Technology enabled remote monitoring for chronic obstructive pulmonary disease: a rapid evaluation

Study Protocol

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Chief Investigator: Nikki Newhouse[1],
Evaluation Team: Agne Ulyte[2], Hampton Toole[2], Jackie Van Dael[1], Sonja Marjanovic[2], Sara Shaw[1]
[1] Oxford University, Nuffield Department of Primary Care Health Sciences
[2] RAND Europe

Abstract

Background

COPD is a common, treatable (but not curable), and largely preventable lung condition. It is a leading cause of death globally (3.23 million deaths in 2019), with chronic respiratory disease a major contributor to health inequalities and COPD one of the five areas of clinical focus in NHS England's Core20PLUS5 strategy. Approximately 3 million people in the UK are living with COPD and emergency hospital admissions for exacerbations are the second largest cause of hospital admissions. Around 1 in 4 patients are readmitted within 3 months. Timely identification of patients at risk of deterioration is therefore crucial, as is supporting access to pulmonary rehabilitation (PR), which is strongly associated with increased self-management, a reduction in exacerbations, and a reduction in primary and secondary care utilisation. However, referral rates to PR are low due to lack of clinical clarity around the operationalisation and benefits of PR, compounded by barriers to access and a growing (post-pandemic) backlog, all of which are impacting PR take up and completion.

Use of technology-enabled remote monitoring (TERM) is seen as one (of several) potential means that can help to address these challenges, involving the use of digital applications to record patient clinical data in their own home and share it electronically with a health professional. The aim is for technologies to support people with COPD to live in their own homes and to free up resources and capacity across the wider health system. However, there remain key gaps in the evidence relating to the provison of TERM in the COPD care pathway, particularly in relation to models of delivery, implicaitons for the worksforce, the patient experience of using such technologies, and equity of access. This evaluation proposes to inform decision-making around TERM for COPD and support seasonal service planning.

To shape evaluation focus we sought views from a diverse group of 29 stakeholders including national and regional decision makers, providers actively using TERM in COPD, technology suppliers, representatives from Health Innovation Networks, patient representatives, and those progressing evaluation in this space. Our scoping discussions affirmed widespread interest in technology-enabled remote monitoring of COPD, surfaced a number of established and emerging technology-enabled service models within respiratory care, and flagged a number of challenges and facilitators to implementing and adopting TERM in COPD pathways.

Current examples of TERM in the COPD pathway range from use of smart inhalers to apps providing access to virtual pulmonary rehabilitation to dedicated hubs providing 24-hour proactive monitoring. These potentially offer valuable insight into the real-world application and impact of technology-enabled remote monitoring of patients living with COPD and, in line with current policy drivers, how such technology may become more systematically embedded within respiratory care pathways. The proposed rapid evaluation is intended to inform planning for winter pressures, in line with the strategic priorities of the NHSE LungHealth@Home team – the policy customer for this work. We will work with the proposed case sites and the NHSE Lung Health@Home team to gain a deeper understanding of technology-enabled remote monitoring of patients living with COPD, and generate transferable lessons on the resources, systems, people and structures needed to achieve sustained adoption at scale.

Aims, objectives and research questions

The aim of the proposed evaluation is to define good practice in the implementation and use of technology-enabled remote monitoring in the COPD care pathway and draw transferable lessons that can inform potential spread and scale up. The objectives are:

1) To develop a rich picture of technology-enabled remote monitoring of patients with COPD.

2) To surface, explore and interpret the interacting influences on sustained use of such service models in respiratory care.
3) To provide a deeper understanding of staff and service users' experiences using and supporting use of technology-enabled remote monitoring of COPD.
4) To explore the potential value of technology-enabled remote monitoring of COPD for services and service-users.
5) To capture and disseminate learning to inform planning for 2024/25 winter pressures, for services and service users.

Underpinning research questions for the evaluation are:

1. How, where, why and by whom is technology-enabled remote monitoring being used in the COPD care pathway, who is it for and how does it help provide care to service users?
    a. To what extent does implementation of TERM in the COPD pathway require proactive identification and proactive monitoring (as opposed to self-escalation on the part of the patient) to identify early signs of deterioration and prevent escalation?
    b. What can we learn from implementation of TERM in different patient populations (e.g., those at highest risk of exacerbation versus those recently diagnosed or clinically stable)?
    c. In what ways does implementation of TERM support digital pulmonary rehabilitation technologies and/or digital technologies for patient self-management of COPD?
    d. What might be the key mechanisms of action in TERM for COPD: e.g., measurement of vital signs, patient education?
2. What can we learn from implementation and use of existing TERM (by patients and clinicians) that can inform potential rapid take up and use in the context of winter planning, and beyond?
3. What impact and value does TERM have in the COPD care pathway, and how could this be locally evaluated and monitored in the future?

Design and methods

This evaluation will take a multi-site, qualitative approach involving four focused case studies, allowing us to build a formative picture of current technology-enabled remote monitoring in the COPD care pathway and the system-wide factors that may influence and shape sustained adoption at scale.

Data collection and analysis will be guided by the NASSS (Non-adoption, Abandonment and challenges to Scale up Spread and Sustainability) framework, in order to surface and explain the system-wide challenges and complexities in the technology-supported service change.

The project will comprise two consecutive phases:

Phase 1 (focused case studies and formative reporting of emerging findings to inform winter planning) will focus on collection of qualitative data: (i) with key stakeholders from four sites that are actively using varied approaches to TERM for COPD, and (ii) with patient-facing organisations and/or representatives. Qualitative data will include interviews or focus groups with up to 24 staff and system stakeholders (estimated 4-6 in each site) to explore the (inter)organisational resources, processes and challenges to implementation. In addition, we will conduct qualitative work with up to 10 service users to understand the lived experience of such technology, how it helps them (or not) in their everyday lives, and concerns and/or unintended consequences for the individual and/or their networks of care. We aim to capture the challenges for users with complex support needs and issues associated with inequalities in access, use and support.

Phase 2 (co-design, final summative reporting) will focus on co-design of freely available (and adaptable) web-based resources that can support service users and/or providers in implementing, adopting and using technology-enabled remote monitoring in the context of COPD care pathways. This final phase of work (and allied reporting) will also consider potential next steps in evaluation and (with HS&DR approval) development of a further topic specification. This builds on discussion with the NHSE LungHealth@Home team who have prioritised the above rapid evaluation to inform current winter planning and requested a potential second evaluation involving a 'deep dive' of subsequent implementation of TERM in selected sites, to inform wider scale up and spread.

Timelines for delivery

This project is anticipated to begin in April 2024 and complete in July 2024, with an interim report made available to the policy customer in June 2024 to feed into cyclical planning for winter pressures.

Anticipated dissemination and impact

Outputs from the evaluation as a whole will include a final report with executive summary, summative findings and key recommendations for policy, practice and future evaluations (following a formative internal report of emerging findings specifically for the policy customer). The outputs from the codesign workshops will include materials for use by patients and clinicians in order to support the implementation and uptake of remote monitoring technologies for COPD. The specific nature of these outputs will be determined iteratively through synthesis of project data and workshop collaborations.

The final report and executive summary will be made freely available through the DECIDE website. A lay summary will also be made available with the support of a project PPIE group. We will build interest and raise awareness more widely about the project from the outset, and work with our policy customer to inform ongoing national strategy in technology-enabled remote monitoring in the COPD care pathway.

Background and rationale

Introduction

The burden of COPD

Chronic obstructive pulmonary disease (COPD) presents a major burden for patients and the health care system. An estimated 1.2 million people in the UK had a COPD diagnosis in 2012, with nearly 30,000 people dying from COPD annually.[1] The prevalence of COPD is estimated to increase from 1.8% to 2.2% of the population from 2011 to 2030 in England, with rising number of deaths.[2] The increasing prevalence of COPD means that the health care system will need to adapt to the higher demands for patient care. COPD exacerbations often lead to repeated hospitalisations, driving the costs of care. Hospitalisations due to exacerbation constitute the highest share of direct health care costs for COPD patients.[3] In England, annual direct healthcare costs of COPD are expected to increase from £1.5 billion to £2.3 billion from 2011 to 2030.[2] COPD exacerbations are the second most frequent cause of emergent hospitalisations, accounting for 1 in 8 admissions in the UK.[4] COPD patients with exacerbations experience impaired quality of life and are at risk of repeated hospitalisations.[5] Exacerbations that require a hospitalisation are associated with increased risk of death.[4] Additionally, COPD leads to indirect costs due to loss of productivity, absence from work, and short-term disability, which can result in reduced income.[3] Exacerbations can sometimes be prevented. Early diagnosis is crucial but can be missed in the UK – according to a 2010 study in North London by Bastin et al[6], a substantial proportion of COPD patients are first diagnosed only after experiencing an acute exacerbation. Early treatment of exacerbations is associated with faster recovery and better health-related quality of life, and a potential to avoid emergency hospitalisations.[7] While evidence remains mixed, systematic reviews on the effectiveness of pulmonary rehabilitation,[8] including home-based programmes,[9] show that it improves COPD patient outcomes (such as quality of life and exercise capacity) and that such self-management programmes reduce hospital admissions.[5,10]

In the UK, interest is growing to find innovative ways to optimise COPD care and improve patient outcomes, including by using digital technologies. Increasing prevalence of the disease means that unless NHS capacity is significantly expanded, many patients will likely not receive timely services. Thus there is increased interest, in both policymaking and clinical practice, to examine the potential in using technologies that can support remote care.[11] For example, the NHS Long Term Plan flags ambitions to detect and diagnose respiratory diseases earlier and improve the efficiency of pulmonary rehabilitation and other components of the COPD discharge bundle (such as education on inhaler and medication use, self-management plan, smoking cessation support, and follow-up care),[12] including through using digital tools.[13] Improving self-management capacity and reducing the need for healthcare services could potentially also release resources for other priority health policy and clinical practice areas.[14] The National Institute for Health and Care Excellence (NICE) has recently launched a new programme of Early Value Assessment (EVA) for medtech. Two of the EVAs as of March 2024 focus on technologies supporting pulmonary rehabilitation (PR) and self-management (SM) for COPD [11,15] and the topic of virtual wards for COPD exacerbations was identified as a policy priority.[16] While these EVAs do not explicitly focus on evaluating remote monitoring functionalities of the technologies of interest (i.e. the EVAs do not focus primarily on direct information exchange between patients and healthcare professionals and remote care services), such remote monitoring functions are provided by many of the evaluated technologies.

What is technology enabled remote monitoring for COPD?

Informed by the literature, the DECIDE (Digitally Enabled Care In Diverse Environments) programme[17,18] defines TERM broadly as “the use of technology, devices or apps to help people who take up care and support to monitor and manage their ill-health, disability, or limiting long-term

physical or mental health conditions or general well-being. It also seeks to enable the remote exchange of information, primarily between a service-user and health or care professionals, and to assist them in diagnosis, monitoring and management of better health and wellbeing."
Focusing specifically on COPD, technology-enabled remote monitoring (TERM) or remote patient monitoring (RPM) for COPD have several definitions. Typically, the academic literature identifies four common components: [19–22]

1) collection of patient health data, often continuous and automatic,
2) happening at patient's home or another non-healthcare provider location, without a physical presence of a healthcare professional,
3) remote transmission of information for evaluation by a healthcare professional,
4) with a purpose of disease or health condition management.

When technologies enable remote monitoring (i.e. as opposed to remote consultations via telephone or video), they typically consist of a platform where data is stored and analysed, as well as separate interfaces for patients (e.g., available as a computer, tablet, or smartphone application) and a dashboard for healthcare professionals. Below are exemplar definitions of TERM/RPM in the field of COPD:

1. "Remote patient monitoring (RPM) enables the collection of patient health data using peripheral measurement devices or specific questionnaires about their condition without necessitating an in-person visit to obtain these measurements. Typically used in the comfort of the patient's home environment, this form of monitoring involves the real-time transfer of data to a dedicated platform where healthcare professionals can receive and/or access it."[20]
2. "Remote monitoring" /…/ "encompasses automatic continuous physiological data transmission and processing, decision support, the prediction of deteriorations, and alarming."[21]
3. "Telehealth and telemedicine encompass comprehensive interventions that provide self-management programs, education, consultation, or monitoring over a distance. In contrast, telemonitoring is a term used exclusively for distance monitoring of a patient's health components as part of a larger chronic care model."[22]
4. "Tele-monitoring involves digital wireless transmission of physiological and other non-invasive data, such as a patient's health symptoms. /…/ The information transmitted by transmitting devices is usually evaluated by healthcare professionals such as doctors or nurses."[19]

Review of technology-enabled remote monitoring in the COPD space

As part of the development of this protocol, we conducted a rapid scoping review of the literature to examine what is known about the purposes, applications and impacts of technology enabled remote monitoring in the COPD space. This review focused on key academic literature, policy documents and evaluations in the grey literature. For the academic literature, we focused on available systematic reviews and meta-analyses as well as studies from the UK identified through the systematic reviews, academic literature searches, and snowballing of references. Grey literature search focused on the UK context, and included documents from NICE, NHSE, and evaluations or reports involving one of the remote monitoring technologies used in the UK. In addition,

We summarise the evidence on the potential uses of remote monitoring for COPD below. Before doing so it is important to note a few caveats in the identified literature:

- The terms technology-enabled remote monitoring and remote monitoring are often used interchangeably in the research literature. It is therefore not always possible to make clear deductions on levels of tech-enablement (e.g. in studies that informed the systematic reviews referenced here). In addition, the distinction of TERM and other patient-supporting technologies is not always clear in the literature, as remote monitoring is often only one of the functions that are integrated in the technology.

- Remote monitoring technology for COPD is a rapidly changing and evolving field. Studies conducted several years ago are likely to describe interventions with different or lower levels of tech-enablement, and a different set of hardware and software than currently used (e.g., a set of separate sensors, information display and a modem, instead of integration in an online or smartphone app).
- The quality of the evidence base has been flagged as low in many reviews.[22–25] We did not systematically assess the quality of the evidence presented in the individual studies reported here, although we flag some of their caveats (e.g., small sample sizes).
- We focused on international reviews and UK studies. It was beyond the scope of the current work to check whether UK studies were represented in each and every (systematic) review covered.

Why, for what and how is technology-enabled remote monitoring used in the COPD space?

Technology-enabled remote monitoring (TERM) has the potential to improve COPD care and prevent exacerbations but the evidence base on the extent to which this is achieved in practice is nascent and inconclusive. A NICE EVA on digital self-management technologies identified that digital technology *could* (i.e. have the potential to) improve outcomes for people with COPD through:[14] 1) reducing the risk of an initial exacerbation; 2) reducing the likelihood of repeated exacerbations and rehospitalisations; 3) improving symptoms; 4) improving knowledge of COPD medication, exercise use, and awareness of changes and deterioration; and 5) reducing health inequalities in access and outcomes. Remote monitoring applications can be used both in chronic (regular monitoring or pulmonary rehabilitation) and acute (detection of new exacerbations and their management) COPD phases.[20] According to a review by Bourbeau et al (2020),[26] which looks at COPD care pathways more broadly and considers remote monitoring and other uses of digital technologies that can support care (such as technologies to support pulmonary rehabilitation as a treatment intervention), such technologies could be implemented across the continuum of COPD exacerbations as part of care pathways: support for chronic care (e.g., self-management interventions), domiciliary care during an exacerbation (e.g., virtual wards), and discharge bundles. According to a review by Tomasic et al (2018) and also supported by evidence in other studies, there are four opportunities/scenarios for remote monitoring of COPD patients:[21] 1) during daily activities for prediction and early detection of exacerbations, 2) during home treatment of mild exacerbations (such as through virtual wards/hospital at home), 3) monitoring oxygen therapy, and 4) monitoring exercise (including pulmonary rehabilitation).

A number of studies illustrate the potential of technologies to improve COPD patient outcomes at these different time-points in the care continuum. A range of self-management technologies, often covering multiple diseases, include functions such as personalised management plans which can support daily activities and often also include recording of outcomes, medication adherence support, exacerbation management, communication with healthcare professionals, support for exercising, trigger identification, and smoking cessation support.[14] A systematic review of early supported discharge and hospital at home models of care for patients with COPD in 2016 found a trend towards such care being associated with lower mortality and fewer readmissions as well as lower costs, although the structure of virtual wards varied considerably across studies.[27] An evaluation of remote monitoring of non-invasive ventilation (NIV) (i.e. oxygen therapy) was tested in a small retrospective feasibility study in Scotland using ResMed Lumis device for NIV and ResMed AirView technology in 2017,[26] demonstrating the feasibility of this technology. A study by Bourne et al (2017) in a single centre in the UK showed that remote, digitally-supported pulmonary rehabilitation (PR) delivered similar results to standard face-to-face programmes;[28] however, this study did not include remote monitoring in a sense of remote information exchange between patient and provider.

A range of technologies are available in the UK, offering a combination of functions, such as education, pulmonary rehabilitation programmes, subjective monitoring of symptoms, approved assessment tools, and vital signs. A review by Coutu et al (2023) found that physiological information captured by wearables or other devices include heart rate and its variability, blood pressure, respiratory rate and its variability, oxygen saturation, activity, body temperature and metabolic function, sleep metrics, and other.[20] In a systematic review of telemonitoring interventions by Jang et al (2021), oxygen saturation and symptoms were recorded the most often, followed by vital signs and spirometry.[22] Finally, in a systematic review, Hong et al (2019) noted that many remote monitoring interventions include various elements of education and exercise training, which can make it difficult to disentangle the mechanisms of change in health outcomes.[19]

Below are some examples (not an exhaustive list) of technologies with remote monitoring functions for COPD patients, that are tested, piloted or used in clinical practice in the UK:[14]

- CliniTouch Vie (Spirit Health): remote monitoring platform with patient education, subjective and vital sign tracking, and clinician dashboard for real time risk scoring. It also includes a 6-week digital pulmonary rehabilitation programme. As of October 2023, the technology was being used in in Staffordshire, with clinical use alongside evaluation.[29]
- Current Health: self-management app which includes remote monitoring functions to prevent unnecessary hospital admissions and facilitate early hospital discharge, offering clinical team capacity through a Central Monitoring Hub.
- DOC@HOME (Docobo): remote patient monitoring with vital signs collection and symptoms log, alerting healthcare professionals to critical changes, and offering self-help information for patients.
- Lenus COPD Support Service: offers standardised and personalised care plans, with an option for clinicians to activate a rescue plan when necessary. It also records patient-reported outcomes measures, and offers self-management resources, while clinicians can access a dashboard, integrating data from electronic health records, PROMs, and wearable devices. As of September 2022, it was reported by the technology provider to be used across the NHS in Scotland and as being piloted in England.[30,31]
- Luscii: self-monitoring patient-facing app, integrating monitoring devices for vital sign tracking, education resources, and possibility to contact healthcare team via the app.
- myCOPD (my mhealth): self-management platform with educational resources, prescription assessment, symptom tracking, and possibility for clinicians to remotely monitor and support patients. It also includes a 6-week digital pulmonary rehabilitation programme. In October 2023, it was reported by the technology provider to be used in 30 Integrated Care Boards, with use in the NHS since 2017.[29]
- Space for COPD: self-management structured programme of exercise, education, and psychosocial support, including possibility for clinician monitoring of patients' progress and answering posted questions. In October 2023, it was reported by the technology to be used by 73 trusts during the COVID-19 pandemic, with use in NHS since 2018.[29]

Other technologies, for instance, identified in the NICE EVA on digital self-management technology for COPD patients (2024), include Active+me REMOTE, COPDhub, COPD Predict, patientMpower, and Wellinks.[14] Further examples of technologies with remote monitoring functions in COPD include Doccla and Hailie. In many cases it is not clear how widely the technologies listed above are in routine use or in testing phases.

The evidence base for technology enabled remote monitoring for COPD

The evidence on clinical effectiveness, patient outcomes and health service impacts

Before the COVID-19 pandemic, remote monitoring technologies were not routinely recommended in the UK for COPD diagnostics or management. In 2018, NICE guidance on COPD management in adults recommended against offering routine telehealth monitoring of physiological status as part of management for stable COPD.[32] Most of the earlier, pre-pandemic studies on the clinical effectiveness of remote monitoring technologies for COPD patients did not show significant benefits over standard care. The evidence is mixed, with several of these earlier major international randomized trials of COPD remote support, such as self-management programmes including telemonitoring or telehealth (remote consultations) indicating no benefit, and others suggesting some potential benefit; for example:

1. Kessler et al (2018) did not show a statistically significant reduction in all-cause hospitalisations but did show a reduction in acute care hospitalisation days and mortality in a study in several European countries;[33]
2. Cartwright et al (2013) evaluated the monitoring of vital signs, symptoms and self-management behaviour with telehealth devices in England, and did not find a benefit for health related quality of life or mental health symptoms,[34]
3. Ancochea et al (2018) looked at daily measurement of vital signs and remote patient management in Spain and did not find an impact on the proportion of patients with a severe exacerbation, the number of exacerbations or total duration of hospitalisation,[35] and
4. Walker et al (2018) studied daily vital sign monitoring in several European countries, including the UK, and did not find an impact on time to first hospitalisation or other primary outcomes.[36]

The more recent evidence base is also inconclusive, primarily due to the low quality of studies and their mixed results, depending on the studies and outcome measures considered. For example:

- A Cochrane review conducted by Janjua et al (2021) of telehealth interventions for COPD patients, examining RCTs up to 2020,[24] on the effectiveness of remote monitoring alone or as an add-on to usual care compared to usual care alone, found that evidence of benefit was informed mostly by low quality evidence, such that it is difficult to arrive at robust conclusions. Even in areas where some benefit was shown, such as reduction of hospitalisations, the conclusion was based on a single study of moderate quality. This review included three studies from the UK (published in 2010, 2012, and 2017), none showing a benefit of the studied remote monitoring and self-management systems.[37–39]
- A 2022 review, capturing studies up to 2018, identified multiple studies on effectiveness of remote monitoring in COPD patients, but the quality of evidence was low or very low as assessed by the authors using GRADE (the Grading of Recommendations, Assessment, Development and Evaluations) tool.[25] While remote monitoring appears to be safe, it did not appear to improve health-related quality of life, frequency of exacerbations, lung function, self-efficacy, or mental health symptoms. However, in the studies included in this review, patients reported high overall satisfaction with the technology, and some (but not all) of the studies reported improved exercise capacity and lower hospitalisations and outpatient visits in patients using remote monitoring technology.
- Lack of consistent improvement across measured outcomes, with generally low quality of evidence, was found in several earlier systematic reviews,[22,23] although individual studies sometimes reported positive changes in specific health outcomes. In general, many studies are potentially too short (12 months or less) to demonstrate appropriate behaviour change leading to better disease management and reduced health care utilisation.[25]

As new technologies are being tested and implemented, evidence is still emerging. Lack of high-quality evidence showing a benefit of remote monitoring technologies for COPD patients do not necessarily exclude showing such benefit in the future. For example, a pre-post study by Cooper et al (2022) found

that the use of myCOPD app for self-management of COPD patients in remote and rural populations in the UK resulted in a trend towards reduced inpatient days and hospital admissions for patients with very high usage of the app, suggesting that outcomes could be related to the intensity of technology use (though further research is needed).[40] A small feasibility study by North et al (2020) of the same technology used in a discharge bundle pathway showed the initial results of lower re-exacerbation and readmission rates compared to standard practice.[41] In a validation study of COPD prediction algorithm by Patel et al (2021), the digital application providing early warning of imminent exacerbation based on remote monitoring of COPD patients showed initial high sensitivity and high negative predictive value.[42] A focused evaluation by Eastern Academic Health Science Network (AHSN), commissioned by NHSE, found limited evidence that virtual wards (VW) could reduce length-of-stay of hospitalised patients and could be cost-effective, when evaluating the outcomes of 46 COPD patients in VW in 2021-2022.[43]

Evidence is lacking on how technology-enabled remote monitoring (and other supportive technology to support care interventions) should be integrated within COPD care pathways to bring the best outcomes. Evidence on which patient groups would benefit from remote monitoring the most is lacking, although some remote monitoring technologies seem to be more effective among severe, post-exacerbation rather than stable, community-based COPD patients.[24] Based on expert statements, the NICE EVA on digital supported self-management technologies stated that the biggest value of remote monitoring technologies might be for moderate to severe COPD patients and patients discharged after an exacerbation, to provide insights for both the patient and their clinical care team.[11] Indeed, most of the randomised trials in a recent systematic review included participants with a history of severe COPD exacerbations, and often recruited patients hospitalised for COPD exacerbation.[22]

The evidence on implementation and cost effectiveness of TERM in the COPD pathway

Implementation and scaling up of TERM across systems, while avoiding exacerbation of existing disparities, present a challenge for successful use.[14] Published evidence on the successful adoption of the technologies focuses on factors related both to service users and service providers, as well as factors such as demography, service-user and healthcare professional skills and preferences, workload-related requirements, funding and technological considerations. To illustrate:

- According to a NICE EVA on digital self-management technologies (2024), COPD patients, who tend to be over 50 and from lower socioeconomic background, might be less comfortable and skilled at using digital technologies or having the needed devices. Implementation of a new technology might also initially increase, rather than reduce staff workload, especially if technologies are used as adjunct, rather than replacement of usual care. On the other hand, in areas of high unmet need and large backlogs of face-to-face services technologies could increase access to services such as pulmonary rehabilitation.[44]
- Based on a scoping review by Ramachandran et al (2023), major barriers to adopting digital health interventions for COPD management identified by patients include poor digital literacy, views that care delivery is impersonal, and fear of being controlled by telemonitoring of data.[45] In the same study, care providers identified barriers related to factors such as increased workload, lack of interoperability with existing health systems, lack of funding and dedicated, trained personnel as the biggest barriers.[45] The study also identified some facilitators of implementation such as improved disease understanding and management by patients, bi-directional communication between patients and healthcare providers, remote monitoring and feedback from patient perspective, and improved efficiency and training programmes from the providers perspective.[45]

In the UK, several evaluations and case studies published by NHSE or other sources describe the experience of individual adopting sites, but do not offer systematic evaluations. An evaluation of

Doctaly Assist platform, operating via WhatsApp messaging, in 33 GP practices in Lewisham, conducted by HIN South London, noted that while the users were satisfied with the technology overall, they noted a number of issues such as lack of interoperability, lack of clarity around healthcare professional's identity, and technical issues. Staff also noted the learning curve of adopting new technology, and remote assessments sometimes taking longer than face-to-face ones.[46] Further individual case studies are reported on NHSE Transformation Directorate[47] and in its Digital Playbook,[48] as well as various implementation projects, covering technologies such as Luscii,[49,50] CliniTouch Vie[51], Lenus[52], myCOPD[53] and Docobo.[54]

Evidence on the cost-effectiveness of remote monitoring technologies for COPD patients is inconclusive, partly as the clinical effectiveness and the use-case for most of the technologies is not clearly demonstrated yet. One study evaluating the cost effectiveness of a pilot telehealth (remote monitoring; BOSCH Health Buddy) program in 2018 in two primary care trusts in the UK, found it to be different across the two sites, resulting in savings of £140k in one and increase of costs of £10k in the other, with an average saving per patient per year of £1,023.[55] The study concluded that the differences were likely related to the specific setup of how the technology was introduced and applied within the team – and within the care pathway. A systematic review in 2022 found that the few studies that examined cost-effectiveness found no difference between patients using remote monitoring versus standard care.[25]

Reimagining models of care

The pressures faced by health services in England have led to a reconsideration of how traditional models of care might be delivered. This is particularly salient in the context of COPD where seasonal changes directly impact the condition and people's subsequent use of health services. Hospital admissions due to complications of respiratory illness increase sharply in the winter months[56] and this is exacerbated by further drops in temperature; of the 1.8 million bed days attributed annually to COPD in the UK, around 622,000 (34%) occur in the winter months.[57] The UKHSA's syndromic surveillance service[58] illustrates a peak in daily ambulance calls due to breathing difficulties in December/January (nearly 3000 compared to approximately 1300 in April). Furthermore, admissions quadruple in winter for patients considered to be from the lowest 10% socioeconomic backgrounds.[59]

An appetite for a more seasonal approach to the care of people living with COPD was surfaced in our consultations with stakeholders and this is echoed at an emergent policy level. For example, the NHS@home and the Clinical Policy Unit are leading on the development of an approach for chronic respiratory disease management, to enable and support ICBs to prepare for winter and beyond. It is hypothesised that identification of patients with rising risk coupled with establishing processes of care that stop or lessen exacerbations will decrease symptoms that require primary care input, ED attendance or hospital admission. The objective is to provide strengthened support for those in respiratory crises in winter through approaches which identify and support those at risk of high service utilisation. Although the work is not focused on technology-supported solutions *per se*, there is evidence (anecdotal if not supported by the published evidence described above) to suggest that TERM for COPD may play a role in achieving these objectives.

Why this evaluation is needed now and who is it aimed at?

There is some evidence that TERM in the context of the COPD care pathway can deliver benefits in practice. The published evidence and the scoping work conducted with stakeholders highlight examples of ways in which TERM benefits individuals and clinical teams: for example, individual patient testimonies of the positive impact on subjective wellbeing, as well as increased knowledge and improved self-management of the condition itself; fewer hospital admissions and home visits due to a reduction in exacerbations per patient; reduced harm from overuse of rescue pack medications. However, questions remain as to whether, when and how to introduce remote monitoring

technologies into the COPD care pathway, for whom and why. A variety of products and services are on offer that largely provide similar functions and yet are implemented in different ways, for different cohorts of patients, for different amounts of time, and maintained within different kinds of staffing models. These models are site-specific and sometimes involve highly tailored versions of the technology, which leads to questions around scalability, long-term interoperability, and transferability of understanding about how the TERM is working and for whom. This is connected to a lack of clarity around what the technology is perceived by clinical teams and patients to be 'for'. Technologies involved in TERM for COPD are typically multi-component or are 'bolted on' to other technologies in order to offer a richer user experience of self-reported physiological data capture, education, pulmonary rehabilitation, data visualisation, clinical interaction, for example. Picking apart the active ingredients in these technologies and understanding what makes them 'work' in the context of patient behaviour change and embedding in clinical teams is challenging and is an important part of developing a better understanding of the role of TERM in the COPD care pathway.

Our review of current evidence, alongside scoping discussions with key stakeholders have flagged a series of key challenges that include (but are not limited to):

1. A diverse and evolving technology market that can be challenging to navigate, offering different technical capabilities and associated services, and bringing potential infrastructural challenges (e.g. in relation to interoperability). The evolving technical capabilities and ever-increasing range of products and services in this space brings challenges in establishing a consistent plan and stable service model. In addition, tailored, site-specific monitoring capabilities tend to be used within one service model, and sustaining this (while recognising the need for evolution of both services and technologies) brings complexities to planning and providing technology-enabled services and challenges the development of transferable understanding of how TERM for COPD 'works'.
2. A high degree of organisational variation in the introduction, delivery and maintenance of TERM in the COPD care pathway. Services may be developed and led by motivated individuals or, conversely, by established and multi-skilled pre-existing monitoring hubs. TERM may be initiated, and patients onboarded, by clinicians or support staff connected to the supplier of the technology. Patient interaction with TERM may depend on self-escalation in the context of deterioration but this is not always the case.
3. Unclear objectives in the usage of TERM for COPD mean that technology is sometimes introduced into a care pathway to achieve a broad aim of supporting symptom management. Unfocused implementation may impact on coherence of care and transferability of learning across settings, which leads to limitations and inconsistencies in evaluation methods and in developing a local business case to maintain technology-enabled remote monitoring for COPD patients.
4. A desire to move TERM beyond being about data collection tools. There is a aspiration to bring about system-wide change for those wanting to embed TERM for COPD in the wider respiratory care landscape, particularly across inter-organisational boundaries. However, this is challenging. New ways of working, using data gathered using TERM to connect to Acute Respiratory Hubs, Virtual Wards and the patient record are strongly perceived as being a key objective in the medium- to long term. However, scoping discussions have also given a very strong steer that the preconditions, resources and the mechanisms for change to achieve this need to be better understood in order to deliver quantifiable benefit, particularly in relation to reducing pressure on primary care services.
5. Limited knowledge of the subjective patient experience of using TERM for COPD and how this relates to the 'active ingredients' of understanding how TERM works and for whom.
   Similarly, we have limited knowledge of the 'hidden work' involved in using TERM for COPD by staff, patients and caregivers alike. Stakeholder consultations have indicated the extent of

notional work that goes into setting up and managing TERM for COPD in clinical settings and the heavy reliance on 'soft' skills such as relationship building and negotiation.

6. Limited knowledge of who might want to use TERM for COPD but is not offered/able. There is evidence of some degree of clinical gatekeeping when it comes to selection of patient suitability for accessing TERM. Similarly, equity of access is typically considered in terms of digital literacy. There is a need to avoid a technosolutionist approach to the introduction of TERM to COPD patients: a consistent message in the stakeholder consultation work focused on the need to increase awareness of TERM amongst the digitally competent, easing pressure on services and subsequently allowing staff to support patients who simply do not want to use a remote monitoring system. Furthermore, questions remain around what TERM solutions exist for those with dexterity or cognitive challenges.

Given current priorities in health to support ICBs to prepare for winter crises through practical and proactive approaches to identify and support those at risk of high service utilisation, and the potential benefits of TERM to achieve this objective, the need for further evaluation on this is urgent.

Evaluation Plan

Aim, objectives & research questions

The aim of the proposed evaluation is to define good practice in the implementation and use of technology-enabled remote monitoring in the COPD care pathway and draw transferable lessons that can inform spread and scale up. The objectives are as follows:

1. To develop a rich picture of technology-enabled remote monitoring of patients with COPD.
2. To surface, explore and interpret the interacting influences on sustained use of such service models in respiratory care.
3. To provide a deeper understanding of staff and service users' experiences using and supporting use of technology-enabled remote monitoring of COPD.
4. To explore the potential value of technology-enabled remote monitoring of COPD for services and service users.
5. To capture and disseminate learning to inform planning for 2024/25 winter pressures, for services and service users.

Underpinning research questions for the evaluation are:

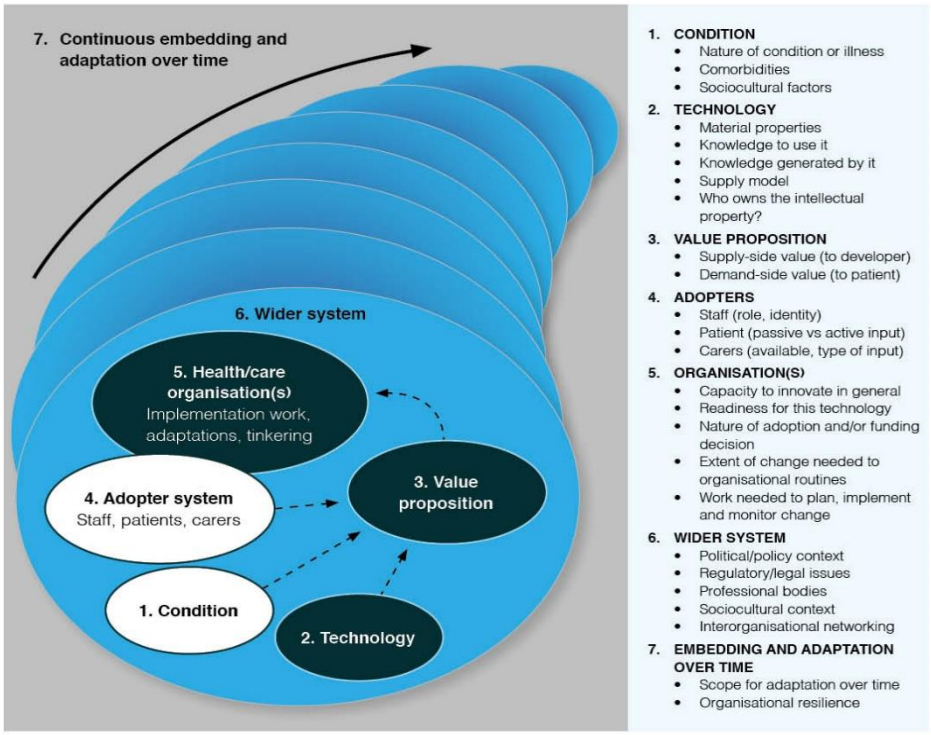
1. How where, why and by whom is technology-enabled remote monitoring being used in the COPD care pathway, who is it for and how does it help provide care to service users?
    a. To what extent does implementation of TERM in the COPD pathway require proactive identification and proactive monitoring to help identify early signs of deterioration and prevent escalation?
    b. What can we learn from implementation of TERM in different patient populations (e.g., those at highest risk of exacerbation versus those recently diagnosed or clinically stable)?
    c. In what ways does implementation of TERM support digital pulmonary rehabilitation technologies and/or digital technologies for patient self-management of COPD?
    d. What might be the key mechanisms of action in TERM for COPD: e.g., measurement of vital signs, patient education?
2. What can we learn from implementation and use of existing TERM (by patients and clinicians) that can inform potential rapid take up and use in the context of winter planning, and beyond?
3. What impact and value does TERM have in the COPD care pathway, and how could this be locally evaluated and monitored in the future?

Study design & methodology

Evaluation approach

The study is positioned in the tradition of developmental evaluation, an emergent, flexible approach to evaluating an initiative that captures data that can be fed back to the people leading the initiative to inform ongoing developments and adapts to the particular needs and challenges of the service change.[60] Given that TERM for COPD is an emerging and evolving model within respiratory care, and includes diverse approaches and technology providers, our focus will be on building a detailed picture of how such technology is used and becomes embedded within health care ecosystems. Working in partnership with four study sites in England (respiratory teams using TERM for COPD), we will conduct a rapid exploration of the influences on the implementation, adoption, use of TERM in the COPD care pathway - and potential for spread, scaling up and sustainability - and draw transferable lessons for policy and practice. We will work collaboratively with stakeholders in each setting to support mutual learning about how the technology impacts quality of care and service-level outcomes, and the organisational changes needed to achieve sustained adoption at scale.

Data collection will be informed by the NASSS (non-adoption, abandonment and challenges to scale up spread and sustainability) framework.[61] The NASSS framework was developed by our team as an analytical tool to surface and explain the challenges and complexities in technology-supported service change.[62] It includes seven interacting domains: the condition or illness, the technology, the value proposition, the adopter system (intended users), the organisation(s), the wider system (especially regulatory, legal and policy issues) and emergence over time (see Figure 1 below). These domains will guide data collection (including interview schedules and sampling strategy), thematic analysis and cross-case comparisons. The approach will enable a rich picture of each site's experience and how TERM for COPD is experienced by respiratory teams, allied professionals and patients. Qualitative data collection will be conducted with staff, patients, informal carers and other key stakeholders, in order to provide detailed insights into different perspectives and experiences of the technology within routine practice.



Note: Adapted from Greenhalgh T, et al. 'Beyond adoption: a new framework for theorizing and evaluating nonadoption, abandonment, and challenges to the scale-up, spread, and sustainability of health and care technologies'.[1]

Figure 1: NASSS framework

Study design and methods

This rapid evaluation will take a multi-site qualitative approach to understanding the factors that influence the implementation, adoption, use and embedding of TERM for COPD. This will include recruitment offour study sites (potential sites described below). The evaluation will involve service users and staff participating in interviews/focus groups and codesign workshops.

Data collection will comprise two consecutive phases. Figure 2 privides an overview of both pahses, with detail of each provided in the sections below.

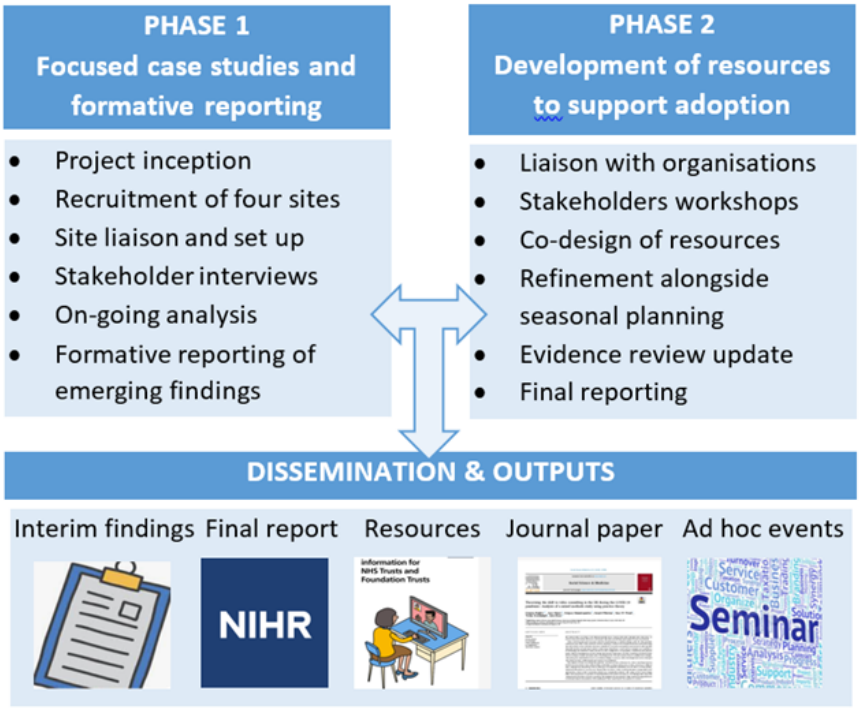


Figure 2: Overview of evaluation phases and work involved

Phase 1: Focused case studies and formative reporting of emerging findings to inform winter planning (May/June 2024)

Phase 1 will include preparatory work for the rapid evaluation, including project set up, establishing key lines of liaison with the study sites, and establishing a PPIE and project advisory group. The main focus of work in this phase will be collection and analysis of qualitative data with key stakeholders from sites actively using varied approaches to TERM for COPD and with representatives from patient-facing organisations/groups.

Case site sampling

The case study sites will include health settings where TERM for COPD is being or has been previously implemented as part of service transformation. Case study sites will be selected in consideration of our aim to learn from a range of organisations that have incorporated TERM in the COPD care pathway and/or who can provide scope for informing winter pressures planning. To this end we will seek out a purposive sample of sites with variation sought with regard to the type, scale, delivery and maturity of TERM being used, extent of adoption and experience with the technology (e.g. early use versus routinised in service delivery); health care setting; and target user populations (e.g. patients at highest risk of hospitalisation or exacerbation versus recently diagnosed or clinically stable), with inequalities being a key theme of interest.

Through scoping work we have already explored a range of possible sites that meet the above sampling criteria, facilitated by various networking channels, including the DECIDE Steering Committee and Internal Advisory Group, regional Health Innovation Networks, the NHSE/Lung Health@ Home team, and professional networks. In total, we have engaged with 9 sites regarding current set up and potential participation as case study sites. These engagements have highlighted the diversity in approaches to TERM in the context of COPD, encompassing variation in models of implementation and management. There is variation in the type and use of technology (even in how the same technologies are used in different settings, utilisation of the workforce, how they connect with wider health systems, and the maturity of embedding of the model. From these discussions, we have identified the following four candidate sites that are actively using TERM in the COPD care pathway and have expressed interest in participating in the rapid evauation work.

1. Soar Valley Primary Care Network, where they are investigating the feasibility and acceptability of TERM in high-risk patients treated for COPD in primary care. Conducted as a 'Case for Change', the project is a collaboration between Adherium Europe Limited (a digital smart inhaler company), Helicon Health Ltd (a medical technology development company), clinical investigators based at Soar Valley PCN and NHSE Lung Health at Home. The two main facets of this approach will be the implementation of Haillie, a smart inhaler device to measure medication adherence and technique. In addition, it will include the implementation of a digital app which will allow early access to pulmonary rehab for patients that are awaiting PR or top up therapy for those who have already undertaken it. It intends to focus on supporting and embedding behaviour change in order to improve medication adherence in a range of patients, from those who are newly diagnosed to those living with the condition for a number of years. This is a small-scale feasibility study with patient data being used to inform scheduled face to face meetings between the patient and their respiratoty team (our team is already aligned and in discussion with the group conducting that study which will be complimentary to the planned evaluation).

2. Bristol, North Somerset and South Gloucestershire Integrated Care System (ICS), where TERM for COPD is currently being introduced for the first time through a cross-organisational approach which involves collaboration between NHS Bristol, North Somerset and South Gloucestershire ICB, Sirona care & health, North Bristol NHS Trust (NBT), University Hospitals Bristol and Weston Foundation Trust (UHBW), One Care and NHS England, together with technology partners Doccla and My mHealth. Around 9,000 people will be invited to download the myCOPD app and remote monitoring equipment will be provided to the most vulnerable patients. The pilot is expected to run for around six months (January-June 2024) and has a particular focus on informing a seasonal approach to COPD care and winter pressures planning.

3. NHS Dorset, where TERM for COPD was introduced into the COPD care pathway by the Digital Access to Services at Home (D@SH) team to support patients with self-management in the form of self-report of physiological data and structured education. Patients were offered lifetime access to the myCOPD digital app as part of a self-escalation pathway, with the service being offered as a 'remote management' rather than a remote monitoring system. However, the implementation of the service has surfaced important and transferable considerations around workforce gap analyses, remote monitoring in practice, integration with wider digital skills and services initiatives and, crucially, around interoperability and provision of equitable care. The D@SH team are in the process of developing an overarching and bespoke remote monitoring system for people with COPD which they believe can better meet the needs of patients and clinicians.

4. Airedale NHS Foundation Trust, which has a long history of digitising patient services and provides the MyCare24 COPD remote monitoring service via a Digital Care Hub. The service commenced in

2018 and supports patients living at home wth severe or very severe COPD. Service users record their daily oximeter readings measuring blood oxygen saturation levels and pulse rate readings into Luscii, a digital app. Data entered into the app is automatically transmitted to the DCH and monitored by Band 6 Clinical Assessors, supported by Band 3 Health Care Assistants who are responsible for onboarding patients and taking first-line calls into the hub. Abnormal readings trigger an alert and prompt follow-up with the service user. As of March 2023, over 2000 patients had been onboarded to the service across two Acute Trusts and comparison of the six-month period prior to their service referral to the six months post referral demonstatred and overall decrease of 31% in A&E attendances; numbers of non-elective admissions with a respiratory condition as the primary diagnosis decreased by 48%; on a per patient basis, the likelihood that an individual patient was admitted with a respiratory diagnosis also decreased by 43%. Qualitative feedback indicates that both service users and service providers perceive the MyCare24 COPD service as highly effective, preventing escalation to secondary care. However, there are staffing and capacity issues associated with running the service, and further key barriers include challenges with the onboarding process, language, literacy, and digital exclusion.

We have confirmed expressions of interests to participate in the evaluation from all four of the sites listed above. As we shift into Phase 1 of the work we will discuss site selection with the policy customer in consideration of winter planning work and then make a final decision on site selection. We are also in touch with a further 5 sites (via our initial scoping work) and have collected information via our professional networks about a wider group of sites using TERM in COPD. Hence if one of the four sites above withdraws or is not suitable for evaluation, we will seek to quickly recruit another site from this pool.

Data collection and analysis

Qualitative data will include virtual/telephone data collection (interviews or focus groups) with up to 24 staff and system stakeholders (estimated 4-6 in each site) to explore the (inter)organisational resources, processes and challenges to implementation. Data collection may be conducted in pairs/groups where appropriate (e.g. colleagues within the same team). We will use a combination of purposive and snowball sampling, initially connecting with teams (many of which we are already in touch with via scoping work) via the lead clinician and/or staff members involved in setting up and/or running the technology-enabled remote monitoring service, and then 'snowballing' from there (asking interviewees who else we should be speaking to) to explore emerging topics and fill in knowledge gaps where necessary. Where relevant we will ask interviewees to share relevant service documents (e.g. business case, protocol, audit or evaluation reports) to aid understanding of the adoption and use of TERM in each service.

We will conduct qualitative interviews (virtually/ by telephone) with up to 10 service users to understand the lived experience of technology-enabled remote monitoring in the COPD space, how it helps them (or not) in their everyday lives, and concerns and/or unintended consequences for the individual and/or their formal and informal networks of care. A key element will be to capture the challenges for users with complex support needs and issues associated with inequalities in access, use and support. Recruitment will be supported by NHSE Patient and Public representatives (drawn from the Strategic Co-production Group, the Personalised Care Group and the Respiratory Patient and Public Voice Group; allof which we are already in touch with and have fed into this aspect of the work). Qualitative data will be analysed using constant comparative analysis,[63] and will be guided by the NASSS framework (see Figure 1).

Key outputs from this phase: emergent findings intended to inform 2024 winter pressures planning. This will likely take the form of (i) an overarching, tabulated description of existing technologies, including, but not limited to, functionality, where implemented, for whom, and any information

relating to evaluation; (ii) theoretically-informed analysis of case study qualitative data; (iii) cross-case synthesis to surface key recommendations.

Phase 2: Development of resources to support adoption and use of TERM in COPD care pathways (June/July 2024)

Working with an applied design agency (Design Science, www.designscience.org.uk), and building on a set of existing resources the team has previously developed to support technology-enabled health care, we plan to develop co-designed resources (freely available, adaptable and web-based) that can support set up, access to and/or use of technology-enabled remote monitoring in the context of COPD care pathways. Buidling on our experience with co-design in the context of remote and technology-enabled care,[64] the exact focus of resources will be informed by the co-design process and in discussion with the LungHealth@Home team as they review emerging findings from Phase 1, consider TERM pathways for COPD and seek experssions of interest from sites.

We plan two stakeholder workshops, one with service users (patients and, where relevant, carers) and one with health professionals/providers and decision makers (including, but not limited to, members of the LungHealth@Home team), sharing learning and refining (and, where feasible/relevant, extending) insights from Phase 1 to guide thinking and discussion on the use of different kinds of technology and ways of monitoring in COPD pathways and the challenges and potential benefits of this across different groups of service users. Guided by discussions with the DECIDE User Advisory Group, and with specific input from the NHSE Patient and Public representatives (drawn from the Strategic Co-production Group, the Personalised Care Group and the Respiratory Patient and Public Voice Group – all of whome we are already in touch with) together with the project PPI representative from National Voices, we will also focus on issues of equity of access and use of digital technologies for those potentially accessing services in the context of winter pressures. A focus on equity of access links with DECIDE's cross-cutting theme of inequalities. The aim here is, not only to ensure a breadth of service user voices are included within evaluation, but also facilitate access to technology-enabled remote monitoring where relevant and helpful for service users in ways that support equity and address wider concerns relating to digital inequality.

For the service user workshop, we will seek a range of experiences of COPD, and COPD services, along with use (and potentially non-use) of technology to support access and use of COPD-related monitoring and wider services. We will work with our PPI representative from National Voices, along with NHSE patient and public representatives (see above) and case study sites from Phase 1, to identify and recruit a diverse group of up to 20 services users (including patients and, where relevant, carers). Following a similar approach that we have used in previous work, and working closely with Design Science colleagues, we will post on social media to seek wider/diverse input if/as needed. We have a dedicated PPI budget for this work, and will recompense participants for their time and costs in line with standard INVOLVE rates. For the stakeholder workshop with healthcare porviders/system leaders, we will seek input from the LungHealth@Home team, Phase 1 case study sites and other providers adopting or actively using technology-enabled remote monitoring in COPD pathways (identified via initial scoping work, see above).

Workshops will be online to facilitate access, follow a similar format, and be facilitated by Design Science, an applied design company that we have been working with during/beyond the pandemic to develop a suite of resources on technology-enabled care and remote/video consulting (see www.phc.ox.ac.uk/research/resources/video-consulting-in-the-nhs for examples).

Extending this previous work (and making use of existing visuals, formats and layouts, wherever helpful and feasible – particularly important given the speed of the project and this phase of the work), we will now focus specifically on use of technology-enabled remote monitoring in the COPD pathway.

In line with the co-design process, and guided by the emerging findings from Phase 1, the exact focus of resources will by informed by on-going discussion with users and providers, and be targeted at supporting feasible and equitable access to COPD remote monitoring as this is taken by sites in the context of winter pressures. At this stage, we anticipate that this might involve: (i) **using patient/service user narratives and experiences from Phase 1** (as a starting point to follow patients' learning journey from 'not knowing about' technology-enabled remote monitoring to 'knowing and using' different technologies and services, (ii) **understanding this learning journey** in more detail, highlighting and discussing problems that people encounter before and during different technology-enabled remote monitoring services; (iii) using case study findings from Phase 1 to **appreciate the options available for technology-enabled remote COPD monitoring and development**; (iv) developing initial visuals and branding, and agreeing resources that will be most helpful (e.g. patient quick guide, or set up guide for providers); (v) **producing resources, refining these virtually with service users and providers** and ensuring compatibility with multiple devices (also potential for hard copy versions, where relevant). We will make web-based resources **freely available** (e.g. via NHSE), **and disseminate via existing networks** (e.g. QCommunity). In previous work we have worked closely with NHSE/I Comms Team to ensure wider dissemination (e.g. via FutureNHS) and will do the same with this.

Key outputs from this phase: co-designed resources to support take up of technology-enabled remote monitoring services for COPD service users; final report and consideration of a second 'follow up' phase of evaluation focused on implementation of TERM models of care and learning from these to inform wider spread and scale up.

Anticipated outputs, impact and plans for dissemination

We plan a series outputs tailored for different audiences and purposes.

Reporting

In line with NIHR requirements, we will produce a final report with an executive summary. This will include narratives based on the qualitative data, summative findings and key recommendations for policy, practice and future evaluations. We will produce an interim report for internal use, with the specific purpose of sharing emerging findings from Phase 1 with the policy customer. Patient- and/or clinician- facing materials will be produced as an output to the codesign workshops.

Public

The final report and executive summary will be freely available through the DECIDE website. A lay summary will also be produced and made available on the website with the support of the project PPIE group. Patients will have access to the materials produced as an output to the codesign workshops.

Policy makers

We will build interest and raise awareness more widely about the project from the outset (e.g. project pages on website; social media; using our networks and governance structures to help raise awareness; early communications with NHSE as the policy customer, NIHR, and study site contacts). We will inform ongoing national strategy in technology-enabled remote monitoring of COPD, including feeding into winter pressures planning for 2024/25, as well as regional/local strategy for monitoring and evaluation.

Service providers

We will feed back and report to study site teams on service use, impact and experience. In addition, the findings and study site narrative documents will provide insight and learning for respiratory care services more widely, helping them establish strategic and business cases for the scale up and sustainability of technology-enabled remote monitoring for COPD.

Researchers / evaluators

At lease one open access publication plus conference presentations.

Project timelines

A detailed breakdown of the timeline is provided in Table 1. Groundwork for the project began in March 2024, with protocol submission in April 2024 and the main phase of the rapid evaluation then taking place over three and a half months (mid-April to end of July). Table 1 includes additional time following the end of the project and final reporting to: (a) continue dissemination, (b) consider potential further evaluation, and (c) release final co-designed resources in coordination with wider dissemination and further seasonal planning on the part of the LungHealth@Home team.

Table 1: Project timeline

	Mar	Apr	May	Jun	Jul	Aug	Sep
Groundwork and protocol development							
Rapid evidence review relating to TERM in COPD	x	x					
Consultation with key stakeholders	x	x					
Set up and liaise with PPIE representatives	x	x					
Develop sampling strategy/engage potential sites		x					
Develop and submit protocol (17 April)		x					
Develop project web pages							
Establish Advisory Group		x					
Phase 1: Data collection and interim reporting							
Confirm site selection x 4			x				
Interviews/data collection across sites			x	x			
On-going analysis (using NASSS framework)			x	x			
Maintain spreadsheet of sites using TERM for COPD			x	x			
Recruitment and planning for Phase 2			x	x			
Interim (internal) report to policy customer				x			
Phase 2: Co-design resources and final reporting							
Hold co-design workshops (x 2, online)							
Draft and refine resources, with Design Science				x	x		
Update rapid evidence review					x		
Final report (NIHR format, mid-August)*						x	
Write lay summary, update web pages					x	x	
Ad hoc dissemination (seminars, conferences etc)			x	x	x	x	x
Consider potential next steps in evaluation					x	x	x
Final refinement and release of resources							x

* NIHR final reporting is required 2 weeks after project end and typically consists of a single research article of up to 8000 words (in most cases this standard research article format is sufficient, but there is an opportunity to explore an extended research article if needed).

Project management and quality assurance

Project management

We see project management as an important and continuous effort, and have established staff roles, processes and structures to support effective delivery.

The project leader at University of Oxford (Dr Nikki Newhouse) will lead on ensuring effective delivery to time and budget and will be supported with designated project management and administration support at University of Oxford (Dr Julie Darbyshire, Mrs Charlotte Thompson-Grant and wider administration support in the unit at Oxford) and research assistant support at RAND Europe (Ms Hampton Toole). Overall project delivery will also be supported by oversight by centre leads for DECIDE at RAND Europe (Dr Sonja Marjanovic) and input from Oxford (Prof Sara Shaw).

We suggest regular intervals between the DECIDE Team and policy customer (NHS England) to update on the progress of the project and next steps (through monthly catch-up calls with NHS England). In addition we will establish an advisory group for this project, comprising repsentatives from the policy customer (NHS England), the National Institute for Health and Care Excelence EVA team and at least one individual from our steering committee with particular expertise and experience relevant to this project. We are happy to discuss with NIHR whether they would like to participate as an observer in these meetings. Our service user advisory group for this evaluation will comprise representation from the DECIDE user advisory group and will be complemented with PPIE representatives with particular experience with COPD. We will maintain open lines of communication with NIHR and NHS England throughout the project.

Both RAND Europe and The University of Oxford are experienced in delivering projects of this nature. The direct team will be supported by a robust infrastructure that includes appropriate policy documentation and procedures that underpin all aspects of academic activity.

We also apply additional management processes including (butnot limited to): an internal kick-off meeting, to review the project plan for ensuring high quality and timely delivery; and internal team meetings and catch-ups, ensuring clarity in team roles and responsibilities and good internal communication, and maintaining a project vision.

Quality assurance

RAND Europe and Oxford have rigorous QA processes, enabling all project deliverables to be reviewed by QA reviewers not involved in the project. For QA, DECIDE will draw on either our internal advisory group or other senior researchers at RAND and Oxford not involved with the project, and potentially Steering Committee members with relevant expertise. All deliverables will only be cleared for release if they meet DECIDE's QA standard. Engaging with the user advisory group, internally advisory group and steering committee as part of wider DECIDE structures will provide an additional continual layer of quality assurance.

Plans for service user and public involvement

We have via the DECIDE user advisory group and conversations with PPIE representatives as part of the stakeholder consultation work received inputs that will inform topics the evaluation will explore, in particular those related to understanding the service users and carer perspectives, and issues of equity. As outlined above, we have specific PPIE support, drawn from the DECIDE service user advisory group, intended to address knowledge or experience gaps on the topic. Service user and public involvement is a core component of this evaluation and given the scope and speed of this evaluation,

we will endeavour to use patient/service user narratives and experiences from Phase 1 to inform the design of materials to use in subsequent workshops to ensure relevance and accessibility, and in dissemination.

The protocol has also been reviewed by a member of the user advisory group.

Research team

Team member	Role/contribution	Relevant expertise
Dr Nikki Newhouse (University of Oxford)	Overall project lead providing topic, method, and team leadership. Project conception, design, data collection, analysis and synthesis, including oc-design; writing of reports/dissemination, project management	Expertise in conducting qualitative and embedded research and evaluation with service users and clinical teams, including co-design to inform technology-enabled care.
Prof Sara Shaw (PI for Decide, Professor at Oxford University)	Project conception, design, analysis and synthesis, writing of reports/dissemination. Support and mentoring to project lead.	Highly established academic bringing expertise on technology-enabled health care, qualitative, case study and mixed methods design and delivery, and knowledge exchange/impact. Experienced in rapid evaluation and oversight of large research projects and evaluations; overall oversight of all projects under NIHR DECIDE centre.
Dr Sonja Marjanovic, DECIDE Lead at RAND Europe (Senior Research leader in Health and Wellbeing, Director of healthcare innovation, industry and policy portfolio)	Provide support throughout the evaluation. Project conception, design, analysis and synthesis, writing of reports/dissemination	Experienced in health services and healthcare innovation research and evaluation of complex interventions; wide ranging portfolio of work on role of innovation in service delivery; experienced in leading large and rapid projects involving public, third sector and industry stakeholders and collaborative research partnerships.
Dr Agne Ulyte (RAND Europe)	Data collection, analysis and synthesis; literature review; writing of reports and wider dissemination.	Experience in health services research, including telehealth use for chronic disease care.
Dr Jackie Van Dael (University of Oxford)	Data collection, analysis, writing, and co-ordination of codesign aspects of the evaluation.	Expertise in qualitative and participatory approaches to health service evaluation, with a focus on digital innovation, patient experiences, and equity.
Ms Hampton Toole, Analyst (RAND Europe)	Data collection, and analysis. Writing of reports and wider dissemination, plus administrative support	Experienced in health technology research, understanding landscape for innovation in health services and analysis of policy initiatives.

Dr Julie Darbyshire (University of Oxford)	Project Management and PPIE liaison	Experienced in academic project management including multi-site international drug trials, large data analysis studies, and use of digital tools to support healthcare management and delivery. Has led patient/carer stakeholder work packages in a number of NIHR funded research projects.
Ms Charlotte Thompson-Grant (University of Oxford)	Project Co-ordination and PPIE liaison	Experienced in academic administrative processes including contracting, budget monitoring, meeting logistics, and liaison across teams.

Ethical, regulatory and governance considerations

Risks and their management

Ethical issues and required approvals

We will submit a classification request to the Research Governance Ethics and Assurance (RGEA) team at the University of Oxford (sponsor) to confirm the appropriate approval process. This will either be classified as (a) service evaluation that does not require research ethics approval, (b) research not requiring NHS HRA ethical approval, or (c) research requiring NHS HRA approval.

(a) Service evaluations are within the remit of the organisation commissioning the evaluation. In this situation we would expect to put agreements in place at each site participating in this piece of work. These agreements will cover expectations with regards to site and DECIDE team activities, responsibilities, and data access and use.

(b) Research projects that do not require NHS HRA approval will be submitted for review by the Central University Research Ethics Committee (CUREC) in Oxford. Individual site agreements will also be required.

(c) Research projects that require NHS HRA approval require an Integrated Research Application System (IRAS) application, and subsequent NHS R&D review/approval.

We anticpate that the project will be classified as service evaluation, which is in line with classifictions of prior DECIDE rpaid evaluation projects. This will faciliaite the rapid timeline required for the project (see Table 1).

In line with the above the DECIDE Programme Manager will contact the relevant local research and development (R&D) offices at each site where evaluation activities will take place for advice regarding the local requirements for approval and/or registration of service evaluations. As required, we will put agreements in place with individual sites participating in this piece of work. These agreements will include clauses that cover activities to be undertaken at the site, including (but not limited to) recruitment of participants, transfer of funds, physical access to the site, and access (and use and subsequent storage of) data required to support outcome findings.

The Investigator will submit and, where necessary, obtain approval from the above parties for all substantial amendments to the original approved documents.

Informed consent

All participants will have capacity to provide informed consent. The participant must personally sign and date the latest approved version of the Informed Consent form before any study specific activities are undertaken.

Written and verbal versions of the Participant Information and Informed Consent will be presented to the participants detailing the nature of the study, what it will involve for the participant, the implications and constraints of the protocol, and any risks involved in taking part. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, and with no obligation to give the reason for withdrawal.
The participant will be allowed as much time as wished to consider the information, and the opportunity to question the study evaluation team or other independent parties to decide whether they will participate in the study. Written Informed Consent will then be obtained by means of participant dated signature and dated signature of the person who presented and obtained the Informed Consent. The person who obtained the consent must be suitably qualified and experienced, and have been authorised to do so by the Chief/Principal Investigator. A copy of the signed Informed Consent form will be given to the participant. The original signed form will be retained at the study site.

During the course of the study a participant may choose to withdraw early at any time. This may happen for several reasons, including but not limited to:

- The occurrence of significant distress during study interviews
- Inability to comply with study procedures
- Participant decision

Discontinuation/withdrawal

Participants may withdraw their consent at any time. Options for participants wishing to withdraw will be explained in the information sheet.

1) Participants may withdraw from all study communication but allow the study team to continue to access their medical records and any relevant data that has been recorded as part of routine standard of care and is held by the study team; i.e., disease progression data, routine patient reported outcome data and quality of life questionnaire data etc.

2) Participants can withdraw from the study but permit data obtained up until the point of withdrawal to be retained for use in the study analysis. No further data would be collected after withdrawal.

3) Participants can withdraw completely from the study and withdraw the data collected up until the point of withdrawal. The data already collected would not be used in the final study analysis*.

*In cases where data have already been incorporated into analysis it will not be possible to exclude these data. It is also not possible to exclude data collected from any group discussions as an individual's data will likely be directly related to that of other participants.

The reason for withdrawal by researcher (and by participant, if this information is volunteered) will be recorded in a study file.

Data management and storage

Data Recording and Record Keeping

Datasets collected and collated for this service evaluations will include:

- Observational and ethnographic data from on-site field work. These will be primarily field notes, either completed in digital form at the time or hand-written and transcribed into digital format by the research team at a later date. It is possible this dataset could also include photographs and diagrams. It is difficult to be explicit about the volume/scope of these data but likely to be the equivalent of up to ~50hours of observation. Fieldwork data will be collected by a small number of the DECIDE centre team (~4/5). The resulting data files will be available for analysis by a larger number of people from the DECIDE centre team (~10). Electronic files will be saved on password-accessible areas of the University of Oxford network and remote access to these files will be granted to members of the DECIDE centre team as required for analysis and reporting purposes.
- It is likely that the research team will interview participants about their use of the technology under evaluation. These will generate interview recordings which may be audio only (conducted using digital recorder devices or Teams/Zoom), or audio-visual (e.g., Teams or Zoom). If transcription is required, these recordings will be transferred to professional transcriber services (using services and processes approved by the University of Oxford). During the transcription process any identifying information will be removed. Files for analysis will therefore be considered pseudonymised. The team will need to collect contact and basic demographic data from participants. The demographic data will be stored alongside a project ID and will not be directly linked to an individual's contact details. Again, it is difficult to be precise about numbers of people who will be interviewed but likely numbers would be 10-15 people per evaluation. Interview data will be collected by a small number of the DECIDE centre team (~4/5). The resulting data files will be available for analysis by a larger number of people from the DECIDE centre team (~10). Electronic files will be saved on password-accessible areas of the University of Oxford network and remote access to these files will be granted to members of the DECIDE centre team as required. The original recordings will be deleted when transcribed files have been checked and there is no further need for the original recording.
- DECIDE will also collect contact details for key personnel involved in the evaluation where this information is required to arrange site activities or similar. This will consist of name, email address, and phone number. These data will be stored in the University of Oxford network files and remote access will be granted as required to those within the DECIDE team.

Data will be collected and stored in accordance with the University of Oxford (Sponsor) data policies. The University of Oxford requires all projects to register project data sets as 'information assets'. The DECIDE programme reference is IAR 561. This register supports obligations under General Data Protection Regulation (GDPR) and links to 'data protection by design' policies which include initial screening to confirm the level of data protection documentation required. Results of the screening will indicate that either a Data Protection Assessment (DPA) or, for data sets that include special category data, or where activity is likely to result in high risk to those individuals whose personal data are being processed, a Data Protection Impact Assessment (DPIA) form needs to be completed.
Any data generated from this piece of work will be processed in line with this protocol and stored in secure environments at the University of Oxford and RAND Europe. These secure environments are hosted within each institution and are accessible through a dual-authentication password process. As the primary award holder, the University of Oxford will act as the data controller for DECIDE. The University of Oxford data storage servers will therefore be the primary repository for all data. Members of the team who are employed by RAND Europe will be granted remote access to these files. As per any data storage clauses in the individual site agreements, RAND Europe may also store data files pertaining to this piece of work.

Participant Confidentiality

The study will comply with the General Data Protection Regulation (GDPR) and Data Protection Act 2018, which require data to be de-identified as soon as it is practical to do so. The processing of the personal data of participants will be minimised by making use of a unique participant study number only on all study documents and any electronic database(s). All documents will be stored securely and only accessible by study staff and authorised personnel. The study staff will safeguard the privacy of participants' personal data.

Access to data

Data will be accessible to the immediate team. This includes employees of The University of Oxford and RAND Europe who will be collecting and analysing the data for this evaluation.
Direct access to the data will also be granted as required to authorised representatives from the Sponsor or host institution for monitoring and/or audit of the study to ensure compliance with regulations.

Archiving

Identifiable personal data will be deleted as soon as it is practical to do so. De-identified (pseudonymised) data will be stored for a minimum of three years after the end of the project in line with University of Oxford data management and storage policies.

Sponsorship, indemnity and insurance

The University of Oxford will act as the main sponsor and guarantor for this study.

The University of Oxford maintains Public Liability and Professional Liability insurance, which will operate in this respect.

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