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Chronic obstructive pulmonary disease underdiagnosis

Submission date 31/01/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 21/03/2025	**Overall study status** Ongoing	
Last Edited 30/09/2025	**Condition category** Respiratory	

Plain English summary of protocol
Background and study aims
This study aims to investigate opportunities for improving outcomes in chronic obstructive pulmonary disease (COPD) in underserved populations.

Who can participate?
Participants for the cross-sectional prevalence survey will be registered within Primary Care Networks in North Sheffield, SAPA5, and The Foundry, and must be adults of over 18 years of any gender, while participants for the qualitative semi-structured interview must be over 18 years and have lived experience of COPD as a healthcare worker, carer, or person living with COPD.

What does the study involve?
This is a mixed methods explanatory sequential study design consisting of two phases quantitative followed by qualitative.
It consists of five work packages that will run over five years.
• 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.

What are the possible benefits and risks of participating?
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 the co-development of fit-for-purpose interventions. Findings will be disseminated through publication, social media, community groups and existing stakeholder networks.

The specific risks associated with this project are low. Post-bronchodilator spirometry, blood tests and chest X-rays are offered routinely as usual care in symptomatic individuals to make a diagnosis of COPD in primary and secondary care. These would be offered to participants as part of the study and are low-risk.

There is a small chance participants might be found to have COPD, asthma or another condition. If this is the case depending on the clinical condition of the patient, they would be referred to their GP or an acute medical service as appropriate. Any diagnoses, such as COPD or asthma, that are made, but don't require immediate intervention, would be shared with the patient's GP to ensure that they have the appropriate ongoing care for their condition.

Where is the study run from?
University of Sheffield, UK

When is the study starting and how long is it expected to run for?
November 2023 to December 2029

Who is funding the study?
National Institute for Health and Care Research (NIHR)

Who is the main contact?
Dr Shamanthi Jayasooriya, Email: s.jayasooriya@sheffield.ac.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)

331290

Central Portfolio Management System (CPMS)
57283

National Institute for Health and Care Research (NIHR)
303606

Study information

Scientific Title
Missed opportunities for improving outcomes in chronic obstructive pulmonary diseases in underserved populations

Study objectives
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 more common in deprived communities where it is 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 who are first-generation immigrants are likely to have alternative risk factors. Despite this, the proportion of people from minoritised ethnic groups diagnosed with COPD appears 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 underestimated.
To explore barriers and enablers of primary care interventions (smoking cessation, vaccination and pulmonary rehabilitation).

The associated research questions are:
To what extent is COPD under-detected in underserved (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?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/06/2025, London City and East Research Ethics Committee (Research Ethics Committee Centre, 2nd Floor
2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 1048171, +44 (0)207 1048 170; cityandeast.rec@hra.nhs.uk), ref: 25/LO/0429

Primary study design
Observational

Study design
Mixed methods quantitative modelling cross-sectional prevalence survey and qualitative semi-structured interviews leading to intervention co-design

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Chronic obstructive pulmonary disease in underserved populations (depriver and minoritised ethnic groups)

Interventions
This is a mixed-method explanatory sequential design study 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.

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 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.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Modelled estimate of underdiagnosis of COPD in general practice measured using data collected from publically available NHS fingertips data in 2025
2. Estimate of the prevalence of COPD in underserved general practice populations measured using cross-sectional breathing assessment data collected from a random sample of primary care network populations from 2025 to 2028
3. Understanding of the barriers and facilitators of COPD diagnosis in an underserved general practice population measured using qualitative interview data collected from people living with or caring for people with COPD, and primary care health professionals looking after them between 2026-2028
4. Understanding perceptions of primary care for COPD in an underserved general practice population measured using qualitative interview data collected from people living with or caring

for people with COPD, and primary care health professionals looking after them between 2026-2028
5. Co-design an intervention to address the under-diagnosis of COPD and uptake of primary care interventions for managing COPD through multi-stakeholder engagement workshops

Key secondary outcome(s)
A greater understanding of perceptions of primary care interventions (smoking cessation, vaccination, pulmonary rehabilitation) for COPD measured using data collected through qualitative interviews with people living or caring for people with COPD, and the health professionals caring for them.

Completion date
01/12/2029

Eligibility

Key inclusion criteria
1. Cross-sectional prevalence survey:
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 (> 18 years).
2. Qualitative semi-structured interview:
Participants must be over the age of 18 years and have lived experience of COPD as a healthcare worker, carer or a person living with COPD.

Participant type(s)
Patient, Health professional, Carer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
150 Years

Sex
All

Key exclusion criteria
Cross-sectional prevalence survey:
1. Participants will not be eligible if they are unable to provide informed consent or are children or adolescents (< 18 years).
Qualitative semi-structured interviews:
2. Participants unable to provide informed consent or below the age of 18 years
Any participant that has no lived experience of COPD.

Date of first enrolment
01/10/2025

Date of final enrolment
01/09/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
SAPA5 Primary Care Networks
63 Palgrave Road
Sheffield
United Kingdom
S5 8GS

Study participating centre
The Foundry Primary Care Network
87 Wincobank Avenue
Sheffield
United Kingdom
S5 8AZ

Sponsor information

Organisation
University of Sheffield

ROR
https://ror.org/05krs5044

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr S Jayasooriya: s.jayasooriya@sheffield.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 0.2	03/02/2025	05/02/2025	No	No