# Guidance assessment consultation document for: HTE10030 Digital technologies to support self-management of COPD: early value assessment

## **Guidance development process**

Early value assessment (EVA) guidance rapidly provides recommendations on promising health technologies that have the potential to address national unmet need. NICE has assessed early evidence on these technologies to determine if earlier patient and system access in the NHS is appropriate while further evidence is generated.

The medical technologies advisory committee has considered the evidence and the views of clinical and patient experts. EVA guidance recommendations are conditional while more evidence is generated to address uncertainty in their evidence base. NICE has included advice in this guidance on how to minimise any clinical or system risk of early access to treatment.

Further evidence will be generated over 3 years to assess if the benefits of these technologies are realised in practice. NICE guidance will be reviewed to include this evidence and make a recommendation on the routine adoption of this technology across the NHS.

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# 1 Recommendations

# Can be used in the NHS while more evidence is generated

- 1.1 Eight digital technologies to support self-management of chronic obstructive pulmonary disease (COPD) in adults can be used in the NHS during the evidence generation period. The technologies are:
  - Active+me REMOTE
  - Clinitouch
  - COPDhub
  - COPDPredict
  - Lenus
  - Luscii
  - myCOPD
  - SPACE for COPD (this technology can only be used once it has appropriate regulatory approval).
- 1.2 The companies or developers of these technologies must confirm that agreements are in place to generate the evidence (as outlined in NICE's evidence generation plan). They should contact NICE annually to confirm that evidence is being generated and analysed as planned. NICE may withdraw the guidance if these conditions are not met.
- 1.3 At the end of the evidence generation period (3 years during which 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 the evidence and assess if the technology can be routinely adopted in the NHS.

# Can only be used in research

1.4 More research is needed on Doccla to support self-management of COPD before it can be used in the NHS.

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1.5 Access to Doccla should be through the company, research, or non-core NHS funding, and clinical and financial risks should be appropriately managed.

## **Evidence generation**

- 1.6 Evidence generation is needed on:
  - how well the digital technologies work compared with standard management of COPD without digital technologies, which may include face-to-face appointments and monitoring, measuring the following outcomes:
    - health-related quality of life using the EQ-5D-3L
    - respiratory function using the COPD Assessment Test score
    - resource use, including:
      - ◊ technology costs including licence fees
      - ◊ COPD exacerbation-related costs
      - o number of primary care visits
      - number of hospital visits and admissions, and associated costs related to COPD
      - ◊ staff time needed to support the service
      - ◊ training costs
      - ◊ implementation costs
    - uptake rates
    - intervention adherence rates
    - preferences and experiences of people with COPD
    - adverse events
    - COPD exacerbation rate
  - where the technologies are used in the care pathway
  - outcomes in the following subgroups:
    - people living in urban areas compared with people living in rural areas

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- people with a new COPD diagnosis compared with people who have established COPD
- people recently discharged from hospital after a COPD exacerbation, within 4 weeks of the exacerbation.

The evidence generation plan gives further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources for the technologies listed in section 1.1. It includes how the evidence gaps could be resolved using real-world evidence.

For more detail on the committee's considerations about the evidence gaps for the technologies in 1.4, see sections 3.11 to 3.16 and sections 3.24 to 3.30.

#### Potential benefits of use in the NHS with evidence generation

• Access: When people have exacerbations of COPD symptoms, they generally present to their GP or emergency department. For those who are hospitalised, there is a risk of readmission. The COPD clinical audit from the National Asthma and COPD Audit Programme reports that 23.9% of people are readmitted within 30 days and 43.2% within 90 days after discharge. This highlights the importance of effective self-management to prevent exacerbations and readmissions. Digital technologies to support self-management may help people who may not be able to access face-to-face appointments. For example, it may benefit people living in rural areas with limited availability, those unable to travel because of how severe their COPD is, and those who cannot or do not want to take time off work. Digital technologies will not replace face-to-face appointments in the care pathway. Offering digital technologies as an option to support self-management of COPD in adults could improve access, engagement, and adherence to self-management plans.

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- Clinical benefit: Clinical evidence for the technologies suggests that these technologies may improve symptoms of COPD, enhance respiratory function, and reduce exacerbations. There are no safety concerns with using digital technologies for supported self-management. These technologies may address an unmet need for people with COPD who do not have access to face-to-face appointments.
- **Resources:** Digital technologies to support the self-management of COPD may be cost saving to the NHS by reducing exacerbations and associated costs, which may involve hospitalisation. But, this is uncertain because of the limited evidence base, as there is uncertainty about how effective these technologies may be at reducing these symptoms in practice.
- Equality: COPD is most common in people aged over 50, with men at higher risk of developing COPD than women. There is a higher prevalence of respiratory diseases in people with lower socioeconomic status, because of the effects of living in deprived areas and higher rates of smoking. Also, people living in deprived areas have a lower life expectancy than the general population. COPD is responsible for 8% of the life expectancy difference in men and 12% of the difference in women. Widening access to digital technologies to support self-management of COPD may help address some of this inequality, because digital technologies provide self-education and stopping smoking advice.

#### Managing the risk of use in the NHS with evidence generation

- **Costs:** There may be costs associated with implementation, staff training, integration with NHS Patient Medication Record systems such as EMIS, and providing smart devices with an internet connection.
- Equality: Support and resources may be needed for people:
  - unfamiliar with digital technologies
  - without access to smart devices or the internet
  - with visual, hearing, or cognitive impairment, problems with manual dexterity or a learning disability

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- with a mental health condition
- with a lower reading ability (including people unable to read English)
- with cultural, ethnic or religious backgrounds that may affect their opinion on using digital technologies to support self-management of COPD.

# 2 The technologies

- 2.1 Digital technologies to support self-management of chronic obstructive pulmonary disease (COPD) provide various aspects of self-management. These technologies are multicomponent and include at least 2 components of self-management:
  - education about the condition
  - an individualised self-management plan within the technology
  - symptom tracking by the user
  - remote monitoring functionality
  - exercise
  - communication features with healthcare providers.

While some of these technologies also feature pulmonary rehabilitation and virtual ward components, these are not included within the scope of this health technology evaluation.

- 2.2 Thirteen technologies were identified for this health technology evaluation. Recommendations were made for 9 technologies. No recommendations were made for 4 technologies because:
  - there was a lack of evidence for Current Health, DOC@HOME and patientMpower
  - Welllinks is not being currently used in the NHS and does not have regulatory approval in the UK
  - Current Health is no longer available in the UK and so is not available in the NHS.

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## Active+me REMOTE

2.3 Active+me REMOTE (Aseptika) is a cloud-based platform that supports self-management and remote monitoring of adults with COPD at home. The Active+me REMOTE app includes an education programme delivered in small lessons and interactive exercise videos that increase in difficulty as a person's fitness and strength improve. The technology also collects patient-generated data through an add-on pulse oximeter, spirometer, and smart inhaler. The technology can be accessed through a mobile phone, tablet, or desktop.

# Clinitouch

2.4 Clinitouch (Spirit Health) is a web-based or app-based self-management platform that enables remote clinical monitoring of people with COPD. People can log into the platform to answer clinically approved questions and measure various vital signs, such as blood pressure and oxygen saturation. The platform supports monitoring of COPD by providing health status and health trend data. Also, the platform offers secure messaging, video conferencing and educational content, including exercise programmes.

# COPDhub

2.5 COPDhub (The Institute of Clinical Science and Technology) is a digital personalised care plan for people with COPD delivered by an app. It includes a monthly COPD checker to track symptoms and has real-time guidance to identify those at risk. The technology provides educational content including videos on inhaler techniques and breathing exercises, downloadable care summaries, and reminder features to support self-management of COPD. It also features the COPD Assessment Test (CAT) and the Modified British Medical Research Council (mMRC) score functionality for assessment. It can be used to record healthcare data such as GP appointments.

# COPDPredict

2.6 COPDPredict (NEPeSMO) is a digital self-monitoring app with artificial intelligence-enabled exacerbation prediction capability for people with COPD. The technology focuses on prevention by combining remote monitoring and patient-personalised exacerbation prediction. Prediction algorithms are constructed from time-series data on symptoms, lung function, and biomarkers in blood or saliva supplied by people using a bespoke app that connects wirelessly to monitoring devices. There is also an online Clinician Early Warning System that provides alerts on impending exacerbations, allowing timely intervention.

# **Current Health**

2.7 Current Health (BEST BUY Health) is an individually tailored selfmanagement app. It helps people manage their care with automated messaging and reminders. Current Health technology supports people with COPD by enabling remote monitoring and facilitating early hospital discharge. People showing signs of clinical deterioration who present to emergency departments or in community care are monitored at home, which may prevent unnecessary hospital admissions. This technology has clinical team capacity through a central monitoring hub, staffed by trained staff proactively monitoring vital signs and responding to health alarms.

> No recommendation was made for this technology because no relevant evidence was identified by the external assessment group (EAG). The company have also informed NICE that they are no longer trading in the UK, so the technology is not available for use in the NHS.

# DOC@HOME

2.8 DOC@HOME (Docobo) is a digital platform for remote monitoring and case management, that can be used by people with COPD at home and in care homes. It enables remote patient monitoring by collecting vital signs such as blood oxygen levels through home pulse oximetry kits,

blood pressure, weight and temperature. Users can also log their Guidance – Digital technologies to support self-management of COPD: early value assessment Page 8 of 25 Issue date: September 2024

symptoms. The platform offers self-help information and alerts healthcare professionals to critical changes such as reduced blood oxygen levels, allowing medical intervention if needed.

No recommendation was made for this technology because no relevant evidence was identified by the EAG. There was also no information provided by the company.

#### Doccla

2.9 Doccla (Doccla) is a remote self-management and monitoring service for people with COPD who have been discharged from hospital wards, aiming to reduce the need for in-person visits. This includes mobile and web apps to track health metrics through wearable and spot-check devices, communication with healthcare providers, and access to information about their condition and a self-management plan. The app also provides automated alerts if health metrics fall outside predefined thresholds and can provide reminders to take medicines and attend appointments. Clinicians can use an online portal to review clinical data and communicate with users. This portal is within a virtual ward platform that allows the simultaneous monitoring of many users whilst integrating with electronic health records for ease of data exchange.

#### Lenus

2.10 Lenus COPD Support Service (Lenus Health) is a remote management app for people with COPD. The technology offers standardised selfmanagement advice and personalised care plans, with the option for clinicians to activate a rescue plan when necessary. Users can input patient-reported outcome measures and maintain a symptom diary. They can also communicate non-urgent queries with their clinical care team through a messaging feature. A website provides additional selfmanagement resources. A clinician dashboard integrates data from electronic health records, PROMs, and wearable devices for remote monitoring. The technology combines data from patient-reported

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outcomes, medical and wearable devices and clinical records, and can highlight anyone at risk enabling early intervention. People can also manage their appointments through the platform.

#### Luscii

2.11 Luscii (Luscii) is a self-management app for people with COPD. It allows users to self-monitor by recording their symptoms, completing assessments from standardised questionnaires and measuring vital signs, such as oxygen saturation levels. The app is accessible through any internet connected device and integrates with portable monitoring devices to upload data. It also provides educational resources including updates, information on effective inhalation methods, strategies for coping with COPD and motivational messages to promote self-management of COPD. The app allows users to contact their healthcare team and supports video consultations.

#### myCOPD

2.12 myCOPD (my mhealth) is a self-management platform for people with COPD. The app provides education on correct inhaler use, a personalised self-management plan, prescription assessment and detailed symptom tracking with daily reporting and monthly COPD Assessment Test (CAT) scores. The self-management plan can be updated by clinicians and integrated into the patient review process, supporting shared care. Additional features include structured education, an activity diary, breathing techniques, communication with healthcare providers, webbased access, and therapeutic interventions such as inhaler instruction, chest clearance guidance, cognitive behavioural therapy, mindfulness exercises, and stopping smoking advice. It also offers a structured exercise, education and psychosocial support programme. These features allow clinicians to monitor and support people with COPD remotely.

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## patientMpower

2.13 The patientMpower (patientMpower) platform is designed for people with respiratory conditions, focusing on remote monitoring and selfmanagement. It includes a patient-facing app with integrated medical devices for data collection as well as questionnaires. This app records physiological parameters such as spirometry, pulse oximetry, and blood pressure, as well as patient-reported outcomes. Users can also monitor exercise, air quality, and medicine adherence. The platform empowers healthcare professionals to create virtual care pathways. It allows remote monitoring of clinical data and gives medicine reminders, supporting people with stable COPD and enabling quick intervention for deteriorating cases through a clinician web portal.

No recommendation was made for this technology because no relevant evidence was identified by the EAG.

# SPACE for COPD

2.14 SPACE for COPD (University Hospitals of Leicester NHS Trust) is a digital self-management programme designed to help people with COPD manage their condition more effectively. SPACE for COPD is a structured programme of exercise, education and psychosocial support. The programme contains educational topics including information about medicine, breathing control, exercise and nutritional advice. Users are encouraged to set goals, progress through a prescribed exercise programme and achieve weekly targets. The technology can be accessed through a mobile phone, tablet, or desktop. Clinicians can monitor user logins, progress and wellbeing on the programme, and answer any questions that the user sends to them.

# SPACE for COPD is being developed into a new programme, i-IMPACT, that offers cardiac rehabilitation, not just COPD care and pulmonary rehabilitation. The developer stated that the resources

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are being reviewed and updated, and the functionality of the website is being enhanced. The new website will follow the same methodology for COPD, while adding features for other long-term conditions. i-IMPACT is currently undergoing DTAC assessment and CE marking assessment. When reviewing the guidance, the committee will revisit its recommendation and assess any evidence on the new programme.Wellinks

2.15 Wellinks (Wellinks) is an online platform designed to empower people with COPD. It offers health coaching for self-management support by respiratory professionals, and a patient-centred app with connected devices such as pulse oximeters and spirometers for remote monitoring and education.

No recommendation was made for this technology because the technology is not used in the NHS and does not have the relevant regulatory approval.

## **Care pathway**

2.16 In 2020 to 2021, NHS Digital reported that about 1.17 million people (1.9% of the population) in England have been diagnosed with COPD. It is estimated that a further 2 million remain undiagnosed. Incidence of diagnosed COPD has risen from 1.7% to 1.9% of the population over the last 10 years. Chronic lower respiratory diseases were reported as the third most common cause of death in England and Wales in 2023 (Office for National Statistics, 2023). COPD is much more common in areas of high deprivation. People living in these areas have a lower life expectancy than the general population, and COPD is responsible for 8% of this difference in men and 12% in women. Managing COPD in the UK costs the NHS over £800 million a year.

 2.17 <u>NICE's guideline for the diagnosis and management of COPD in over 16s</u> states that COPD care should be delivered by a multidisciplinary team
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© NICE 2024. All rights reserved. Subject to Notice of rights. that includes respiratory nurse specialists. Self-management plans should include education and an individualised exacerbation action plan for people at risk of exacerbations. These plans should improve the confidence and knowledge of people with COPD. Treatments and plans including inhaler technique and onward referral for exercise interventions should be revisited at every review. People with COPD should be on the primary care COPD register and should attend a follow-up review in primary care at least once a year and more often if needed. The current model of delivery of these interventions is usually face-to-face interactions between people with COPD and specialist respiratory staff.

2.18 People who have had in-hospital care after an exacerbation are given care bundles. Care bundles aim to help people cope better once home from hospital and potentially prevent further readmission by improving outcomes. There were 75.5% of people with COPD exacerbations discharged from hospitals in England, Scotland and Wales between October 2019 and February 2020 who were given a discharge bundle, according to the National Asthma and COPD Audit Programme (NACAP) COPD clinical audit (PDF). Despite this, mortality within 30 days of index admission was 6.3%, and mortality within 90 days was 12%. There is a need to support people to self-manage COPD more effectively, which may reduce the risk of the initial exconacerbation and potentially reduce the likelihood of people being readmitted after their initial exacerbation.

## The comparator

2.19 The comparator for this health technology evaluation is standard care. Standard care includes self-management of COPD without digital technologies. This may include face-to-face appointments and monitoring.

# 3 Committee discussion

<u>NICE's medical technologies advisory committee</u> considered evidence on digital technologies to support self-management for people with chronic obstructive pulmonary disease (COPD) from several sources, including an early value Guidance – Digital technologies to support self-management of COPD: early value assessment Page 13 of 25 Issue date: September 2024

assessment (EVA) report by the external assessment group (EAG), and an overview of that report. Full details are in the project documents for this guidance on the NICE website.

## **Unmet need**

3.1 COPD is a long-term and progressive respiratory condition that can cause breathlessness, a persistent chesty cough, persistent wheezing, and frequent chest infections. The incidence of COPD in the UK is increasing (see section 2.15). COPD is a common cause of emergency hospital admissions, accounting for 1 in 8 UK hospital admissions. The 2017/2018 National Asthma and COPD Audit Programme (NACAP) COPD clinical audit (PDF) reports that 23.9% of people are readmitted within 30 days and 43.2% within 90 days after discharge, highlighting the importance of effective self-management to prevent exacerbations and readmissions.

## Implementation

- 3.2 The clinical experts and patient experts explained that barriers to implementation of the digital technologies would include:
  - the point where the digital technology is used in the care pathway
  - digital literacy and setting up the technology for users
  - language and cultural considerations
  - social and environmental factors
  - additional resources needed in terms of healthcare professionals' time
  - ensuring data that is captured is beneficial to users and healthcare professionals
  - usability of the technologies.

The clinical experts also explained that an additional barrier to implementing these technologies is ensuring that staff are not overburdened. The likelihood of this occurring likely depends on the amount and format of clinical information being shared, which may be difficult and time consuming for healthcare professionals to interpret. But

Guidance – Digital technologies to support self-management of COPD: early value assessment Page 14 of 25 Issue date: September 2024 clinical experts suggested that, because the technologies are to support self-management, less input may be needed from staff. Users should be better equipped to manage their condition themselves, seeking medical advice only if needed.

## **Patient considerations**

- 3.3 Patient experts explained that they thought that digital technologies were predominantly focused on supporting the healthcare professionals, rather than people with COPD. One of the patient experts also emphasised that COPD management should be a partnership between healthcare professionals and the person with COPD (as well as carers, when applicable).
- 3.4 Although the patient experts had not used the technologies, they agreed that there may be potential benefits for the user. The patient experts suggested that the technologies should provide advice on triggers, like environmental factors, and tracking of routine symptoms that may cause a person's health to deteriorate and lead to an exacerbation. They suggested that having this information was equally as important as the general health monitoring aspects of the technologies.
- 3.5 Although the evidence base predominantly included people with more severe and established COPD, the patient experts stated that people with COPD should have access to these technologies early in the care pathway, from the point of diagnosis. They suggested that earlier intervention with supported self-management using digital technologies could delay the worsening of COPD. This would not only benefit people with COPD (and their carers, when applicable), but could also be cost saving to the NHS.
- 3.6 The patient experts suggested that these technologies could supplement routine primary care appointments, but not completely replace them, because they felt that there should still be clinical oversight from healthcare teams.

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### Benefits of the technologies

- 3.7 The committee discussed the potential of digital technologies to improve COPD care through effective self-management and to address the unmet need of people who are unable to access appointments with their healthcare team.
- 3.8 Clinical experts explained that digital technologies to support selfmanagement can provide timely education and individualised COPD plans, including exacerbation action plans for people at risk of exacerbations, in line with NICE's guideline on chronic obstructive pulmonary disease in over 16s: diagnosis and management. These technologies can also improve other aspects of COPD care, including inhaler technique and recognising exacerbations. The clinical experts emphasised that people with COPD would still need face-to-face reviews at least annually, even when using digital technologies for selfmanagement. They explained that people with COPD should be on the primary care COPD register and should attend a follow-up review in primary care at least once a year, and more often if needed. Both patient experts and clinical experts thought that these technologies may help provide information for the annual review. The committee agreed that digital technologies to support self-management would provide another option for people with COPD, but they would not completely replace all appointments in the care pathway.
- 3.9 Because of the wide range of features in the digital technologies that contribute to self-management, the committee wanted to clarify which aspects of the technologies are most useful for self-management. The committee considered that remote patient monitoring might not be a tool used regularly, because self-management of COPD should generally function independently of clinical oversight from the healthcare team. The experts stated that people with more severe COPD might need additional face-to-face care rather than self-management. The committee suggested that stratification according to the severity of COPD and the features of

Guidance – Digital technologies to support self-management of COPD: early value assessment Page 16 of 25 Issue date: September 2024 the technologies would be useful when generating evidence to help inform practice.

## **Clinical effectiveness**

#### **Evidence from research studies**

3.10 The evidence was not evenly distributed across the technologies and clinical outcomes. Prioritisation for study selection, extraction, and synthesis was based on the relevance to the decision problem scope and the quality of evidence, with the highest quality and most relevant evidence selected for each scoped technology. The EAG prioritised 17 studies across 10 technologies. Outcomes were inconsistently reported across the evidence base, using different tools, different reporting methods and different timepoints, making it difficult to draw meaningful conclusions from the evidence base. When more than 1 comparative study reported the same outcome measure, the direction and size of effect was not consistent across studies. There was a consistent direction of effect for some outcomes in people with acute exacerbations of COPD, but not all differences reached statistical significance. Not all technologies had evidence for all key outcomes. Data was limited for quality of life, GP visits and exacerbations, with the most data available for respiratory function and hospital admissions. A number of limitations across the evidence base were also identified. Samples in the randomised controlled trials were not adequately powered for appropriate clinical outcome measures, limiting their ability to identify statistically significant differences. Many trials had short follow-up periods, limiting the generalisability of the evidence to NHS settings where COPD selfmanagement technologies are expected to be used as long-term tools. Details of usual care were generally not adequately reported, making comparisons between studies difficult. Also, the features of the evaluated technologies were often unclear, affecting the generalisability of the evidence between studies and technologies. The variability in the length

of time since hospitalisation in the post-discharge group and the unclear Guidance – Digital technologies to support self-management of COPD: early value assessment Page 17 of 25 Issue date: September 2024 COPD severity in the other 6 studies further impacted generalisability. The extent of overlap with the COVID-19 pandemic varied and was sometimes unclear, making it difficult to generalise findings across studies done before and after the pandemic. The committee acknowledged these limitations in the evidence base, and considered this uncertainty when making recommendations.

3.11 Randomised controlled trial (RCT) or cluster RCT evidence was prioritised for 3 technologies in this assessment. RCTs have the most methodologically robust study design, producing evidence that is more likely to identify any differences between the technologies and standard care. But the committee noted that the RCT and cluster RCT evidence identified had limitations. All RCT evidence had small sample sizes, limiting their ability to assess statistical significance. Also, most of the RCT evidence applied a non-intention-to-treat analysis method, excluding people who were eligible for inclusion in the trial after randomisation. This may have impacted the results by excluding people who did not fully adhere to the study protocol as intended. Some RCT evidence had baseline imbalances between treatment arms, despite an appropriate randomisation method being used. The cluster RCT evidence applied non-intention-to-treat analysis for some outcomes, again limiting the number of people included in the analysis and potentially introducing bias in the selection of the reported results. The cluster RCT evidence was in a non-UK setting, meaning the contents of standard COPD care and how these relate the NHS are unknown, limiting the generalisability of this evidence. These limitations in the RCT and cluster RCT evidence meant that the committee was unable to conclude with certainty whether the differences in outcomes were attributable solely to the technologies, and if these differences would be seen in NHS practice.

3.12 Ten studies reported COPD severity, with 9 of these studies only involving people who have had an acute exacerbation of COPD. One of these studies recruited people immediately after discharge from the emergency

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department or hospital admission for a COPD exacerbation. One study recruited people within 2 weeks of their discharge from hospital for an exacerbation, while 1 study did not report the timeframe or number of previous exacerbations needed for recruitment. One study recruited people with at least 2 exacerbations in the past 12 months. The other 5 studies recruited between 6 and 24 months after an exacerbation leading to hospitalisation. Because the evidence from the acute exacerbation subgroup was broadly positive, the committee discussed whether the recommendation could be limited to this population. Clinical experts and committee members agreed that by recruiting people who have had an acute exacerbation of COPD, there is a tendency for the COPD to improve over time, independently of the technology. This may overestimate the impact of the digital technology. The committee suggested that this effect should be explored in the evidence generation plan through RCTs. Clinical and patient experts agreed that there would be more benefit from the technologies if they prevented the initial exacerbation, rather than waiting to offer a self-management technology after clinical deterioration.

- 3.13 The evaluated evidence did not raise any particular concerns about adverse events associated with the digital technologies. Overall, the committee agreed that the evidence showed potential clinical benefits for people using technologies for supported self-management, and had the potential to address an unmet need. There were concerns about the generalisability of the results because some effects did not reach the level of clinical significance, and there was potential underperformance of comparators because these were not clearly defined in some studies.
- 3.14 The committee concluded that Active+me REMOTE, Clinitouch, COPDhub, COPDPredict, Lenus, Luscii, myCOPD, and SPACE for COPD can be used in the NHS while more evidence is generated, because they showed potential benefit in their existing evidence base. More research is needed on Doccla before it can be used in the NHS.

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3.15 For the other 4 technologies, evidence on effectiveness was limited or lacking, or there was no information provided by the company. No relevant evidence was identified for patientMpower and Current Health, and Current Health is no longer available in the UK. No information was provided for DOC@HOME. Wellinks is not currently used in the NHS and does not have regulatory approval. The committee made no recommendations for these 4 technologies.

## **Equality considerations**

3.16 Equality considerations highlighted to the committee included general and digital literacy, speaking a different language to English or having English as a second language, and access to equipment and internet. The committee recognised that additional support and resources may be needed for people who are unfamiliar with digital technologies or who do not have access to smart devices or the internet. Most of the companies stated that their technologies are available in other languages. The companies also stated that they promote engagement and digital inclusion by supporting people with onboarding and training when the technology is initially prescribed. One company indicated that socially and economically deprived areas show a higher uptake of digital health services relative to less deprived areas. The committee understood that additional support may be needed for people with accessibility needs or who are unable to read or understand English. But the digital technologies are not intended to replace face-to-face contact so usual care will still be an available option for people with COPD.

#### Costs and resource use

3.17 A cost-comparison model was developed to assess the potential benefits of the technologies over a 1-year period. Limited evidence was available to model the potential impact of digital technologies to support selfmanagement of COPD for all companies. The model focused on estimating resource use, such as GP visits, non-hospitalised

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exacerbations, and hospitalisations. The EAG excluded costs related to mortality to avoid double-counting. The effectiveness of the digital technologies was evaluated based on potential reductions in resource use.

- 3.18 The results of the economic modelling suggested a potential cost saving of £337 per person when using digital technologies compared with standard care. The committee acknowledged uncertainties in the data used to inform the modelling, particularly the impact of digital technologies on healthcare resource use, such as hospitalisations because of COPD. The committee also noted that, because the data predominantly came from people with severe COPD, the results may report a higher potential benefit than may be the case for people with less severe COPD, particularly for those recently experiencing acute exacerbations. Both the committee and clinical experts agreed that the average hospital admissions used in the economic model represented a more severe COPD cohort compared to mild-to-moderate cases and this should be considered when interpreting the results.
- 3.19 The only difference in the economic model between the different technologies was the cost of the technology, because all other assumptions remained constant. Costs varied among companies, affecting the assessment when comparing technologies based on price alone. The EAG highlighted that one limitation of the model was pricing uncertainty because of different factors, including setup fees, licence fees varying depending on number of users, and the possibility that some technologies may offer medical devices as part of their package (which was not costed). The economically justifiable price was estimated at £620 per person, with 1 technology exceeding this cost. The results are indicative and not perfectly representative of all digital technology providers.

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- 3.20 The committee noted that the results should be considered cautiously because of the limitations of the clinical data informing the modelling. The comparative effectiveness of digital interventions was unclear, particularly in mixed or unclear treatment settings. Some studies showed benefits, but others did not, reflecting the heterogeneous nature of the evidence and varied methodologies used. Potential improvements in COPD management using digital technologies were indicated by improvements in COPD Assessment Test scores, inhaler use, and reductions in exacerbations and admissions. But results were mixed and somewhat inconsistent across different patient populations and studies.
- 3.21 Sensitivity and scenario-based analysis indicated that digital technologies generally remained cost saving except in scenarios with the highest costs of the digital technologies, and when there was no reduction in hospitalisation rates. The cost of hospitalisation in the base case, based on the latest NHS cost data, was significantly higher than in previous iterations. So, using a lower cost for hospitalisation reduced the cost-saving potential of digital technologies.
- 3.22 The committee agreed that the general direction of efficacy data for digital technologies was positive, suggesting improvements over standard care. By reducing hospitalisations, exacerbations and GP visits, digital technologies to support self-management of COPD are likely to be cost saving rather than cost incurring.

#### **Evidence gap review**

3.23 For all the technologies, the evidence gaps related to the population, intervention and outcomes, including resource use and health-related quality of life.

#### Population

3.24 The patient and clinical experts highlighted that people with newly diagnosed COPD should be included in the recommendation population,

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rather that only those with established COPD diagnoses, including the subgroup of people with acute exacerbations of COPD. This is because if COPD progression is delayed, this can have positive impacts on people with COPD and their carers and families. Also, delayed COPD progression could lead to reduced resource use, such as fewer emergency department visits and admissions, which would have a positive impact on the NHS. The committee agreed that only recommending the technologies for the subgroup with acute exacerbations of COPD could introduce bias and overestimate the impact of the technologies, because of natural variations in people's COPD.

- 3.25 The committee noted the short time horizons of the trials and agreed with clinical experts that long-term studies with a minimum data collection period of 1 year would be useful to capture the effectiveness and resource use of the technologies.
- 3.26 The committee discussed the importance of stratifying COPD severity using the Global Initiative for Chronic Obstructive Lung Disease (GOLD) classification. It noted that individuals with a more severe GOLD classification may need more intensive care, and clinical effectiveness and resource use may vary depending on COPD severity. Capturing outcome data such as health-related quality of life or respiratory function would provide valuable insights into how digital technologies impact people with different severity levels of COPD. The committee agreed that it would be beneficial to include this information in future studies, to better understand and optimise the use of digital technologies in managing COPD.
- 3.27 The committee noted that there was no comparison of outcomes for people living in urban and rural settings.

#### Intervention

3.28 The committee was aware that it is important to capture patient

preferences and experiences as well as uptake and adherence rates for Guidance – Digital technologies to support self-management of COPD: early value assessment Page 23 of 25 Issue date: September 2024

these technologies. Because these technologies are heterogeneous and have different functionalities, it would be useful to capture which features of these technologies are contributing to the outcomes recorded.

### Outcomes

3.29 Gaps in the outcomes included inconsistent reporting of outcome data across a wide range of measures, making it difficult to draw conclusions. The evidence gaps included respiratory function, health-related quality of life, and details on the number of exacerbations, hospital visits, and outpatient visits. The committee noted that long-term data was also needed to evaluate the true effectiveness of these technologies. The companies and technology developers agreed with this.

# 4 Committee members and NICE project team

## **Committee members**

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

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

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

Additional specialist committee members took part in the discussions and provided expert advice for this topic:

## **Specialist committee members**

#### Dr Rob Hallifax

Consultant in respiratory medicine and senior research fellow, Oxford University NHS Foundation Trust, and University of Oxford

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#### **Ravijyot Saggu**

Consultant respiratory pharmacist, Central London Community Healthcare Trust

#### **Cheryl O'Sullivan**

Advanced nurse practitioner, chief nursing information officer and clinical safety officer, NHS Dorset

#### **David McLean**

Patient expert

#### **Rashmi Agrawal**

Patient expert

# **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.

#### Aamer Jawed

Health technology assessment adviser (acting)

#### Haider Shamsi

Health technology assessment analyst

## Amy Crossley Health technology assessment adviser

**Toby Sands** Health technology assessment analyst

# **Catherine Pank**

Project manager

ISBN: