NICE National Institute for Health and Care Excellence

Evidence generation plan for digital technologies to deliver pulmonary rehabilitation programmes for adults with COPD

Implementation support

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1 Purpose of this document

NICE's assessment of digital technologies to deliver pulmonary rehabilitation programmes for adults with chronic obstructive pulmonary disease (COPD) recommends that myCOPD can be used in the NHS while more evidence is generated, to deliver pulmonary rehabilitation programmes for adults with chronic obstructive pulmonary disease (COPD) who cannot have or do not want face-to-face pulmonary rehabilitation. Other technologies considered in the guidance can only be used in research and are not covered in this plan.

This plan outlines the evidence gaps and what real-world data needs to be collected for a NICE review of the technology again in the future. It is not a study protocol but suggests an approach to generating the information needed to address the evidence gaps. Well-conducted randomised controlled trials are the preferred source of evidence for assessing comparative effects if these are able to address the research gap.

The company is responsible for ensuring that data collection and analysis takes place. Support for evidence generation may be available through schemes such as the NIHR-funded HealthTech Research Centres.

Guidance on commissioning and procurement of the technology will be provided by NHS England, which is developing a digital health technology policy framework to further outline commissioning pathways.

NICE will withdraw the guidance if the company does not meet the conditions in section 4 on monitoring.

After the end of the evidence generation period (3 years), the company should submit the evidence to NICE in a form that can be used for decision making. NICE will review all the evidence and assess whether or not the technology can be routinely adopted in the NHS.

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2 Evidence gaps

This section describes the evidence gaps, why they need to be addressed and their relative importance for future committee decision making.

The committee will not be able to make a positive recommendation without the essential evidence gaps (see section 2.1) being addressed. The company can strengthen the evidence base by also addressing as many other evidence gaps (see section 2.2) as possible. This will help the committee to make a recommendation by ensuring it has a better understanding of the patient or healthcare system benefits of the technology.

2.1 Essential evidence for future committee decision making

Effect on exercise capacity using a validated measure

Evidence considered by the committee indicates that improved exercise capacity is associated with improved quality of life for people with COPD. Robust data showing that the technology improves exercise capacity up to 12 months, using a validated measure such as the 6-minute walk test or the incremental shuttle walk test, will help the committee to understand the clinical and cost effectiveness of the technology.

Adverse events

Reporting of intervention-related adverse events is essential to assess any risk associated with the technology's use in the NHS.

Comparison with current practice

More evidence is needed comparing the effectiveness of the digital technology to deliver pulmonary rehabilitation with current NHS care for COPD. The British Thoracic Society's guideline recommends face-to-face pulmonary rehabilitation as the 'gold standard'. The committee also highlighted that comparisons with not having or waiting to have a face-to-face programme are important. This will help understand the potential effect of the technology for people who cannot access, or do not want to have, face-to-face pulmonary

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rehabilitation.

Resource use

More information is needed on resource use to calculate the cost effectiveness of the technology. This should include overall costs, and the broader resource impact that COPD has on the healthcare system. The committee identified key areas that will help to address this evidence gap:

- technology costs
- exacerbation costs, including any emergency department visits, hospital admissions and GP visits associated with exacerbations
- implementation costs, for example, healthcare professional training.

Position in the care pathway

A key part of the committee discussion was around when and where in the care pathway the technology is being or could be used. Collecting evidence to address this will help the committee understand how the technology's use will affect the NHS. An important part of this would be data about when and where assessments are done to determine if people are eligible for the technology.

Engagement and adherence

Evidence on intervention completion rates, patient preference, and uptake rates will help NICE's committee assess the real-world uptake of the technology, and its acceptance by people who need pulmonary rehabilitation for COPD.

2.2 Evidence that further supports committee decision making

Health-related quality of life

The committee asked for more information about how the technology affect health-related quality of life, using a validated measure. The EQ-5D is the preferred tool for measuring

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this outcome. This information can be easily included in health economic evaluations, for which quality of life is an important driver.

Effectiveness in different subgroups

The committee noted that the current evidence comparing the effectiveness of the technology in some subgroups is limited. It recommended for any evidence generated to consider the following groups:

- people living in urban areas compared with people living in rural areas
- people with a new COPD diagnosis compared with those with an existing diagnosis
- people who are dependent on supplemental oxygen to manage COPD
- people recently discharged from hospital following an exacerbation. This data will help the committee understand the technology's effectiveness in different groups.

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3 Approach to evidence generation

3.1 Evidence gaps and ongoing studies

Table 1 summarises the evidence gaps and ongoing studies that might address them. Information about evidence status is derived from the external assessment group's report. More information on the studies in the table can be found in the supporting documents.

Table 1 Evidence gaps and ongoing studies

Evidence gap	myCOPD
Effect on exercise capacity using a validated measure	Limited evidence
Adverse events	Good evidence Ongoing study
Comparison with current practice	No evidence
Resource use	Limited evidence Ongoing study
Position in the care pathway	No evidence
Engagement and adherence	Good evidence
Health-related quality of life	Good evidence Ongoing study
Effectiveness in different subgroups	No evidence

3.2 Data sources

There are several data collections that could potentially support evidence generation. NICE's real-world evidence framework provides detailed guidance on assessing the suitability of a real-world data source to answer a specific research question.

The National Respiratory Audit Programme (NRAP) is a clinical audit dataset for people with respiratory disease (including COPD). It collects information about people referred from primary care. It includes much of the data needed to address the evidence gaps,

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such as face-to-face pulmonary rehabilitation use, exercise capacity outcome measures and EQ-5D data. NRAP can be linked to other datasets such as the Hospital Episode Statistics dataset, and this combined dataset used to estimate resource use. Some people with COPD who need pulmonary rehabilitation may have treatment solely in primary care, so data about these people is not recorded in NRAP. The dataset can be quickly and easily amended to support additional data collection where necessary.

The Clinical Practice Research Datalink (CPRD) and The Health Improvement Network (THIN) systems are primary care databases of anonymised medical records from general medical practitioners. They can be linked to secondary care data and may be able to provide data that will help address the evidence gaps. They are not national, and modification to add new data fields is unlikely to be possible.

The quality and coverage of real-world data collections are of key importance when used in generating evidence. Active monitoring and follow up through a central coordinating point is an effective and viable approach of ensuring good-quality data with broad coverage.

3.3 Evidence collection plan

Use-case survey across services

Clinical leads would be contacted to understand how the technology is currently used across the NHS and in what settings. The survey should also ask how the technology could be optimised or used in different positions in the clinical pathway. This should include, when and where assessments are done to determine if people are eligible for the technology, eligibility criteria for using the technology and who refers people to use the technology. This will help to inform future evidence generation and study design.

Real-world prospective cohort studies

Prospective controlled cohort studies are the proposed approach to addressing the evidence gaps. The studies should enrol a representative population, that is, people who would be expected to be offered face-to-face pulmonary rehabilitation in the real world but cannot have it or do not want it. The studies should compare people with COPD having digital pulmonary rehabilitation with a similar group having an appropriate comparator, such as face-to-face pulmonary rehabilitation, wait list or no treatment. Eligibility for

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inclusion should be clearly defined and consistent across comparison groups.

Data should be collected in all groups from the point at which a person would become eligible for pulmonary rehabilitation. The data from both the intervention and comparison groups should be collected at appropriate time intervals and up to 12 months. Data from people in different centres, with comparable standard care and patient population, but no access to digital pulmonary rehabilitation, could form the comparison group. Ideally, the studies should be run across multiple centres, aiming to recruit centres that represent the variety of care in the NHS.

Non-random assignment to interventions can lead to confounding bias, complicating interpretation of the treatment effect. So, approaches should be used that avoid selection bias and balance confounding factors across comparison groups. For example, using matching or adjustment approaches such as propensity score methods. To achieve this robustly, data collection will need to include prognostic factors related both to the intervention delivered and patient outcomes. These should be defined with input from clinical specialists.

Data could be collected using a combination of primary data collection, suitable real-world data sources, and data collected through the technology itself (for example, engagement data).

Data collection should follow a predefined protocol, and quality assurance processes should be put in place to ensure the integrity and consistency of data collection. See NICE's real-world evidence framework, which provides guidance on the planning, conduct, and reporting of real-world cohort studies to assess comparative treatment effects.

3.4 Data to be collected

Study criteria

- At recruitment, eligibility criteria for suitability of using the digital technology and inclusion in the real-world study should be reported, and should include:
  - a clinical diagnosis of COPD
  - position of the technology in the clinical pathway, and

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  - the point that follow-up starts.

- Description of the standard care offered.

Baseline information and outcomes

- Exercise capacity measurement using either the 6-minute walk test or the incremental shuttle walking test at baseline and over follow up (up to 12 months).
- Changes in COPD symptoms, including exacerbation rates, at baseline and over follow up (up to 12 months).
- Information on healthcare resource use and exacerbation-related hospitalisation costs, including emergency department visits, hospital admissions, length of stay, and GP visits.
- Costs of digital pulmonary rehabilitation, including:
  - licence fees
  - use and implementation of the technology
  - healthcare professional staff and training costs
  - integration with NHS systems.
- EQ-5D at baseline and over follow up (up to 12 months).
- Any adverse events arising from using digital pulmonary rehabilitation.
- Access and uptake, including the number and proportion of people who were able to access digital pulmonary rehabilitation, from the broader population needing pulmonary rehabilitation.
- Engagement with and information about stopping digital technology for pulmonary rehabilitation, including reasons for stopping. This should include:
  - the number of people starting digital pulmonary rehabilitation
  - engagement
  - the number of people who finish the digital pulmonary rehabilitation course, and

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  - reasons for stopping (for example, because of improvements in symptoms, adverse effects, or other reasons).

- Information about individual characteristics at baseline, for example, sex, age, ethnicity, clinical diagnosis, medicines (including supplemental oxygen use), comorbidities and past medical history (including time since diagnosis and recent hospitalisations), urban or rural location. Other important covariates should be chosen with input from clinical specialists.

3.5 Evidence generation period

The evidence generation period should be 3 years. This will be enough time to implement the evidence generation study, collect the necessary information and analyse the collected data.

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4 Monitoring

The company must contact NICE:

- within 6 months of publication of this plan to confirm agreements are in place to generate the evidence
- annually to confirm that the data is being collected and analysed as planned.

The company should tell NICE as soon as possible of anything that may affect ongoing evidence generation, including:

- any substantial risk that the evidence will not be collected as planned
- new safety concerns
- the technology significantly changing in a way that affects the evidence generation process.

If data collection is expected to end later than planned, the company should contact NICE to arrange an extension to the evidence generation period. NICE reserves the right to withdraw the guidance if data collection is delayed, or if it is unlikely to resolve the evidence gaps.

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5 Implementation considerations

The following considerations around implementing the evidence generation process have been identified through working with system partners:

- Some people with more advanced COPD may have difficulty with mobility or completing some of the exercise capacity measures. In the National Respiratory Audit Programme (NRAP), these are reported as '0' or 'failure'.
- People who interact more with healthcare services, for example, those currently having face-to-face pulmonary rehabilitation, may report higher rates of exacerbation because of greater awareness and opportunity for diagnosis. But they may have relatively shortened hospital stays with better outcomes. Selection criteria and follow up (up to 12 months) should carefully address the potential for surveillance bias.
- COPD is most common in people over 50 years old, with men at higher risk of developing COPD than women. There is also a higher prevalence of respiratory diseases in people with lower socioeconomic status. This is because of the effect of living in deprived areas and higher rates of smoking. The company should consider including people from these subgroups to ensure generalisability of findings.
- The company should provide training for staff to support use of the technology.
- Evidence generation should be overseen by a steering group including researchers, commissioners, practitioners, and people with lived experience.
- The evidence generation process is most likely to succeed with dedicated research staff to reduce the burden on NHS staff, and by using suitable real-world data to collect information when possible.
- Careful planning of the approach to information governance is vital. The company should ensure that appropriate structures and policies are in place to ensure that the data is handled in a confidential and secure manner and to appropriate ethical and quality standards.
- Using the EQ-5D requires a licence, with an associated cost.

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