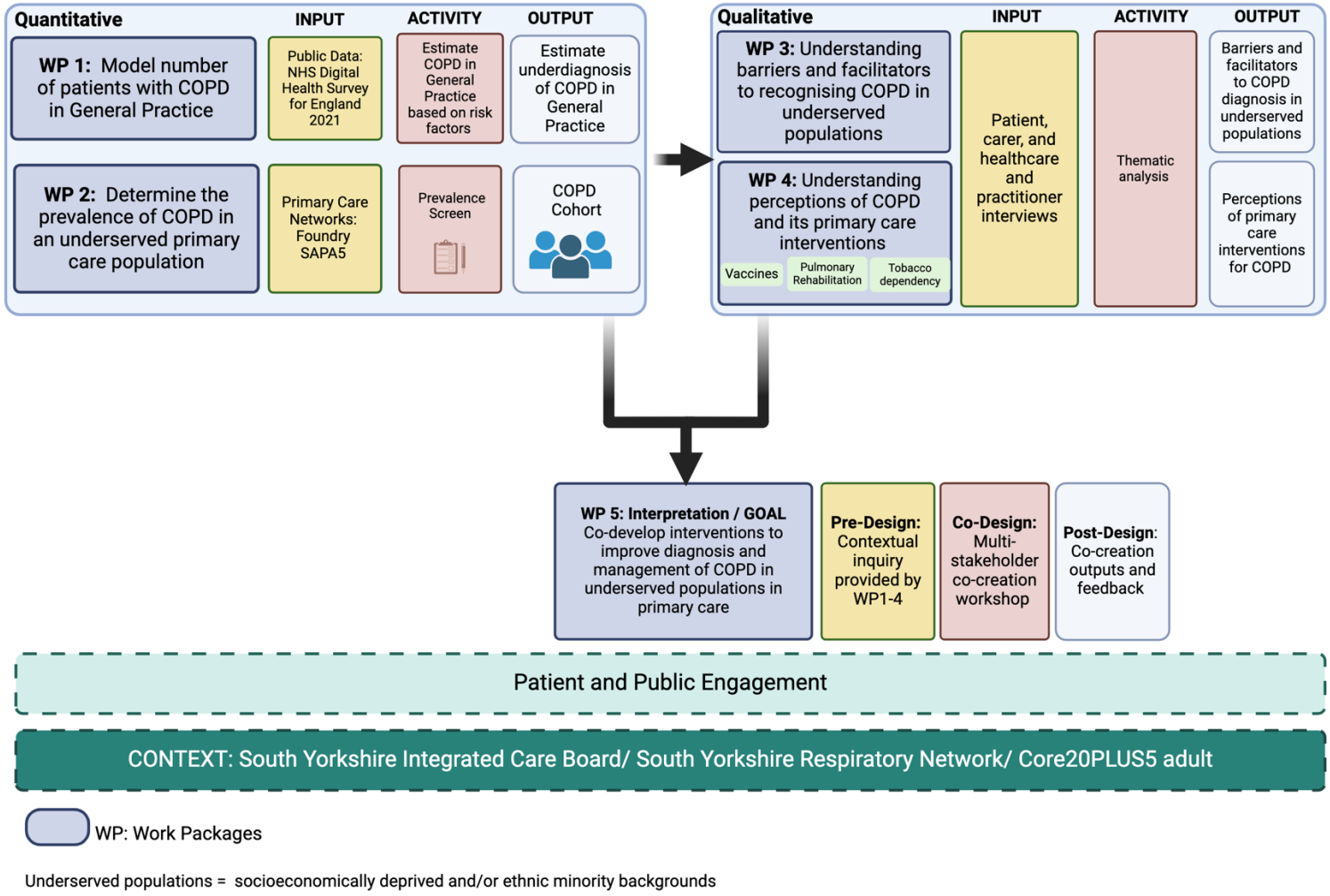
Figure 1: Explanatory Sequential Design: Study Flow Chart



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2 BACKGROUND AND RATIONALE

2.1 What is the problem being addressed?

Chronic obstructive pulmonary disease (COPD) is a preventable and treatable chronic lung disease affecting three million people in the UK[1] and is associated with a substantial healthcare burden.[2,3] It is the fourth leading cause of death globally[4] and accounts for 10% of all premature deaths in England annually.[5] Data from four epidemiological studies in 27 countries demonstrated that COPD was undiagnosed in >50% of people, and 79.6% of COPD cases in London were previously undiagnosed.[6] Patients with undiagnosed COPD are often first encountered in primary care,[7,8] but opportunities for diagnosis are commonly missed.[9] COPD is commoner in deprived communities,[10] where risk factors for COPD such as smoking, air pollution, occupation, and poor housing are more common.[11] People living with COPD in the most socioeconomically deprived areas are up to ten times as likely to have increased morbidity and mortality compared to those in the least deprived areas.[12,13] Some ethnic minority groups are likely to be at higher risk of developing COPD as they are more likely to smoke[14] and live in the most income-deprived neighbourhoods (e.g. >25% Pakistani men smoke and 30.7% live in deprived neighbourhoods).[15] Current approaches to COPD diagnosis are opportunistic and reliant on a history of tobacco dependency. Emerging data has identified COPD unrelated to smoking ('non-smoking COPD') as more likely in patients from ethnic minority backgrounds, who have other risk factors such as increased infections in childhood and exposure to indoor air pollution from cooking stoves.[16] The latter may increase the risk of COPD in non-smoking women in particular.

A recent multivariable analysis conducted using publicly available data from all general practices in Sheffield showed that the greater the percentage of ethnic minorities in a practice, the lower the percentage of patients diagnosed with COPD (adjusting for age, smoking and decile of index of multiple deprivations).[17] The same pattern is observed within South Yorkshire regional and general practice data from England as a whole.[18] These data suggest that current strategies used for recognising COPD are disproportionately missing cases in ethnic minority populations at high risk of COPD.[19] Further work is required to confirm this at the level of individual patients.

This study will explore diagnosis of COPD in populations from deprived and/or ethnic minority backgrounds, estimating the extent of underdiagnosis in these populations. Furthermore, perceptions of COPD and primary care interventions for COPD (vaccination, pulmonary rehabilitation, and treatment of tobacco dependency) will be explored, facilitating co-development of strategies to improve patient uptake of these interventions and improve health outcomes.

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2.2 Why this research is important?

The extent and impact of underdiagnosis of COPD in socioeconomically deprived and/or ethnic minority populations is unknown. However, people with undiagnosed moderate-to-severe COPD have higher hospitalisation rates, increased symptoms, and poorer health-related quality of life than people without COPD.[20,21] The impact of undiagnosed COPD is likely to be greatest in the most deprived areas, where the burden of disease is highest.[11]

A first acute presentation to hospital with COPD represents a missed opportunity for exacerbation prevention through prior early diagnosis. One-fifth of patients for whom hospitalisation is their first COPD presentation die within one year of discharge.[22] COPD is responsible for one-in-eight emergency hospital admissions in the UK[1] and COPD admission rates are associated with deprivation.[23] One of the five clinical focus areas in NHS England's Core20PLUS5 (adults) approach to reducing healthcare inequalities is chronic respiratory disease, specifically targeting COPD vaccination uptake and exacerbation rate reduction.[24] Underdiagnosis and limited uptake of evidence-based interventions for COPD are long-standing problems, leading to significant excess morbidity and mortality in the most deprived areas.[25] Early diagnosis and treatment (e.g. vaccination, pulmonary rehabilitation, treatment of tobacco dependency) are important in reducing symptom burden, improved health related quality of life, reducing mortality, and reducing the cost impact of COPD.[3] Improving timely diagnosis and engagement with COPD care in the most deprived areas will reduce demands on the health system in an already overburdened NHS.

2.3 How does the existing literature support this study

The Burden of Obstructive Lung Disease (BOLD) study has demonstrated that there is a high prevalence of undiagnosed COPD in multiple settings globally. The overall prevalence was 10.1% using data across 12 sites.[26] In the UK, around 2% of the population and 4.5% of people aged >40 years live with diagnosed COPD.[27] This would suggest that 5.6% of people with COPD remain undiagnosed, but the prevalence in underserved populations remains unknown.

The underdiagnosis of COPD is an issue in general practices in deprived communities,[28] within which there are often significant populations of people from ethnic minority backgrounds. Irrespective of age, smoking, and socioeconomic status, lower percentages of COPD diagnosis are seen in general practices in England with higher percentages of ethnic minority populations.[18] Current strategies for identifying people with COPD in the UK almost exclusively require patients to be smokers. This approach is likely to disproportionately miss cases in populations with greater proportions of non-smoking COPD such as ethnic minority groups.[29] The 2023 Global Initiative for Chronic Obstructive Lung Disease (GOLD guidance) notes the heterogeneity of processes that contribute to COPD such as premature birth,

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childhood infections, tuberculosis, and household or ambient air pollution.[16] It highlights that COPD is no longer considered a single disease caused by tobacco smoking, but multiple subtypes defined by functional or pathobiological mechanisms.

Prior research on how to address underdiagnosis has focused predominantly on case finding strategies targeted at active smokers in primary care in predominantly white British populations.[30] The NIHR BLISS programme grant conducted a trial among smokers (85% white British) to identify new cases of COPD and used routinely collected primary care data to develop the TargetCOPD score to identify patients at high risk of having COPD.[31] The validity of using this score in people with COPD from ethnic minority backgrounds who have never smoked is unknown.

Primary Care interventions for patients with COPD: COPD forms part of the quality outcomes framework (QOF)[32] in general practice and therefore once diagnosed, patients are added to a register to target on-going disease specific care. Despite this, uptake of evidence-based primary care interventions for COPD was low in the most socioeconomically deprived areas in Sheffield.[17] Less than 50% of patients with COPD agreed to pulmonary rehabilitation referral or to pneumococcal or influenza vaccinations. This is in keeping with previous findings demonstrating that socioeconomic status has a consistent impact on COPD morbidity and mortality, suggesting that lack of engagement with evidence-based primary care interventions for COPD could be a contributory factor to poor outcomes for those living in deprived areas.[13]

Vaccinations, pulmonary rehabilitation, and treatment of tobacco dependency are the most cost-effective interventions as indicated by the London Respiratory Network 2013 value pyramid.[33] Vaccines are an effective preventative measure for reducing respiratory infections and hence exacerbation frequency in patients with COPD.[34] In Deep End general practices in Sheffield, only a median of 60.8% (IQR 58.6,62.8) of people with COPD received seasonal influenza vaccination and only a median of 24.4% (IQR19.6,36.0) had ever received a pneumococcal vaccination.[17] Whether this reflects the nationwide poor uptake of influenza vaccination in individuals <65 years in clinical risk groups[35] or added issues of delivery to underserved populations requires further investigation.

Pulmonary Rehabilitation (PR) is a highly effective education and graded exercise intervention for the management of COPD,[36] but there is a need to understand why uptake of PR in primary care has been consistently poor. A median of 47% patients with COPD in Deep End general practices in Sheffield declined referral for PR.[17] Previous studies have identified multiple barriers at the interfaces between PR services, primary care, and patients with COPD. Issues around language barriers and transport were highlighted as specific to the South Asian community.[37] This study will involve underserved communities to increase understand of, and co-design healthcare solutions at the primary care level for patients diagnosed with COPD.

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Finally, there is high-quality evidence that COPD patients that smoke are over twice as likely to quit when they receive behavioural support and medication compared to those that receive behavioural support alone.[38] A systematic review of the impact of specialist and primary care tobacco dependency services on socio- economic inequalities in cessation highlighted the paucity of data available.[39] In Scotland, where adequate data were available, lower quit rates were seen in patients from low socioeconomic groups. An understanding of perceptions of patients with COPD from underserved communities around treatment of tobacco dependency and how it is delivered is needed to inform the delivery of future care.

A recent scoping review of co-creation practices for COPD identified only four studies conducted in the UK, all of which involved either supported self-management strategies or utilisation of mobile applications.[40] No co-creation studies have explored improving implementation of multiple primary care-based interventions for COPD in underserved populations. This project will identify and add patients to COPD registers, in line with NICE guidance, and will target implementation of healthcare strategies to understand recognition and management of people with COPD from underserved communities.

3 AIMS AND OBJECTIVES

3.1 Aims

To determine the burden of disease caused by COPD in underserved populations and why it may be under-estimated.

To explore barriers and enablers of primary care interventions (vaccination, pulmonary rehabilitation, and treatment of tobacco dependency) for people diagnosed with COPD in underserved populations.

3.2 Objectives

Estimate the number of people with undiagnosed COPD in underserved populations in England (**WP1**)

Determine the actual prevalence of undiagnosed COPD in an underserved primary care populations (**WP2**).

Understand barriers and facilitators to recognising COPD in underserved populations (**WP3**).

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Understand how COPD and its primary care interventions (smoking cessation, pulmonary rehabilitation, and vaccination) are perceived in underserved populations (**WP4**).

Co-develop interventions to improve uptake of primary care interventions (smoking cessation, pulmonary rehabilitation, and vaccination) for COPD in underserved populations (**WP5**)

4 STUDY DESIGN/ METHODS

4.1 Overall design and conceptual framework

This is a mixed methods explanatory sequential study design consisting of two phases: quantitative followed by qualitative leading to co-design of an intervention. The quantitative data on COPD in underserved populations will be sought first through modelling of publicly available General Practice data (**WP-1)** and a cross-sectional prevalence survey (**WP-2)** conducted in North Sheffield Primary Care Networks. The qualitative data will be collected second informed by the findings from **WP-1 & 2**. This will explore and explain the findings from the quantitative results, through semi-structured interview studies (**WP-3 & 4)** of health care professionals, patients and carers in North Sheffield Primary Care Networks. The two phases will be integrated at analysis. The rationale for this approach is that the quantitative data and their subsequent analysis provide a general understanding of the research problem. The qualitative data and their analysis refine and explain those statistical results by exploring participants' views in more depth. (Cresswell et al. 2003) Finally these data will look to inform co-design of an intervention (**WP-5)** to address the findings from **WP-1-4**

4.2 Setting/context

This study is looking to explore the diagnosis of COPD in underserved populations, describing and exploring, how and why diagnoses are or are not made. It is the first of its kind to be delivered at a Primary Care Network (PCN) level to ensure research can be conducted independent of the delivery of clinical primary care, recognising the high burden placed on the health care professionals working with underserved communities, and the lack of capacity in those settings.

WP 2-5 are set in Sheffield in two PCNs); The Foundry and SAPA5, providing care to 58,100 and 36,556 patients respectively. These networks include six of the nine practices within the NIHR Deep End Clinical Research Network (DE CRN). This research cluster has an established track record in conducting socially inclusive research.[41–43] Both PCNs cover socioeconomically deprived areas of Sheffield, but differ with higher

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levels of ethnic diversity found in The Foundry network, whereas SAPA5 is predominantly white British. Rebecca Reeves and Nicky Normington (PCN Managers), and Dr Josh Meek and Dr Tom O'Brien (Clinical Directors of the PCNs) have been involved from the outset in this proposal and are key stakeholders in the project. Alongside the PCNs, Primary Care Sheffield (PCS),[44] a not-for-profit company set up by general practice in Sheffield with research infrastructure, will host a research nurse and project manager involved in the study.

4.3 Quantitative modelling study (WP1)

In **WP-1** national routinely collected public data sets; Fingertips, NHS digital and the Office National Statistics will be used to model the expected prevalence of COPD in General Practices in England. Publicly available general practice variables known to be associated with COPD such as tobacco dependency, age and deprivation will be used to create model estimates of the expected prevalence of COPD in general practice.

Data Analysis:
Regression analysis will be used to predict expected COPD prevalence in each general practice in England, based on the prevalence of risk factors (e.g. tobacco dependency, poor housing, age and deprivation) and their magnitude of association with COPD from published literature. These expected COPD rates will be compared with NHS digital actual prevalence data in general practices from COPD QOF registers.[32] This will allow estimated to be made of the shortfall in COPD diagnosis nationally at a general practice level. Factors that may be associated with underdiagnosis of COPD such as the percentage of patients from ethnic minority backgrounds will be explored. The model estimates of COPD prevalence will also be compared with the 2010 Health Survey for England Data on respiratory and lung health which included a subset of people who underwent spirometry to diagnose COPD.

As this will utilise routinely collected data already in the public domain no formal ethical approval is required to conduct this work.

4.4 Cross-sectional prevalence survey (WP2)

WP-2 is a cross-sectional prevalence survey which is the first of its kind to attempt recruitment at a primary care network level (PCN). Each general practice within PCNs, SAPA5 and The Foundry, will individually sign a research agreement, but the delivery of the research in terms of participant selection and approach will be delivered at a network level. The study will look to recruit patients over a three-year period using the Burden of Obstructive Lung Disease (BOLD) methodology, which has been used in multiple international settings globally to conduct COPD prevalence studies.

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Sample size:
The two PCN patient registers will be randomly sampled to obtain 4,761 people >35year, these people will be invited to participate in the study and undergo a breathing assessment. The BLISS cohort study (NIHR Programme grant) had a 30% uptake following a postal invitation. Anticipating a 30% uptake, 1,428 people will undergo a breathing assessment and assuming a 7% prevalence, a cohort of 100 patients with COPD from underserved communities will be recruited. This would allow a prevalence estimate with ±4-5% precision for a 95% confidence interval. This would be sufficient to compare with and validate model estimates from WP1, and allow comparison with registered COPD diagnoses from the COPD QOF register

Recruitment and screening for COPD:
The random sample of 4,761 people (40/week) will initially be telephoned (using interpreting services if their registered language is not English) and invited to participate in the study. This initial approach will be conducted by a PCN administrator (and then a follow-up call made by the research team only to those who are interested in participating and informed consent obtained.

A breathing assessment will then be arranged by the study team within the PCN, at a medical practice which patients are familiar. The breathing assessment will include a validated symptom-based questionnaire and in those that are symptomatic the following:

- Quality assured post-bronchodilator spirometry
- Chest radiograph
- Full blood count

The definition of COPD by the Global Initiative for Obstructive Lung Disease (GOLD) 2023 report[16] will be used. A fixed post bronchodilator FEV1/FVC ratio <0.7 will be used to establish the diagnosis of COPD as per GOLD guidance.

Interpreters will be used for patients whom their registered language is not English, and home visits conducted for housebound patients where possible. De-centralising and offering assessment within general practice settings may be necessary. To maximise recruitment, a flexible approach will be taken, modifying the breathing assessment offer if uptake is low, within the limits of the capacity of the research team.

Consent will be obtained for details to be held as part of a COPD cohort for approaching for recruitment into the qualitative interview study in **WP3 & 4**, as well as offering other potential opportunities for further involvement in future research work.

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Only 1/5th of patients diagnosed as part of the Target COPD screening trial in the BLISS Cohort study[45] were entered on to general practice COPD Quality and Outcomes (QOF) registers post study. To maximise engagement of general practices, and to ensure timely diagnosis impacts patients care we will ensure that all COPD QOF targets (recorded number of exacerbations in the previous 12mths, Medical Research Council (MRC) Dyspnoea Scale, if MRC Dyspnoea scale is ≥ 3 referred to pulmonary rehabilitation) are met for patients diagnosed with COPD in the study. This has been discussed with PCN managers and local practice partners.

Data management:
Data will be pseudonymised and collected using REDCap, a secure web-based application supporting electronic data capture. Data will be held on a secure server with a back-up schedule. Data will only accessible via the University of Sheffield encrypted network and all extracts and entries logged via REDCap audit trail. A data manager will set up REDCap and be involved in clinical records form development. They will continue to carry out server maintenance for the duration of the clinical study. Data will be cleaned and exported for further downstream analysis in R, always held on secure university storage and approved devices.

4.5 Qualitative semi-structured interviews (WP3-4)

Recruitment:
Using purposive sampling of general practices within The Foundry and SAPA5 PCNs, we will recruit 10-15 health care workers (General practitioners, Practice Managers, Practice Nurses, Advanced Nurse Practitioners, Health Care Assistants, Care Coordinators, and Physicians Associates). This number might vary according to emerging findings and through an on-going iterative process.

Purposive sampling informed by the findings from **WP1 & 2** will recruit 15-25 people with lived experience of COPD (subject to data saturation) from underserved populations. Purposive sampling will be informed by factors such as general practice registration, age, sex, deprivation, non-english speaking, and ethnicity. We will seek to include patients for whom language/literacy is often a barrier in-line with Include NIHR guidance.[46]

Qualitative interviews with health care workers:
Interviews will be conducted face-to-face wherever possible informed by a literature review. They will build on findings from quantitative **WP1-2** using these findings to inform interview content. Health care workers within both PCNs, the Foundry and SAPA5, will be invited to participate and informed consent obtained. Each interview will take between 60-90 minutes, and participants will be asked questions from a topic

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guide relating to diagnoses and management (vaccination, pulmonary rehabilitation and treatment of tobacco dependence), of patients with COPD from underserved communities.

Qualitative interviews with people with lived experience of COPD:
Interviews will be conducted as detailed above for health care workers, again informed by a review of the literature and specifically building on quantitative findings of **WP1-2**.[47] There will be 15-25 people (subject to data saturation) with lived experience of COPD (patients and carers) recruited. They will be invited to participate in their documented primary spoken language. Information sheets and consent forms will also be provided in patients' primary spoken language (English, Pakistani, Urdu, Slovak or Arabic). Once informed consent has been obtained interview dates will be set with those who respond affirmatively with an interpreter as needed. Each interview will take between 60-90 minutes and participants will be asked questions from the topic guide relating to their diagnosis and primary care management of their COPD (vaccination, pulmonary rehabilitation and treatment of tobacco dependence).

Conducting interviews:
Interviews with health care workers and people with lived experience of COPD will be conducted by an experienced member of the research team. They will be recorded on an encrypted hand-held device and transcription conducted in real-time with regular meetings held with the qualitative research support team (Professor Chris Burton, Dr Shoba Dawson) to allow for reflexivity in the analysis process. This iterative process will enable previous interviews to inform the questioning of subsequent ones as new concepts emerge. Participants will be offered a £25 shopping voucher as a gesture of thanks, as commonly practiced in similar local research.

Data analysis:
Analysis will be an on-going, iterative process beginning at the early stages of data collection and continuing throughout. Thematic analysis,[48] informed by the candidacy model,[49] will be used for patient data to explore people living with COPD and their understanding of the condition and the treatment available. A constant comparative method where all data relevant to each theme is compared to the rest within that category will be used. Independent verification of themes will be performed in duplicate. Discussion of the data within the wider research team will lead to the development of robust themes justified by, and linked to, the interview data. NVivo software will be used to aid data storage and analysis.

4.6 Intervention co-development (WP5)

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This sequential explanatory mixed methods study integrates[50] and links data collection and analysis by both connecting (sampling of the qualitative phase informed by quantitative findings) and building (interview content informed by quantitative findings) approaches. At this stage the two data sets will be merged for analysis and comparison exploring qualitative understanding of quantitative findings. Dependent on findings integration will be conducted through interpretation and reported primarily using a *weaving* narrative approach around quantitative and qualitative data on similar themes and concepts. Following integrated analysis, targeted intervention(s) or implementation strategies to increase the diagnosis of COPD and engagement with evidence-based interventions for people with COPD in underserved populations will be co-designed.

There is a recognised lack of singular consistent conceptualisation of 'co-design' and standardised terminology or conceptual definitions.[51] To mitigate against this, a published generative co-design framework for healthcare innovation will be used.[52]

Steps to co-design:

Pre-design
Step 1 (Contextual Inquiry).
WP1-4 of this mixed methods study will encompass the contextual inquiry.
Step 2 (Preparation & Training).
Data analysis and on-going public involvement will be used to prepare and train specific stakeholders. Prior to the workshop, key stakeholders will be invited to make a two-minute video clip of their perspectives, and this will be incorporated into the visual scribe offering pre-workshop and shown to launch the event. A co-creation stakeholder workshop will be held with representation from integrated care boards, primary care, secondary care, study participants, public involvement COPD group and researchers.
Step 3 (Framing of the issues).
Findings from this study will be shared, a visual summary of integrated data findings from quantitative and qualitative work will be created by nifty fox (visual scribe) and disseminated.
Step 4 (Generative Design).
A live scribe will be utilised for the duration of the meeting. Small groups of varied stakeholder representation will be formed to discuss main themes and define objectives.
Step 5 (Sharing Ideas).
Small groups will then be brought together in a wider discussion bringing findings from small group multistakeholder discussions, creating a roadmap to achieving objectives.

Post-design
Step 6 (Data Analysis).

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Workshop co-created output will be collated alongside visual scribe offerings and shared with all attendees, and more widely.
Step 7 (Requirements Translation).
Assessment of feasibility of options and co-created interventions will be invited from stakeholders and next steps determined.

5 STUDY SCHEDULE

Add Gant Chart

6 ELIGIBILITY CRITERIA

6.1 Cross-sectional prevalence survey (WP2)

6.1.1 Eligibility criteria

Participants will be registered within Primary Care Networks in North Sheffield, SAPA5 and The Foundry.
They can be of any gender and will be adults (>18years).

6.1.2 Exclusion criteria

Participants will not be eligible if they are unable to provide informed consent or are children or adolescents (<18years).

6.2 Qualitative semi-structured interviews (WP3-4)

6.2.1 Eligibility criteria

Participants must be over the age of 18years and have lived experience of COPD as a healthcare worker, carer or be a person living with COPD.

6.2.2 Exclusion criteria

Participants unable to provide informed consent or below the age of 18years
Any participant that has no lived experience of COPD.

7 RECRUITMENT AND CONSENT

7.1 Cross-sectional prevalence survey (WP2)

WP-2 is a cross-sectional prevalence survey which is the first of its kind to attempt recruitment at a primary care network level. Each general practice within PCNs (SAPA5 and

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The Foundry) will individually sign a research agreement, but the delivery of the research in terms of participant selection and approach will be delivered at a network level.

A random sample of 4,761 people (40/week) registered at SAPA5 or The Foundry PCNs will initially be telephoned (using interpreting services if their registered language is not English) and invited to participate in the study (Figure 1). This initial approach will be conducted by a PCN administrator, who will share the patient information sheet, and then a follow-up call made by the research team only to those who are interested in participating and informed consent obtained.

7.2 Qualitative semi-structured interviews (WP3-4)

Using purposive sampling of general practices within The Foundry and SAPA5 PCNs 10-15 health care workers (General practitioners, Practice Managers, Practice Nurses, Advanced Nurse Practitioners, Health Care Assistants, Care Coordinators, and Physicians Associates) will be recruited. This number might vary according to emerging findings and through an on-going iterative process. The research team will contact potential participants through the PCN and share the participant information sheet. Those that are interested will be contacted by the research team and informed consent obtained.

Purposive sampling informed by the findings from **WP1 & 2** will be used to recruit 15-25 people with lived experience of COPD (subject to data saturation) from underserved populations. Purposive sampling will be informed by factors such as general practice registration, age, sex, deprivation, non-English speaking, and ethnicity. We will seek to include patients for whom language/literacy is often a barrier in-line with Include NIHR guidance. Participants (and/or carers) from **WP2** that have consented to being offered further research study involvement will be approached and informed consent obtained.

8 ETHICAL ISSUES

8.1 Assessment and management of risk

This study raises several important ethical issues, particularly around the challenges of conducting research in underserved and vulnerable populations:

1. Informed Consent:
There is a focus on socioeconomically deprived and ethnic minority groups, participants need to fully understand the purpose of the study, its potential risks, and their rights. Some individuals might face barriers to understanding, such as language difficulties or low health literacy. Informed consent is an ongoing process. Participants

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will be reminded that they can withdraw from the study at any time, and their decision will not affect their medical care.

All study materials, including consent forms, will be written in clear, simple language, and, where needed, translations provided in the languages spoken by participants. Visual aids or multimedia materials (videos or infographics) will be used to explain the study's aims, procedures, risks, and benefits.

Consideration will be given to using culturally appropriate methods for delivering information. Sensitisation through engagement with community leaders, such as the Imam at the local Mosque, trusted local health workers and community research link workers, will be used to explain the study. This will help improve understanding and trust in the process.

2. Privacy and Confidentiality:
The research will involve collecting sensitive health data, including personal and medical information. Protecting the privacy of participants is paramount.

All personal and health-related data will be securely stored and anonymised to protect participants' privacy. The individual data collected will be securely stored in the University of Sheffield encrypted databases with access restrictions to safeguard data. Data storage and duration of this will be clearly explained to participants. If any data will be shared publicly (e.g., for publications or presentations), anonymisation will be ensured, and participants informed that their identities will not be revealed.

3. Equity and Inclusion:
While the study aims to focus on underserved populations, care must be taken to ensure that these communities are not exploited or stigmatised. There is a risk that focusing too much on certain populations (e.g., ethnic minorities, low-income communities) might inadvertently reinforce negative stereotypes or lead to a perception that these groups are "diseased" or vulnerable. This study intends to handle the findings in a way that is respectful and empowers these communities rather than marginalising them further.

The study patient and public involvement and engagement (PPIE) group that have been involved in the study from inception reflect the diversity of the populations under study, with representation from the Roma-Slovak, South Asian and Afro-Caribbean communities. The PPIE group helped shape the research questions and will remain involved throughout the course of the study, providing voices from a variety of ethnic, cultural and socioeconomic backgrounds.

4. Risk of Harm:

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The research aims to improve healthcare outcomes for underserved populations, but there could be unintended negative consequences. For example, identifying undiagnosed COPD could result in participants being given diagnoses or treatments that are not fully understood or welcomed by them. Additionally, there might be concerns about whether interventions recommended for these groups will be implemented in a culturally sensitive or effective way, potentially causing distress or disempowerment if not done correctly.

To mitigate against these participants will be informed of the potential emotional or psychological impacts of being diagnosed or having their COPD status re-evaluated. A trained experienced health care professional will deliver the diagnosis to participants sensitively and with care. Initial care required as per the qualities and outcomes framework (QOF) targets will be delivered or signposting to other services that can deliver these e.g. services where vaccination can be undertaken. Diagnoses will be shared with primary care providers to ensure that they are recorded in patients' medical notes and therefore appropriate on-going care provided.

5. Bias and Representation:
The study aims to examine barriers to diagnosis and treatment in underserved populations, but care must be taken to avoid bias in the selection of participants in work packages 2-4. The research should ensure a representative sample of different ethnic and socioeconomic groups within the broader underserved population.

A randomised selection of patients from primary care networks lists will be used to avoid bias and assumptions about certain groups and be open to the full range of experiences that affect COPD recognition and management. Purposive sampling will be used for qualitative sampling using factors such as practice registration, age, sex, socioeconomic status and ethnicity to obtain broad representation.

Where possible basic information on patients declining to participate in the study will be collated and anonymised. These data will enable us to explore any biases and compare those that declined versus those that took part.

6. Community Engagement:
Ethical research in these communities must be conducted with a sense of mutual respect and partnership. The PPIE in this proposal has engaged with local groups, healthcare professionals, and patients and will continue to do so throughout the research process to ensure that their voices are heard and that the interventions developed are truly relevant to their needs. The final work package of the project involves co-design, following sharing of findings to ensure communities have knowledge shared in a timely fashion. This co-development involves working with local

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healthcare providers to integrate study findings into routine care and develop community-driven initiatives to address gaps in COPD care.

8.2 Ethical Approval

The University of Sheffield Ethics Committee and NHS Research Ethics Committee approvals will be obtained for the cross-sectional prevalence survey and qualitative semi-structured interviews **(WP2-4).**

9 PATIENT AND PUBLIC INVOLVEMENT (PPI)

This research study iteratively evolved over two years with input from a COPD public involvement panel formed to input into this research with representatives living in areas of deprivation in North Sheffield. The panel is diverse with representatives from African Caribbean, South Asian, Roma-Slovak and Azshkenazi Jewish communities. At every stage of the research process to date the public involvement group have provided input. Specifically with design of information sheets and patient facing materials, in addition to the design of recruitment.

The public engagement for this project will follow the UK standards for public involvement. The COPD public involvement group will be invited to meet at four monthly project advisory group meetings to provide input, with consultation sought at key additional time points as required. The public involvement group will be providing input into key areas of the project:

- Research study design and recruitment methods
- Research management
- Patient-facing material
- Interpretation of findings
- Co-authorship of outputs

Members of the COPD public involvement panel will be provided with support and training throughout the course of the project to take on supported co-leadership of the COPD public involvement group. The intention being that the group will become a sustainable diverse, inclusive resource open for engagement with future COPD research.

A key workshop will be held towards the end of the study to foster active engagement of the COPD public involvement group in wider dissemination of findings. This will lead onto a further stakeholder event led by the COPD public involvement group along with the research group to build local capacity for public engagement with underserved populations.

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10 FUNDING

This study funding has been reviewed by the University of Sheffield and the NIHR. It has been funded through an NIHR advanced fellowship (independent personal award to Dr S Jayasooriya, NIHR303606), of which the funding amount is £1,165,589.00.

11 DATA HANDLING AND MANAGEMENT

11.1 Data transfer (handling, processing and storage)

11.1.1 Overall Strategy

In this study quantitative data (derived from publicly available dataset [NHS digital, Fingertips and, Office for National Statistics], and the cross-sectional survey) , and qualitative data (semi-structured interviews) will be collected from participants in accordance with the study schedule.

Dr S Jayasooriya will act as the data controller for the study and will process, store and dispose of all quantitative and qualitative data in accordance with all applicable legal and regulatory requirements, including the General Data Protection Regulation) GDPR) and the UK Data Protection Act 2018. Data will not be transferred to any party not identified in this protocol and are not to be processed and/or transferred other than in accordance with the patients' consent. A separate data management plan (DMP) will be created detailing data description, handling and storage in-line with University of Sheffield policy.

11.1.2 Quantitative modelling study (WP-1)

Publicly available data sets from NHS digital Fingertips, Quality and Outcome Frameworks, and the Office of National Statistics will be used to derive a dataset detailing General Practice COPD data including data on risk factor prevalence in General Practice.

These data are anonymised and in the public domain but will be held on a secure university server for analysis and then made available on a university repository.

11.1.3 Quantitative cross-sectional prevalence survey (WP-2)

There will cross-sectional survey data on all participants randomised into the study, 1428 participants will be offered a breathing assessment and cross-sectional prevalence data will be available for each participant and captured on RedCAP electronic data capture held on a secure university server.

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The following raw quantitative data will be generated from the cross-sectional prevalence survey:

- Categorical demographic: sex, ethnicity
- Numerical demographic: DOB, height, weight,
- Numerical spirometry values (e.g. FEV1, FVC), dyspnoea scores and exacerbation frequency
- Numerical laboratory test results: full blood counts
- Categorical chest xray data

These data will be predominantly numerical but include some categorical. They will be entered into RedCAP an electronic data capture software and stored on a University the Sheffield server on the X:drive. It will then be exported as a .csv file for interrogation and further analysis in R.

11.1.4 Qualitative semi-structured interviews (WP-3/4)

There will be qualitative interview raw data recorded on an encrypted, password-protected digital recorded. These encrypted audio files will be anonymised and transferred to the University secure data environment. Derived from these there will be transcribed interview data, which will be transcribed by a university authorised transcription service or the principal investigator Dr S Jayasooriya. These will then be coded, analysed and organised into themes using NVivo software. These data will be in a narrative format in .docx file

12 PEER REVIEW

The study has undergone external peer review through the NIHR advanced fellowship funding application process. This involved topic expert reviews of the study proposal and a 16-member multi-professional panel interview.

13 MONITORING AND AUDITING

The Principal Investigator, Dr S Jayasooriya, will ensure there are adequate quality and number of monitoring activities conducted by the study team. This will include adherence to the protocol, procedures for consenting and ensure adequate data quality. They will inform the sponsor should he/she have concerns which have arisen from monitoring activities, and/or if there are problems with oversight/monitoring procedures.

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The Principal Investigator will provide overall leadership of the project and project team, lead the cross-sectional survey and semi-structured interviews. The project manager, based at Primary Care Sheffield will assist in coordinating activities related to the Primary Care Network cross-sectional prevalence survey and assist in managing the research nurse employed to conduct these activities.

The research team will meet approximately weekly throughout the cross-sectional prevalence study to discuss the status of the project, support progress with data collection and analysis. Wider team meetings will be conducted monthly and chaired by the PI; administration will be provided by the project manager; teleconference and videoconference facilities will be used to optimise participation from research team members.

Project oversight will be provided by a study steering committee (SSC) that will meet bi-annually. In addition to members of the research team, the SSC will comprise of an independent Chair and a wide range of stakeholders, including representatives of service users and carers, commissioners, and academics with expertise in qualitative and quantitative methods

14 TRAINING

This study involves an extensive training programme including the principal investigator completing a three-year distance learning Masters in Epidemiology registered at the University of Edinburgh. The course content and optional modules will relate specifically to the theory and methodology underpinning this research proposal and fit with the timeline of the study.

The basic compulsory epidemiological component relates directly to WP2. Listed below are the three years of study for the MSc and the relevant parts of the study that they will correspond with. Registration for this will take place in September 2025.

Year 1: Core compulsory modules include statistical modelling for epidemiology and data analysis with R, directly relating to **WP1** estimating COPD prevalence in under-served populations. I will be selecting Implementation science: putting evidence-based interventions in to practice as my option providing key training directly relevant to this proposal.
Year 2: I will select the following options, introduction to data science in health and social care, data types and structure in python and R, and Qualitative interviewing and data analysis for public health. These directly relate to the **WP1, WP3** and **WP4.**

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Year 3: A final quantitative dissertation is required to meet the requirements of the programme. The modelling and cohort study from **WP1** and **WP2** will be written up for submission.

15 INTELLECTUAL PROPERTY

This research may generate new IP. Any such product will be dealt with appropriately with guidance from the University of Sheffield.

During the project we anticipate producing the following IP:
Dissemination materials produced throughout the study.
These will be protected by copyright law, according to the Copyright, Designs and Patent Act 1988. Copyright law protects any work which is written and is original. We will use "(c) University of Sheffield" (followed by the year of creation) to make clear that University of Sheffield asserts its right to copyright protection in these works.
IP generated through this research will be managed by University of Sheffield, who will work closely with the project team to ensure that any valuable IP is protected by patent filing or copyright as outlined above.

Our dissemination plan allows for free and open access publication of the intervention manuals and peer-reviewed journal articles. The aim of the project is to generate knowledge for wider benefit. Nothing we will produce will necessarily generate income and it is likely that all our tools and outputs will be maximally accessible and free at the point of delivery.

As the IP from this research will relate to methodological approaches and lessons relating to how to care for people with COPD, we do not anticipate regulatory hurdles associated with medical technologies (e.g. MHRA approval). Barriers to adoption will mainly take the form of stakeholders' lack of awareness of and engagement in the lessons derived from our research. To address this, we will disseminate the findings as widely as possible.

16 INDEMINITY ARRANGEMENTS

Discuss with UoS

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17 PUBLICATION AND DISSEMINATION POLICY

18.1 Dissemination

Approaches to dissemination will be tailored to suit specific audiences by working with the COPD public involvement group and stakeholders.

Disseminate to industry, the third sector, patients and the public:
Distribution of plain language summaries of study progress and findings to relevant stakeholders including specific local community groups such as Sheffield African Caribbean Mental Health and Social Care organisation (SACMHA), Fir Vale Community hub and the Shipshape Health and Wellbeing Centre in Sheffield.

Disseminate to clinical audiences:
Presenting at local medical committee meetings, hospital COPD multidisciplinary team meetings, and primary care network meetings, posting in newsletters to reach healthcare staff and service managers. Continued liaison regionally providing summaries and presenting at the Deep End Research Alliance Symposia, South Yorkshire NHS Integrate Care Board and South Yorkshire Respiratory network.

Disseminate findings to academic audiences:
Publishing papers in high impact, peer-reviewed open access journals of primary care and respiratory health. Presentations at academic conferences such as British Thoracic Society Winter meeting, Primary Care Respiratory Society, Society for Academic Primary Care Annual Conference and Royal College of General Practitioners Annual Conference. Engaging with and presenting to NIHR academic networks such as the Yorkshire and Humber Ethnic Minority Research Inclusion NIHR network and the Yorkshire and Humber Academic Health Sciences Network. Utilising my Twitter account and post regular project updates, signpost to findings. In addition to dissemination to specific groups, a multistakeholder event will be held to bring together groups of researchers, clinicians, managers, and the public with a visual scribe producing lay summaries

18.2 Projected outputs

WP1: National estimates of underdiagnosis of COPD in underserved primary care populations.

WP2: Formation of a cohort of patients diagnosed with COPD providing real world data on underdiagnosis of COPD in underserved primary care populations.

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Health and care of patients, caregivers and the wider public:
This work will have a positive impact on the health and care of patients as interventions designed alongside patient engagement groups are more likely to meet patient's needs. The collaborative approach this body of work takes will directly impact patients diagnosed, encouraging and empowering them to manage their own COPD health. The preliminary patient engagement groups suggest that the qualitative research to determine patients' perceptions of COPD and its primary care treatment will be valuable in broadening our understanding of this from voices that often go unheard.

Health care services:
By proactively recognising patients with COPD and intervening early with primary care-based interventions that improve health and reduce exacerbations, the burden of this condition on both patients and the health system will be reduced. Identifying exacerbations and intervening appropriately in a timely fashion can mitigate against costly hospital admissions. This project has the potential to reduce accident and emergency, inpatient and primary care workload of nonelective care.

18.3 Funder requirements

We will follow the guidance stipulated by the NIHR when communicating our research: Notification of outputs and copies of any paper/article should be sent to the funder 28 days before they are due to be published.

- The NIHR's contribution should be acknowledged in full by including a funding statement.
- Research articles should be published in journals as open access that make the output
- available using the Creative Commons Attribution (CC BY) licence and allow immediate deposit of the final published version in other repositories without restriction on re-use.
- The independent nature of the research and its intellectual property provenance should be emphasised by a disclaimer:

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Wording for researchers who hold Integrated Clinical Academic training or career development funding awards "[Dr S Jayasooriya, NIHR Advanced Fellowship, NIHR303606] is funded by Health Education England (HEE) / NIHR for this research project. The views expressed in this publication are those of the author(s) and not necessarily those of the NIHR, NHS or the UK Department of Health and Social Care."

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