Optimising respiratory integrated care services

Submission date	Recruitment status	[X] Prospectively registered
08/01/2025	Recruiting	<pre>Protocol</pre>
Registration date	Overall study status	Statistical analysis plan
10/02/2025	Ongoing	☐ Results
Last Edited	Condition category	Individual participant data
10/02/2025	Respiratory	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

NHS England has identified respiratory care as one of five clinical areas in which there are substantial health inequalities that may disproportionately affect those in the most deprived 20% of the population and/or those from ethnic minority communities or with other protected characteristics (CORE20PLUS5). Addressing these inequalities is an NHS England priority, with integrated respiratory care proposed as a key means of optimising service organisation and delivery. Integrated respiratory care aims to be patient-centred, delivering care that is seamless, proactive and coordinated through clinical leadership and the multi-professional team working together across organisations, healthcare settings and pathways. Local data demonstrate that Birmingham and Solihull Integrated Care Board (BSol ICB) has the highest COPD admission rate of all ICBs in England at nearly 50% above the national average.

Whilst evidence suggests that integrated respiratory care can effectively manage patients with a range of chronic respiratory conditions, the optimal configuration of such services remains unknown. It is also important that integrating respiratory services by providing specialist-led care does not have unintended consequences. For example, the INTEGR COPD study (2017 to 2019) showed the unexpected finding that significantly more patients were admitted to hospital with respiratory illness in the intervention group vs control. Objective 2 within the proposed study seeks to determine the reasons for this through case review. Given current plans to expand the integrated respiratory service more widely across BSoL ICB, alongside the introduction of COPD risk stratification to identify patients at highest risk of COPD exacerbation, there is a need to understand factors that may affect implementation of integrated respiratory care through additional qualitative work with patients and healthcare professionals (objectives 3 and 4).

By evaluating integrated approaches to provide access to specialist input for patients with common chronic respiratory conditions and to identify those most at risk of deterioration and/or acute hospitalisations, this project aims to draw practical conclusions regarding the factors involved the design and delivery of an optimal integrated respiratory service in a deprived urban area.

This study aims to determine the optimal service configuration for an integrated respiratory service in a deprived urban area.

Study objectives:

1. To systematically review the literature on integrated respiratory care to understand which service models have been used to manage chronic respiratory conditions nationally and internationally.

- 2. To understand whether there is an association between the integration of respiratory clinicians into primary care reviews and the risk of hospitalisation in COPD.
- 3. To gather learning locally and from other sites within the UK that have used integrated care approaches for respiratory conditions, using qualitative interviews with clinicians to identify best practice.
- 4. To understand the impact of service changes to expand integrated respiratory services on healthcare staff and patients.

Who can participate?

Healthcare professionals or trainees working in the NHS in England, whose role includes providing care and support to people with chronic respiratory disease will be eligible to take part in a qualitative interview (objective 3 will be open to professionals from across the UK, objective 4 will be restricted to those working within the Birmingham and Solihull Integrated Care Board region). UK respiratory medicine trainees will be able to participate in a trainee survey.

Patients with a chronic respiratory disease who have been seen within the respiratory integrated care service in Birmingham and Solihull within the last 12 months will be eligible to take part in a qualitative interview (objective 4).

What does the study involve?

The study will comprise four objectives:

Objective 1 involves a systematic review of the literature focusing on models of integrated care for respiratory conditions.

Objective 2 will comprise a further evaluation of data on patient hospital admissions collected in the INTEGR COPD study. A case review of each hospital admission recorded during that study (n = 347) will be undertaken to understand whether there is an association between the integration of respiratory clinicians into primary care reviews and the risk of hospitalisation in COPD.

Qualitative interviews from up to 25 clinicians working within or leading integrated respiratory services locally (n = 10-15) and nationally (n = 5-10) will be undertaken to understand the factors involved in designing and delivering respiratory integrated care services and to identify best practice. A survey will be distributed to respiratory medicine trainees.

An embedded service evaluation in objective 4 will comprise an analysis of routinely collected data on the impact of using different risk stratification approaches for patients with Chronic Obstructive Pulmonary Disease will be undertaken by the Midlands and Lancashire Commissioning Support Unit. Interviews with up to 10 healthcare professionals involved in delivering integrated services within BSol ICB, and up to 10 patients who received integrated respiratory care will be undertaken.

Interviews will last for up to 60 minutes, and surveys will take around 10 minutes to complete.

What are the possible benefits and risks of participating?

There will be no direct benefits to the research participants by taking part in this research, however, patients may find some satisfaction in helping researchers work towards improving integrated respiratory services for others with similar health conditions. Clinical staff participants may feel more engaged and valued in their workplace through the ability to contribute their views to the understanding and planning of the services in their locality. It is possible that participants will be inconvenienced by completing a survey or taking part in an interview. Surveys can be completed in as many sessions as participants may require, with electronic versions allowing saving or partial responses for later completion. Interviews will be arranged at a time and via a format that is most convenient for participants.

There are no risks for patients whose historical hospital admission episode(s) will be assessed using case review (objective 2). Case note review focuses purely on data collected as part of

usual care during the hospitalisation episodes and will not affect any care patients received at the original time of the study or currently.

Where is the study run from?

The study is being run from the University of Birmingham, in partnership with Birmingham and Solihull Integrated Care Board (BSol ICB) (UK)

When is the study starting and how long is it expected to run for? September 2024 to September 2026

Who is funding the study?

National Institute for Health Research Applied Research Collaboration West Midlands (UK)

Who is the main contact?

Dr Lucy Boast (co-investigator), l.a.boast@bham.ac.uk

Contact information

Type(s)

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

348217

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

24/PR/1523

Study information

Scientific Title

Understanding the optimal configuration of respiratory integrated care services

Study objectives

HYPOTHESIS:

- 1. Respiratory integrated care services provide the optimal approach to care for patients with chronic respiratory conditions.
- 2. The geographical and clinical scope of respiratory integrated care services can be improved by better understanding both the patient factors involved in the utilisation of services and the experiences of clinicians working in areas with differing access to integrated specialist care.

AIM:

To determine the optimal service configuration for an integrated respiratory service in a deprived urban area.

OBJECTIVES:

- 1. To systematically review the literature on integrated respiratory care to understand which service models have been used to manage chronic respiratory conditions nationally and internationally.
- 2. To understand whether there is an association between the integration of respiratory clinicians into primary care reviews and the risk of hospitalisation in COPD.
- 3. To gather learning locally and from other sites within the UK that have used integrated care approaches for respiratory conditions, using qualitative interviews with clinicians in order to identify best practice.
- 4. To understand the impact of service changes to expand integrated respiratory services on healthcare staff and patients.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 30/12/2024, London - Fulham Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8084; fulham.rec@hra.nhs.uk), ref: 24/PR /1523

Study design

Mixed methods observational study

Primary study design

Observational

Secondary study design

Mixed methods study

Study setting(s)

Community, GP practice, Hospital, Medical and other records

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Chronic respiratory disease: asthma, bronchiectasis, interstitial lung disease, sleep apnoea

Interventions

This is a mixed methods analysis of real-world clinical practice aimed at determining the important factors for the design and delivery of optimal integrated respiratory services.

The study will comprise four objectives:

- 1. Objective 1 is a systematic review of literature focusing on models of integrated care for respiratory conditions. This is not subject to ethical review.
- 2. Objective 2 will comprise a further evaluation of data on patient hospital admissions collected in the INTEGR COPD study. Case review of routinely collected data for each hospital admission recorded during that study (n = 347) will be undertaken to understand whether there is an association between the integration of respiratory clinicians into primary care reviews and the risk of hospitalisation in COPD. No patient recruitment will be undertaken for this element of the study. Individual patient consent will not be sought for the re-analysis of existing data.
- 3. Objective 3 will collect qualitative data (interviews) from up to 25 clinicians working within or leading integrated respiratory services locally (n = 10-15) and nationally (n = 5-10) to understand the factors involved in designing and delivering respiratory integrated care services and to identify best practice. The training requirements and experiences of respiratory medicine interviews and allied health professionals will also be considered, with individuals from these groups being part of the interviews and a subsequent short survey. Interviews will last for up to 60 minutes, and surveys will take around 10 minutes to complete.
- 4. Objective 4 will focus on understanding the impact of service changes to expand integrated respiratory care services into new localities of the Birmingham and Solihull Integrated Care Board (BSol ICB), and to assess the effectiveness of using risk stratification within primary care to identify patients at high risk of COPD exacerbation. The risk stratification work will be led and

delivered by clinical teams across BSol ICB. An embedded service evaluation in objective 4 will comprise an analysis of routinely collected data on the impact of using risk stratification, interviews with up to 10 healthcare professionals involved in delivering integrated services within BSol ICB, and up to 10 patients who received integrated respiratory care. Interviews will last for up to 60 minutes.

Intervention Type

Other

Primary outcome measure

Objective 2:

Admission episodes in control and intervention groups within the follow-up period of the INTEGR COPD study will be reviewed. The following factors will be measured and the relationship between individual admission factors will be compared between intervention and control groups using both descriptive statistics and multivariate analyses:

- 1. Reason for admission
- 2. Location of admission
- 3. Length of stay
- 4. Number and type of comorbidities (respiratory, cardiac, psychiatric, other)
- 5. Any indication of access to integrated/community services prior/post admission.
- 6. Discharge destination
- 7. Smoking status
- 8. Ethnicity

Objective 3:

Healthcare professional attitudes on the following areas of respiratory integrated care services will be measured using semi-structured qualitative interviews within the coming 12 months:

- 1. Design of current integrated respiratory service and operational details of the service
- 2. How the service was established who, when, why
- 3. Training requirements and provision for staff training, including any involvement of trainees
- 4. Successes/benefits of the service
- 5. Challenges/barriers to the service

Trainee attitudes and experiences of integrated respiratory services will be surveyed within the next 12 months. The following outcomes will be measured:

- 1. Profession
- 2. Training region
- 3. Training level
- 4. Age
- 5. Sex
- 6. Type of training in integrated respiratory services
- 7. Length of training in integrated respiratory services
- 8. Confidence in working within integrated respiratory services
- 9. Plans for involvement in integrated respiratory services after completion of training
- 10. Opinions on outstanding training requirements

Interviews will be transcribed verbatim and combined with the findings from the trainee survey and analysed according to the Framework Method.

Further evaluation of the qualitative data will use the Consolidated Frame for Implementation Research which will allow themes identified during the initial Framework analysis to be mapped to up to five domains (intervention characteristics, outer setting, inner setting, characteristics of individuals and implementation processes).

Objective 4:

Quantitative outcomes will be assessed using routinely collected data compared with the same period 12 months prior and will include:

- 1. Number of AECOPD
- 2. Exacerbation severity
- 3. Number of A&E visits for COPD
- 4. Number of hospital admissions (any cause)
- 5. Number of hospital admissions (COPD)
- 6. Number of hospital readmissions
- 7. Length of stay/bed days in hospital
- 8. Number of respiratory outpatient attendances
- 9. Number of GP consultations for COPD
- 10. CAT score and changes over time
- 11. Contacts with out-of-hours primary care services
- 12. Number of follow-up appointments

Healthcare professional views on the following areas will be measured using qualitative interviews within the next 12 months:

- 1. Experience with new/existing respiratory integrated service
- 2. Use of COPD risk stratification tools
- 3. Expansion of integrated services to other chronic respiratory conditions
- 4. Training and education requirements for the role

Patient attitudes in the following areas will be measured using qualitative interviews up to 12 months after input from the integrated respiratory service:

- 1. Experience of access to an integrated respiratory assessment
- 2. Experience of risk stratification approach to care
- 3. Self-management approaches
- 4. Successes/benefits to the service
- 5. Challenges/barriers to the service
- 6. Factors leading to hospital admission

Qualitative data will be analysed using the Framework method to synthesise study findings into key themes and understand the relationship between themes.

Secondary outcome measures

Objective 2:

Air quality data will also be linked to the admission periods within the next 12 months

Overall study start date

01/09/2024

Completion date

30/09/2026

Eligibility

Key inclusion criteria

Objective 2:

1. Patients will be those identified in the primary research study (INTEGR COPD) as having an admission(s) to hospital due to AECOPD or respiratory illness during the primary study follow up period.

Objective 3:

- 1. Healthcare Professionals (Practice Nurses, General Practitioners, Respiratory Physicians, Resident Doctors, Healthcare Assistants, Paramedics, Advanced Clinical Practitioners, Pharmacists, Physician Associates, Physiotherapists) working within respiratory integrated services (or have been within the last 12 months)
- 2. Staff member (non-clinical) involvement in the organisation/delivery/commissioning of integrated respiratory services (or have been within the last 12 months)
- 3. Respiratory specialist trainees currently holding a respiratory national training number in the UK, respiratory specialist doctors, respiratory associate specialists (or have been within the last 12 months)
- 4. Trainee and qualified allied health professionals currently working (or have been within the last 12 months) within respiratory services in the UK (This is expected to include, but may not be exclusively, the following professional groups nursing, physiotherapy, occupational therapy, pharmacy, dietetics, speech and language therapy, clinical scientist, physiologists)

Objective 4:

The following groups will be eligible to participate in semi-structured interviews:

- 1. Healthcare Professionals (Practice Nurses, General Practitioners, Resident Doctors, Healthcare Assistants, Paramedics, Advanced Clinical Practitioners, Pharmacists, Physician Associates, Physiotherapists) and administrative staff members at GP practice sites within the Birmingham and Solihull Integrated Care Board (BSol ICB) either currently in post or who have been in post within the last 12 months
- 2. Secondary care respiratory service staff at University Hospitals Birmingham NHS Trust (covering Queen Elizabeth Hospital Birmingham, Birmingham Heartlands Hospital and Good Hope Hospital) either currently in post or who have been in post within the last 12 months (Participants will likely include Respiratory Consultants, Specialist Respiratory Trainees, Resident Doctors, Specialist Respiratory Nurses, Physiotherapists, Occupational Therapists, Pharmacists, Advanced Clinical Practitioners, Respiratory Physiologists)
- 3. BSol Integrated Care Board staff contributing to respiratory services either currently in post or who have been in post within the last 12 months (Participants will likely include Respiratory Consultants, Specialist Respiratory Trainees, GPs, Specialist Respiratory Nurses, Physiotherapists, Occupational Therapists, Pharmacists, Advanced Clinical Practitioners, respiratory physiologists and administrators)
- 4. Patients accessing BSol ICB integrated respiratory services within the study period

Participant type(s)

Patient, Health professional

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

45 (Qualitative Interviews - Objective 3 = 25 Objective 4 = 20), Trainee survey target 200

Key exclusion criteria

Objective 3:

- 1. Not a member of clinical or operational staff in an integrated respiratory service within the last 12 months
- 2. Not involved in organisation/delivery/commissioning of integrated respiratory services within the last 12 months
- 3. Unable to consent

Objective 4:

- 1. Healthcare Professional Not a member of BSol ICB catchment area services
- 2. Patient not reviewed by the BSol ICB integrated respiratory service
- 3. Unable to consent

Date of first enrolment

10/02/2025

Date of final enrolment

01/10/2025

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

University Hospitals Birmingham NHS Foundation Trust

Queen Elizabeth Hospital Mindelsohn Way Edgbaston Birmingham United Kingdom B15 2GW

Sponsor information

Organisation

University of Birmingham

Sponsor details

Edgbaston Birmingham England United Kingdom B15 2TT +44 (0)121 414 3344 researchgovernance@contacts.bham.ac.uk

Sponsor type

University/education

Website

http://www.birmingham.ac.uk/index.aspx

ROR

https://ror.org/03angcq70

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research Applied Research Collaboration West Midlands

Results and Publications

Publication and dissemination plan

A written summary of the study findings will be created and shared with the clinicians and commissioners from BSol ICB, University Hospitals Birmingham, University of Birmingham, and all sites involved in the study. Study findings will be submitted for presentation at relevant academic and healthcare/respiratory conferences including the British Thoracic Society Meetings and the Primary Care Respiratory Society conference and via the local respiratory clinical networks. Findings will be disseminated via peer-reviewed, open access publications. All study participants will be able to request a short summary of the study findings by contacting the research team using the contact information on the participant information sheet.

Intention to publish date

01/09/2027

Individual participant data (IPD) sharing plan

The data-sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date