NICE National Institute for Health and Care Excellence

Evidence generation plan for digital technologies to support self-management of COPD

Implementation support

Published: 19 December 2024

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1 Purpose of this document

NICE's assessment of digital technologies to support self-management of chronic obstructive pulmonary disease (COPD) recommends that Active+me REMOTE, Clinitouch, COPDhub, COPDPredict, Lenus COPD Support Service, Luscii, and myCOPD can be used in the NHS while more evidence is generated.

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. For assessing comparative treatment effects, well-conducted randomised controlled trials are the preferred source of evidence if these are able to address the research gap.

The companies are 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 technologies will be provided by NHS England. NHS England is developing a digital health technology policy framework to further outline commissioning pathways.

NICE will withdraw the guidance if the companies do not meet the conditions in section 4 on monitoring.

After the end of the evidence generation period (3 years, during which a minimum of 1 year of follow-up data will be collected), the companies 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 the technologies can be routinely adopted in the NHS.

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 companies 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 impact of the technologies.

2.1 Essential evidence for future committee decision making

Impact of the digital technologies compared with standard self-management of COPD without digital technologies

The technologies should be compared with non-digital standard care in the NHS, which may include face-to-face appointments and monitoring. Information is needed showing the effect of the technologies compared with standard care for the following evidence gaps:

- long-term clinical improvement
- resource use
- engagement and adherence
- adverse events.

Long-term clinical improvement in COPD using a validated measure

Evidence considered by the committee indicates that using digital technologies improves COPD when measured using the COPD Assessment Test score and the number of exacerbations. There is limited robust data to show that the technologies improve COPD symptoms over a long follow-up period. Data collected for 1 year or more will help the

committee to understand the clinical and cost effectiveness of the technologies.

Resource use

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

- healthcare resource use associated with the technologies and NHS standard care, for example:
  - exacerbation-related costs
  - primary care visits
  - hospital visits, admissions and readmissions related to COPD
- implementation costs, for example, set up and training costs and staff time needed to support the service
- technology costs including licence costs.

Engagement and adherence

Evidence on intervention completion rates, patient preference, and uptake rates will help the committee assess the real-world uptake of the technologies. It will also help assess how acceptable the technologies are for people who use them to self-manage their COPD.

Adverse events

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

2.2 Evidence that further supports committee decision making

Health-related quality of life

The committee asked for more information about how the technologies affect health-related quality of life. The EQ-5D-3L is the preferred tool for measuring 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 technologies' effectiveness 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 people who have established COPD
- people with different COPD severity stratified using the Global Initiative for Chronic Obstructive Lung Disease (GOLD) classification
- people recently discharged from hospital, within 4 weeks of a COPD exacerbation.

Where the technologies are used in the care pathway

The committee noted that it is currently unclear exactly where in the care pathway the technologies will be used. Further information about this will support its understanding of how the technologies will be used.

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	Active+me REMOTE	Clinitouch	COPDhub	COPDPredict	Lenus COPD Support Service	Luscii	myCOPD
Impact of the digital technologies compared with standard self-management	Limited evidence	No evidence	No evidence	Limited evidence Ongoing study	Limited evidence	No evidence	Limited evidence Ongoing study
Long-term clinical improvement in COPD using a validated measure	Limited evidence	No evidence	No evidence	No evidence	Limited evidence	No evidence	Limited evidence Ongoing study
Resource use	No evidence	Limited evidence	Limited evidence	Limited evidence	Limited evidence	Limited evidence	No evidence
Engagement and adherence	Limited evidence	No evidence	No evidence	Limited evidence Ongoing study	Limited evidence	Limited evidence	Limited evidence Ongoing studies
Adverse events	Limited evidence	No evidence	No evidence	Limited evidence	No evidence	No evidence	Limited evidence

Evidence gap	Active+me REMOTE	Clinitouch	COPDhub	COPDPredict	Lenus COPD Support Service	Luscii	myCOPD
Health-related quality of life	Limited evidence	No evidence	No evidence	Limited evidence	Limited evidence	No evidence	Good evidence Ongoing study
Effectiveness in different subgroups	No evidence	No evidence	Limited evidence	No evidence	Limited evidence	No evidence	No evidence Ongoing study
Where the technologies are used in the care pathway	Limited evidence	No evidence	No evidence	No evidence	Limited evidence	No evidence	Limited evidence Ongoing study

Abbreviations: COPD, chronic obstructive pulmonary disease.

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 admitted to hospital with an exacerbation of COPD. It includes much of the data needed to address the evidence gaps, such as standard care in the NHS, hospital admissions and exacerbations because of COPD. NRAP can be linked to other datasets such as the Hospital Episode Statistics dataset, and this combined dataset can be used to estimate resource use. The dataset can be amended to support additional data collection where necessary. Some people with COPD who have exacerbations may only have treatment in primary care or at home, so data about these people is not recorded in NRAP. A potential approach to addressing this gap in the data could be to link to primary care datasets such as Clinical Practice Research Datalink (CPRD) and The Health Improvement Network (THIN).

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

Real-world prospective cohort studies

Prospective controlled cohort studies are the proposed approach to address the evidence gaps. The studies should enrol a representative population, that is, people who would be offered standard care, including self-management of COPD, without digital technologies. This may include face-to-face appointments and monitoring. The studies should compare people with COPD using digital technologies for self-management with a similar group having standard care. Eligibility for inclusion, and the point of starting follow up should be clearly defined and consistent across comparison groups to avoid selection bias.

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

To reduce the variability in repeated measurements and therefore the effects of regressions to the mean, people who are selected into the studies should ideally provide multiple baseline measurements.

Despite consistent eligibility criteria, non-random assignment to interventions can lead to confounding bias, complicating interpretation of the treatment effect. So, approaches should be used that balance confounding factors across comparison groups, for example, using propensity score methods. To achieve this robustly, data collection will need to include prognostic factors related to both the intervention delivered and patient outcomes. These should be defined with input from clinical specialists. Subgroup analysis should also be done for important covariates. For example, stratification according to the severity of COPD would be useful when generating evidence to help inform practice.

Data could be collected using a combination of primary data collection, suitable real-world data sources, and data collected through the technologies themselves (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 technologies and inclusion in the real-world study should be reported, and include:
  - a clinical diagnosis of COPD
  - position of the technology in the clinical pathway
  - the point that follow-up starts.
- Detailed description of the standard care offered.
- Detailed description of the technologies including features offered in the technologies, and the specific versions.

Baseline information and outcomes

- Respiratory function using the COPD Assessment Test score at baseline and over follow up (for a minimum of 12 months).
- COPD severity using the Global Initiative for Chronic Obstructive Lung Disease (GOLD) classification at baseline and over follow up (for a minimum of 12 months).
- Changes in COPD symptoms, including exacerbation rates, at baseline and over follow up (for a minimum of 12 months).
- Information on healthcare resource use and exacerbation-related hospitalisation costs related to COPD, including:

  - primary care visits
  - emergency department visits
  - hospital visit and admissions, and length of stay.
- Costs of digital technologies for supporting self-management of COPD, including:
  - licence fees
  - healthcare professional staff time and training costs to support the service
  - integration with NHS systems
  - implementation costs
  - other technology costs.
- EQ-5D-3L at baseline and over follow up (for a minimum of 12 months).
- Access and uptake including the number and proportion of eligible people who were able to, or accepted an offer to, access digital technologies to support self-management of COPD.
- Engagement with, and information about, stopping using digital technologies for supporting self-management of COPD, including reasons for stopping. This should include:
  - the number of people starting to use digital technologies for supporting self-management of COPD
  - engagement over time (for example, use of exercises, symptom tracking, or other features in the specific technology)
  - reasons for stopping (for example, because of improvements in symptoms, adverse effects, or other reasons)
  - people who were offered and have refused the support of digital technologies for self-management, and reason for refusal.
- Information about individual characteristics at baseline, for example, sex, age, ethnicity, clinical diagnosis and when the diagnosis was done (for example, new compared with established COPD), urban or rural location, and whether inclusion was within 4 weeks of a COPD exacerbation. Other important covariates should be chosen

with input from clinical specialists.

Safety monitoring outcomes

- Any adverse events arising from using digital technologies to support self-management of COPD.

3.5 Evidence generation period

The evidence generation period should be 3 years (during which a minimum of 1 year of follow-up data will be collected). This will be enough time to implement the evidence generation study, collect the necessary information and analyse the collected data.

4 Monitoring

The companies 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 companies 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 technologies significantly changing in a way that affects the evidence generation process.

If data collection is expected to end later than planned, the companies 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.

5 Minimum evidence standards

All the technologies that have been recommended for use in the NHS while more evidence is generated have some clinical evidence suggesting that they may improve symptoms of COPD, enhance respiratory function, and reduce exacerbations. None of the technologies reported any safety concerns when using the digital technologies to support self-management of COPD.

In addition to the evidence above, the committee has indicated that it may be able to recommend technologies in this topic area in the future that have evidence for:

- a beneficial impact of the digital technologies compared with standard self-management of COPD without digital technologies
- long-term clinical improvement in COPD using COPD Assessment Test score and the number of exacerbations
- resource use associated with the technologies and NHS standard care
- intervention acceptance, completion rates, patient preference, and uptake rates
- adverse events.

Companies can strengthen the evidence base by also having evidence for:

- effects on health-related quality of life measured through the EQ-5D-3L
- effectiveness in different subgroups
- where the technologies are used in the care pathway.

6 Implementation considerations

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

- The digital technologies for supporting self-management of COPD could be more beneficial if they are used by people who were recently diagnosed with COPD, early in their care pathway. The companies should consider testing the technology at varied points in the NHS care pathway to determine the point where digital technologies could be most beneficial.
- The digital technologies could be more beneficial if they are set up to ensure that language and cultural considerations of their users are met, and the digital literacy of people using the technologies is considered.
- 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 companies 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.
- Recording multiple baseline measures is likely to be challenging. So, the issue of apparent improvement in outcome measurement being potentially caused by 'regression to the mean' effect could be best considered though statistical approaches in analysis, for example, through analysis of covariance (ANCOVA).
- Using the EQ-5D-3L requires a licence, with an associated cost.

ISBN: 978-1-4731-6668-4