NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology consultation document

myCOPD to self-manage chronic obstructive pulmonary disease

How medical technology guidance supports innovation

NICE medical technologies guidance addresses specific technologies notified to NICE by companies. The 'case for adoption' is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This case is reviewed against the evidence submitted and expert advice.

If the case for adopting the technology is supported, the specific recommendations are not intended to limit use of other relevant technologies that may offer similar advantages. If the technology is recommended for use in research, the recommendations are not intended to preclude the use of the technology but to identify further evidence which, after evaluation, could support a recommendation for wider adoption.

1 Recommendations

1.1 myCOPD shows promise for self-managing chronic obstructive pulmonary disease (COPD). However there is not enough good-quality evidence to support the case for routine adoption.

1.2 Further comparative research is recommended to address uncertainties about myCOPD's clinical benefits on outcomes such as the rate of acute exacerbation and how it affects healthcare resource use such as hospital admissions.

Find out more in the section on further research.

Why the committee made these recommendations

Most people with COPD manage their condition at home. myCOPD is an app that helps people with COPD understand the condition and manage their symptoms. myCOPD provides access to online education, self-management advice, symptom reporting and pulmonary rehabilitation. People using the app can share their clinical information with healthcare professionals, to help make shared decisions about treatment.

The evidence suggests that using myCOPD could have clinical benefits compared with standard care. But this is uncertain because the trials were short and included few people.

The cost savings are uncertain, because of the uncertainty about the clinical evidence and how much myCOPD affects healthcare resource use. More evidence is needed to resolve these uncertainties, so further research is recommended.

2 The technology

Technology

2.1 myCOPD is a digital app to help people with chronic obstructive pulmonary disease (COPD) self-manage their condition. It can be used by people with any stage of COPD. The myCOPD app has:

- education on how to use inhalers correctly
- a self-management plan to help people understand what medication to take and when
- a prescription assessment function to cross-check prescribed medication, and identify any conflicts
- a COPD assessment for people to track their symptoms and learn how to control them
- access to an online 6-week pulmonary rehabilitation course with an incremental exercise programme with education sessions to help promote self managing COPD

2.2 Information collected by myCOPD can be shared or reviewed by healthcare professionals, with the person's consent, and can help inform clinical decision making. People can use myCOPD with any digital device that connects to the internet, such as smartphones, tablets and computers.

2.3 The technology was supported by the NHS England's innovation and technology tariff in 2017.

Care pathway

2.4 The NICE guideline on chronic obstructive pulmonary disease in over 16s: diagnosis and management provides recommendations on managing stable COPD, covering smoking cessation, inhaled therapy, oral therapy, oxygen therapy, pulmonary rehabilitation and managing pulmonary hypertension. A recent update of the guideline focuses on monitoring, education and self-management. The guideline notes that most people with COPD can develop adequate inhaler technique if they have training.

2.5 NICE's COVID-19 rapid guideline on community-based care of patients with COPD recognises the need to reduce face-to-face contact and recommends people use online resources.

Innovative aspects

2.6 In the UK, face-to-face appointments are a standard approach when reviewing or monitoring COPD. myCOPD allows health service providers to offer a combination of remote care and face-to-face support. The use of myCOPD potentially could minimise health service contacts and deliver care remotely.

Intended use

2.7 myCOPD is intended to support people manage their COPD. The technology is also designed to support shared care. Healthcare professionals and patients both have access to clinical information for managing and monitoring the condition.

Costs

2.8 The company provides an unlimited licence plan myCOPD licences available for £0.25 per year per person registered with a GP in the clinical commissioning group population, with a 3-year contract. Pulmonary rehabilitation using myCOPD can be through an unlimited licence plan or a pulmonary rehabilitation package that costs £10,000 per year.

For more details, see the website for myCOPD.

3 Evidence

NICE commissioned an external assessment centre (EAC) to review the evidence submitted by the company. This section summarises that review. Full details of all the evidence are in the project documents on the NICE website.

Clinical evidence

The clinical evidence comprises 4 UK comparative studies and real-world evidence from 10 local evaluations

3.1 There were 4 peer-reviewed studies on myCOPD, including 3 randomised controlled trials (RCTs) and 1 observational study. Of the 3 RCTs, TROOPER used a non-inferiority design comparing myCOPD with a face-to-face pulmonary rehabilitation programme (Bourne et al. 2017). RESCUE was a feasibility trial that compared myCOPD with usual care plus additional written support (North et al. 2020). EARLY was a superiority RCT that compared myCOPD with standard care (Crooks et al. 2020). All trials were done in the NHS with 6 weeks or 3 months of follow-up. The sample sizes ranged from 41 to 90 people with mild, moderate or severe chronic obstructive pulmonary disease (COPD).

Real-world evidence is generalisable to the NHS

3.2 There was real-world evidence on clinical benefits, health service use, patient experience and usage of the app. Most evidence was from interim evaluations designed to inform commissioning decisions or service

developments. The methodology, patient numbers or characteristics, clinical outcomes and follow-up periods were not fully reported in these evaluations. However, the EAC concluded that the real-world evidence reflected the use of myCOPD in clinical practice and the findings of these evaluations would be generalisable to local health services.

Evidence shows that myCOPD has clinical benefits

3.3 Using myCOPD improved COPD assessment test (CAT) scores, 6-minute walking test (6MWT) distances and inhaler techniques. RESCUE showed a CAT score reduction of 2.94 (95% confidence interval [CI] -6.92 to 1.05, n=35) with myCOPD at the 3-month follow-up. This difference was clinically important but not statistically significant (North et al. 2020). It also showed a significant reduction in inhaler errors in people using myCOPD compared with people having usual care (relative risk, 0.38; 95% CI 0.18 to 0.80). TROOPER reported no statically significant difference in the 6MWT between the intervention groups, showing myCOPD was not inferior to face-to-face care for pulmonary rehabilitation (Bourne et al. 2017). Real-world evidence reported clinically important improvements in CAT scores with myCOPD (NHS Southend clinical commissioning group [CCG] evaluations, NHS Grampian evaluation and Mid and South Essex NHS Foundation Trust evaluation). A commission expert from Dorset clinical commissioning group also reported that 39.3% of people who activated the app (n=108) had their CATs score improved by 5 points or more. The NHS Grampian evaluation in primary care reported that ‘good inhaler technique’ had increased from 48% to 91% (n=64) at 5-month follow up. The clinical trial evidence showed an improvement in health-related quality of life but the differences between people using myCOPD and people having standard care were not statistically significant.

Evidence on myCOPD's effect on acute exacerbations and healthcare resource use is inconclusive

3.4 RESCUE showed that people using myCOPD were less likely to have exacerbations (relative risk, 0.58; 95% CI 0.32 to 1.04) compared with people having usual care (not statistically significant). But, EARLY showed that people using myCOPD were more likely to have exacerbations (not statistically significant). The arms were unbalanced for baseline rates, making interpretation difficult. Real-world evidence showed a reduced number of people had exacerbations after 6 months of using myCOPD (NHS Grampian evaluation). The EAC concluded that evidence was inconclusive on rates of exacerbations, noting that the RCTs were limited by short follow-up periods (3 months) and small sample sizes (<70). The 12-month NHS Highland evaluation found no statistically significant differences in hospital admissions, inpatient bed days, or other health service use before and after myCOPD app activation (Cooper et al. 2021). However, a subgroup analysis found that those people with the greatest degree of myCOPD engagement did show a reduction in bed days. The NHS Grampian evaluation based on self-reported data found that hospital admissions dropped from 6 to 0 at 5 months, compared with patient data before myCOPD (n=23 patients). In primary care, people had fewer unscheduled GP appointments after using myCOPD (NHS Grampian evaluation).

Adherence to myCOPD declines over time

3.5 TROOPER showed that adherence to using the app declined during the study period (Bourne et al. 2017). After 6 weeks, only 22% of people using myCOPD had completed the recommended 5 or more sessions compared with 77% of people in the comparator group who attended face-to-face sessions. Usage data reported in the RESCUE and EARLY trials showed a continuing decline in using myCOPD. Real-world evidence showed varying use of the app. Evidence on the effect of adherence on clinical benefits is limited.

myCOPD is easy to use but its effect on people's daily life is unclear

3.6 NICE's patient involvement programme did a survey of people using myCOPD. In this, people reported that myCOPD was easy to use (n=297/359, 82.7%) and helped improve their understanding of the condition and manage their symptoms. Three-quarters of responders (n=267/358, 74.6%) felt confident in managing COPD symptoms after using the app. Of those who used the app to control COPD symptoms, 66.1% (n=220/333) of responders felt a reduction in the number of exacerbations they experienced after using the app. People thought that myCOPD was a helpful tool and provided useful information, but some thought that using myCOPD had a limited effect on their daily lives.

Cost evidence

The company developed the cost models in 2 population groups

3.7 The company submitted 2 cost models comparing the costs and health outcomes associated with using myCOPD and standard care in 2 groups. These were people:

- discharged from hospitals after having an acute exacerbation of COPD (AECOPD) and
- eligible for pulmonary rehabilitation.

The company modelled a typical CCG purchasing an unlimited myCOPD licence package based on the size of the CCG population. For people eligible for pulmonary rehabilitation, the company presented an alternative costing scenario in which a pulmonary rehabilitation service provider could purchase the myCOPD licence specifically for pulmonary rehabilitation services. The company models showed that myCOPD was cost-saving by £204,641 per CCG when compared with standard care in the AECOPD group over 1 year. Using the app for pulmonary rehabilitation saved £20,269 per CCG over a 1-year time horizon.

The EAC's changes to the cost models more accurately reflect the uptake rate of myCOPD

3.8 The EAC considered the company's model structure to be appropriate. But, it thought that not all people eligible for myCOPD will use it. RESCUE showed that 46% of people eligible for myCOPD agreed to use it (North et al. 2020). The EAC included this uptake rate of myCOPD in the AECOPD model. For the pulmonary rehabilitation model, it also:

- included a cost for people who started but did not complete their programme
- changed the decision point from when people were referred to a pulmonary rehabilitation service to the point at which people have opted in or shown they would be willing to use myCOPD.

Using myCOPD is cost-saving in 2 groups of people with COPD

3.9 The EAC base-case results showed that myCOPD saved £86,297 per CCG per year in the AECOPD group. This saving was influenced by the uptake rate of myCOPD. The cost difference between myCOPD and standard care is depended on the uptake rate. The EAC's threshold analysis suggested that using myCOPD becomes cost incurring If the uptake rate is below 26%. In the pulmonary rehabilitation subgroup, the EAC's base case resulted in a saving of

- £22,779 per CCG per year and
- £11,093 per pulmonary rehabilitation service provider per year.

The EAC did an additional analysis to calculate the cost person reporting a saving of £170 and £179 per person using myCOPD in the AECOPD and pulmonary rehabilitation groups respectively.

The key drivers for the cost savings included:

- probability of treatment with myCOPD only
- probability of treatment with myCOPD plus face-to-face programme

- probability of referral to pulmonary rehabilitation
- cost of face-to-face pulmonary rehabilitation.

There is uncertainty around the values used to inform clinical inputs in the model.

4 Committee discussion

Clinical-effectiveness overview

Evidence suggests myCOPD has clinical benefits but this is uncertain

4.1 The committee noted that evidence from 4 comparative studies, including 3 randomised controlled trials, showed that myCOPD had clinical benefits. These included improved chronic obstructive pulmonary disease (COPD) assessment test scores, 6-minute walk test and inhaler technique. The committee accepted that there were trends towards clinical benefits, but all the studies had small sample sizes. Populations included in the studies were likely to be heterogeneous in terms of the severity of COPD and the eligibility for different health services such as pulmonary rehabilitation. In particular, RESCUE showed encouraging results but it was designed as a feasibility study. Therefore, the committee concluded that more good-quality evidence is needed (see section 4.10 about further research).

Evidence on the effect of myCOPD on healthcare resource use is needed

4.2 The committee noted the evidence on myCOPD's effect on healthcare resource use is limited. RESCUE showed that there were fewer hospital readmissions for acute exacerbation of COPD in people using myCOPD compared with people having usual care. But the difference was not statistically significant. There was evidence from the local evaluation (NHS Grampian suggesting fewer hospital admission but it was based on patient self-reported data (n=23) and potential for selection bias. There was no evidence on the number of consultations with healthcare professionals in primary and secondary care with myCOPD. The

committee agreed that more evidence is needed to assess the effect of myCOPD on healthcare resource use.

Evidence on the longer-term benefits of using myCOPD is needed

4.3 The evidence from the peer-reviewed studies was relatively short-term follow-ups, mostly up to 3 months. The clinical experts advised that COPD is a chronic condition and on average people have 2 exacerbations every year. Therefore, 90 days may not be long enough to capture the potential benefits of using myCOPD. The committee considered that strong evidence on the longer-term benefits of using myCOPD was not available and concluded that further research is needed to explore this.

Other patient benefits or issues

Usability and patient experience are key to myCOPD's success as a self-management tool

4.4 The committee heard from a commissioning expert from NHS Dorset Clinical Commissioning Group that the evaluation of digital health technologies is complex, and considerations should not only focus on the clinical benefits of the technology, but also the user experience and the usability of the technology. NICE's patient involvement programme survey showed that many people with COPD (83%, n= 297 of 359 people who responded) found the technology easy to use. However, the patient expert suggested there could be improvements, for example, the technology could include nudge messages to remind users to do pulmonary rehabilitation. The committee concluded that the usability and patient experience of the technology for both patients and the healthcare system are fundamental to its success. It considered that more data on patient experience using myCOPD would be valuable (see section 4.12).

Understanding why only some people continue using the app is important

4.5 The committee understood that myCOPD uptake varied widely across services and with people's preferences. The evidence showed that adherence to using myCOPD declines over time. The clinical expert noted

that only 20% of people in their region still used the app after 2 years. The expert explained that the reason for the decrease remains unclear but people who tend to be motivated are likely to be engaged and continually use the app. The committee noted the subgroup analysis of NHS Highland data where people with the greatest degree of myCOPD engagement showed a reduction in bed days, and the EAC's comments that the most important aspect of improving the app's functionality going forward revolves around improving patient use and adherence. The committee understood that the nature of technology means that there are regular updates and refinements to the user experience, and it concluded an improved understanding of people's behaviour when using myCOPD is be important in future iterations to help improve engagement with and adherence to myCOPD.

NHS considerations overview

myCOPD use in clinical practice for remote COPD monitoring requires integration with NHS software systems

4.6 The clinical expert explained that in their local evaluation, people used myCOPD as a self-management tool to collect and store all their COPD-related information in one place. The patient survey highlighted some general frustrations with users over a lack of integration with the healthcare system, including some confusion about whether healthcare practitioners were aware of the data, and whether they could access and respond to it. The company stated the technology can be integrated with systems using SystmOne (a software system used in the NHS that includes a person's health data, which has the capacity to integrate with other NHS software systems). Information can be shared with the patient's consent, but it is unclear to what extent such data is routinely used in clinical practice, and at present, there is no evidence on using myCOPD as part of shared care. The committee considered there needs to be a better understanding of how myCOPD should be integrated with

the healthcare system to help with a supported self-management approach and improve understanding of using the technology in the NHS.

Improving patient engagement will increase the uptake and engagement with myCOPD but is likely to be an additional cost to the health service

4.7 The commissioning expert reported that there was an improvement in the app uptake in her clinical commission group, from 43% to 65%. Such an increase is achieved through support to help people engage. She described their approach of using company-funded digital health advisers to support the implementation of the technology in primary care. The commissioning expert stated that they provided support for people to register and set up the app. On-going support from the commissioning expert's CCG is provided at different time points via text messaging, face-to-face appointments, or over the phone, to help improve patient engagement. The committee understood that uptake of and adherence using myCOPD could be improved but this may affect NHS resources such as staff time which were not included in the cost model.

myCOPD requires users to be able to use a smart device and to understand English

4.8 myCOPD is only available in English. It is difficult to use for people who have limited English language skills. It is also difficult for people not able to use a smart device easily, such as people with a visual or cognitive impairment, or limited manual dexterity, or who are hard of hearing. The company said that myCOPD users could access via any smart device such as a phone, tablet or computer. The company is also working to improve the app accessibility and people may be able to access the app via a smart TV in the future. The committee concluded that computer literacy skills and English skills are needed to use myCOPD.

Further research would help identify people who are most likely to benefit from using myCOPD

4.9 The evidence showed that 2 population groups had clinical benefits with myCOPD (people discharged from hospital with an acute exacerbation of COPD [AECOPD] and people referred for pulmonary rehabilitation). There is currently no clinical consensus on which patients should be offered face-to-face pulmonary rehabilitation or myCOPD. The clinical expert explained that, in their NHS trust, myCOPD is offered to all people with COPD, regardless of patient characteristics. The commissioning expert stated that in primary care in Dorset, the technology is offered to 2 groups of people: those with the highest risk of having exacerbations and those at risk of their COPD becoming worse. Limited evidence from the local evaluations reported an association between clinical benefits and patient characteristics including demographics, disease severity and use of the technology. The committee agreed that there is no clear evidence on who myCOPD would most benefit, and that further research would be helpful to inform patient selection.

Cost modelling overview

Uncertainties about the clinical benefits of myCOPD are reflected in the cost modelling

The committee understood that clinical parameters in the AECOPD model were based on RESCUE, a feasibility trial with fewer than 50 patients. It noted that the key drivers of cost-saving in this model were the uptake of myCOPD and hospital readmissions, and these parameters were uncertain because of the limitations in the evidence. Results from TROOPER were used in the pulmonary rehabilitation model. There were 3 treatment options in the intervention arm and people were able to choose myCOPD, face-to-face pulmonary rehabilitation (PR) and a hybrid model which consists of face-to-face sessions and myCOPD. Key drivers for cost-saving in this model were the uptake of myCOPD alone and a hybrid model, the number of people eligible for pulmonary rehabilitation

and the cost of face-to-face pulmonary rehabilitation. The patient and clinical expert each advised that many people would prefer a face-to-face pulmonary rehabilitation programme. They also advised that the health service is moving towards a hybrid model which combines face-to-face and remote programmes. The committee agreed that variance in the uptake and high attrition rate contributed to the uncertainties in the economic modelling. The committee concluded that to inform the cost modelling, more evidence is needed about myCOPD's benefits in clinical practice.

Further research

Further good quality evidence is needed to address uncertainties about myCOPD's clinical benefits and its effects on healthcare resources

4.10 myCOPD has potential for clinical benefits, but more evidence is needed to reduce uncertainties. The committee considered that an adequately powered randomised controlled trial is needed to show the clinical benefits of using myCOPD and its healthcare resource use in both primary and secondary care. Evaluating the long-term effects of myCOPD compared with standard care is also important. In addition to clinical outcomes such as rates of exacerbations to help inform the economic model the trial should assess the following:

- number of unscheduled care appointments
- number of contacts with healthcare professionals
- number of hospital admissions and readmissions for acute exacerbations
- length of hospital stay, and
- patient-reported outcomes such as health-related quality of life.

4.11 Qualitative data on patient experience using myCOPD such as patient preferences, the uptake of the app and adherence.

5 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of the medical technologies advisory committee, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

YingYing Wang
Health technology assessment analyst

Bernice Dillon
Health technology assessment adviser

Victoria Fitton
Project manager

ISBN: [to be added at publication]