NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology consultation: DHT001 myCOPD for self-management of chronic obstructive pulmonary disease (COPD)

Supporting documentation – Committee papers

The enclosed documents were considered by the NICE medical technologies advisory committee (MTAC) when making their draft recommendations:

1. **EAC assessment report & appendices –** an independent report produced by an external assessment centre who have reviewed and critiqued the available evidence.
2. **Assessment report overview** – an overview produced by the NICE technical lead which highlights the key issues and uncertainties in the company's submission and assessment report.
3. **Scope of evaluation** – the framework for assessing the technology, taking into account how it works, its comparator(s), the relevant patient population(s), and its effect on clinical and system outcomes. The scope is based on the sponsor's case for adoption.
4. **Adoption scoping report** – produced by the adoption team at NICE to provide a summary of levers and barriers to adoption of the technology within the NHS in England.
5. **Sponsor submission of evidence** – the evidence submitted to NICE by the notifying company.
6. **Expert questionnaires** – expert commentary gathered by the NICE team on the technology.
7. **EAC correspondence log** – a log of all correspondence between the external assessment centre (EAC) and the company and/or experts during the course of the development of the assessment report.
8. **Company fact check comments** – the manufacturer's response following a factual accuracy check of the assessment report.

Please use the above links and bookmarks included in this PDF file to navigate to each of the above documents.

Document cover sheet

Assessment report: myCOPD

EAC team:

Project Lead(s): Joyce Craig and Michelle Green

Information specialist: Mick Arber

Clinical evidence reviewer: Angaja Phalguni and Stephanie Wake

Economic evidence reviewer: Judith Shore and Heather Davies

EAC sign-off: Louise Carr and Matthew Taylor

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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technologies guidance
[DHT001 myCOPD]
External Assessment Centre report

Produced by: York Health Economics Consortium (YHEC)

Authors:

Angaja Phalguni, Research Consultant, YHEC

Stephanie Wake, Research Consultant, YHEC

Judith Shore, Senior Research Consultant, YHEC

Heather Davies, Research Consultant, YHEC

Ayeda Nadeem, Research Assistant, YHEC

Mick Arber, Senior Information Specialist, YHEC

Joyce Craig, Associate Project Director, YHEC

Michelle Green, Project Director, YHEC

Correspondence to:

Michelle Green
York Health Economics Consortium
Enterprise House
University of York
YORK
YO10 5NQ
Email: michelle.green@york.ac.uk

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Number of attached appendices: Four
Appendix A - Searches and study selection
Appendix B - Risk of bias assessment

Appendix C - Adherence to myCOPD (PR) from TROOPER
Appendix D - RESCUE, North 2020. App usage and mean days used for the myCOPD arm in participants who did not withdraw from the study

Purpose of the assessment report

The purpose of this External Assessment Centre (EAC) report is to review and critically evaluate the company's clinical and economic evidence presented in the submission to support their case for adoption in the NHS. The report may also include additional analysis of the submitted evidence or new clinical, economic evidence, or both. NICE has commissioned this work and provided the template for the report. The report forms part of the papers considered by the Medical Technologies Advisory Committee when it is making decisions about the guidance.

Declared interests of the authors

Description of any declared interests with related companies, and the matter under consideration. See NICE's Policy on managing interests for board members and employees.

None

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- Professor Tom Wilkinson – Professor of Respiratory Medicine and Honorary NHS Consultant Physician at the University of Southampton and myhealth, founder of myCOPD.
- Ms Jennifer Robson, COPD Specialist Team Lead at Queen Alexandra Hospital, Portsmouth Hospitals NHS Trust

Professor Wilkinson and Dr Hicks declared conflicts of interest.

Responsibility for report

The views expressed in this report are those of the authors and not those of NICE. Any errors are the responsibility of the authors.

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Abbreviations

Term	Definition
6MWT	6-minute walking test
AE	Adverse event
AECOPD	Acute exacerbation of chronic obstructive pulmonary disease
BTS	British Thoracic Society
CACE	Compliance average cause effect
CASP	Critical appraisal skills programme
CAT	COPD assessment test
CCIO	Clinical Chief Information Officer
CCG	Clinical Commissioning Groups
CHFT	Community Health NHS Foundation Trust
CI	Confidence interval
CONSORT	Consolidated Standards of Reporting Trials
COPD	Chronic obstructive pulmonary disease
CRQ	Chronic respiratory questionnaire
CTCAE	Common Terminology Criteria for Adverse Events
EAC	External Assessment Centre
ESF	Evidence standards framework
F2F	Face-to-face
GOLD	Global initiative for obstructive lung disease
GP	General practitioner
HADS	Hospital anxiety and depression scale
HCP	Healthcare professionals
HRQoL	Health-related quality of life
HTA	Health technology assessment
ICS	Inhaled corticosteroids
ICTRP	International Clinical Trials Registry Portal
INAHTA	International Network of Agencies for Health Technology
INHALE	Interactive Health Atlas of Lung conditions in England
IQR	Interquartile range
ITT	Intention to treat
LABA	Long-acting beta2 agonists
LAMA	Long-acting anti-muscarinic agonists
MAUDE	Manufacturer and User Facility Device Experience
MCN	Managed clinical network
MDD	Medical device directives
MHRA	Medicines & Healthcare products Regulatory Agency
mMRC DS	Modified MRC dyspnoea scale
MRC	Medical Research Council
MTEP	Medical Technologies Evaluation Programme

N/A	Not applicable
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NR	Not reported
OR	Odds ratio
PAM	Patient Activation Measure
PICO	Population, Intervention, Comparator, Outcomes
PR	Pulmonary rehabilitation
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QOF	Quality Outcomes Framework
RCT	Randomised controlled trial
RWE	Real world evidence
SABA	Short-acting inhaled beta-agonists
SAMA	Short-acting muscarinic antagonist
SAP	Statistical analysis plan
SBRI	Small Business Research Initiative
SD	Standard deviation
SEAMS	Self-efficacy for appropriate medication use scale
SGRQ	Saint George's Respiratory Questionnaire
SoC	Standard of Care
SWOT	Strengths, weaknesses, opportunities and threats
UKRI	UK Research and Innovation
VAS	Visual analog scale
VSAQ	Veteran Specific Activity Questionnaire
WHO	World Health Organisation
WPAI	Work Productivity Activity Impairment
YHEC	York Health Economics Consortium

Executive summary

myCOPD is a digital tool designed to enable people to self-manage their chronic obstructive pulmonary disease (COPD). The platform is designed to allow shared decision making between patient and clinician to promote self-efficacy and beliefs that the patient can self-manage effectively with the support of myCOPD.

The company identified 4 completed clinical studies (3 RCTs and 1 observational study) and 1 ongoing study. These were reported in 5 documents. The company also submitted 6 published real world evaluations (RWE) of myCOPD, 9 unpublished RWE, usage information (as of January 2021) and unpublished responses from 6 clinicians to a company questionnaire.

The EAC's search did not identify any additional clinical study that was not stated in the company's submission but a further 5 published RWE evaluations were identified by the EAC's searches.

The RCTs described in the submission were the TROOPER study (a non-inferiority RCT that compared myCOPD with a 'face-to-face' PR programme), the RESCUE study (a feasibility RCT that compared myCOPD with 'usual care with additional written support') and the EARLY study (this compared myCOPD with usual care). The EAC noted that, in TROOPER and RESCUE trials, participants in the intervention arm received usual care, but that this was not fully aligned with usual care in the comparator arm. The EAC concluded that the intervention partially matches the scope for these two trials. The EAC concluded that the intervention in the EARLY study matches the scope and the comparators across the RCTs were generally aligned with the scope. The comparative observational study described in the submission (North 2015) explored the efficacy of myCOPD compared with the conventional paper-based system for PR. The study matched the scope of the decision problem in terms of its populations.

The RCTs provide robust evidence. The results from the RWE are potentially more generalisable to NHS patients but are prone to biases in the methods. Hence there are considerable inconsistencies and uncertainties with these results. Using myCOPD was associated with greater improvements in COPD assessment test (CAT) scores, 6-minute walking test (6MWT) and inhaler techniques but evidence was inconclusive on rates of exacerbations. App usage fell over time in all 3 RCTs and in the RWE.

The RCTs had a 3-month follow-up period and small sample sizes (<70), thereby limiting the power to detect statistical significance differences and to match patient characteristics across the arms. Two RCTs were not designed to detect superiority of myCOPD over usual care for clinical endpoints. Across the 3 robust RCTs, benefits are only shown in two patient populations (people discharged from hospital with AECOPD and people referred for PR) but the sample sizes are small.

The company submitted two base case cost minimisation analyses comparing myCOPD plus standard of care with standard of care alone. One model covers a population of patients discharged from hospital after an acute exacerbation of COPD (AECOPD), based primarily on the RESCUE study. The second model is for patients eligible for pulmonary rehabilitation (PR) within a CCG population, with an additional scenario exploring the cost-saving of myCOPD when paid for by a PR provider instead of the CCG. The base case PR model can be considered as an add-on to the AECOPD model and explores the use of myCOPD for delivery of PR programmes. When purchased by the CCG, myCOPD is priced at a cost per member of the CCG population rather than per user.

Changes by the EAC to the company models included the inclusion of uptake to the AECOPD model and a change to the decision point in the PR model which allowed for a cost saving per patient to be calculated. Other changes included minor corrections and revisions to inputs and costs, and the inclusion of a cost for starting and not finishing a PR programme.

Following these revisions, the EAC estimated cost savings with myCOPD of £86,300 per CCG in the AECOPD population, and £22,779 per CCG in the PR population, or £11,093 per PR service provider if considering the PR costing scenario. Deterministic sensitivity analysis demonstrated that the CCG results were sensitive to changes in the uptake of myCOPD and hospital readmission rates in the AECOPD population. Provided that uptake of myCOPD in the AECOPD population is above 29% it is expected that introducing myCOPD is likely to result in cost savings. Provided that, in the PR population, uptake of hybrid myCOPD remains over 16% it is expected that introducing myCOPD into PR delivery is likely to result in cost savings regardless of the uptake of myCOPD alone. Uptake of the hybrid approach can drop down to 0% if uptake of myCOPD alone remains above 10%.

Use of myCOPD outside of the modelled populations could generate additional cost savings should patient benefits outweigh the cost of registering additional patients.

1 Decision problem

The EAC has completed Table 1.1 to critique the evidence in relation to the decision problem. The company did not complete this element of its submission.

Table 1.1: Relevance of submission to scope

Decision problem	Scope	Proposed variation in company submission	EAC comment
Population	People with a diagnosis of COPD	No variation to the scope was proposed in company submission	All evidence identified by the EAC was in people with a diagnosis of COPD. Three RCTs and the real world evidence included a representative sample of the overall COPD population.
Intervention	myCOPD as an add-on intervention to standard care	No variation to the scope was proposed in company submission	All included clinical studies assessed myCOPD in addition to standard care and compared against standard care alone. However, in two RCTs (TROOPER and RESCUE), the elements of standard care differed between treatment arms (that is myCOPD was not the only difference): • In TROOPER, people in the comparator arm received face-to-face PR that those in the myCOPD arm did not receive. • In RESCUE, people in the comparator arm received a written COPD action plan that those in the myCOPD arm did not receive.
Comparator(s)	Standard care without myCOPD as an add-on intervention	No variation to the scope was proposed in company submission	
Outcomes	• COPD symptoms assessment CAT score • Rates of acute exacerbation • Rates of hospital admissions, readmissions or emergency admissions	No variation to the scope was proposed in company submission	Outcomes were included and consistent with the published scope where relevant data were available. EARLY study reported an additional outcome called compliance average cause effect (CACE) to analyse the effect on CAT score in

Decision problem	Scope	Proposed variation in company submission	EAC comment
	• Number of consultations with healthcare professionals in primary and secondary care • Rates of inhaler error • Compliance (adherence) to the use of myCOPD including PR (rate of course completed), education, inhaler technique improvement and exercise. • HRQoL • PAM • Self-efficacy for appropriate medication use • Walking test (a 6-minute walking test) • Device-related adverse events		those using the myCOPD app. The included studies did not report any relevant data for the underlined outcome but limited RWE evidence was available.
Cost analysis	N/A	-	N/A
Subgroups	• Severity of COPD (mild, moderate or severe COPD) • Time since COPD diagnosis	No variation to the scope was proposed in company submission	• No subgroup analyses were reported for TROOPER or, RESCUE. In EARLY, a subgroup of participants in the myCOPD and usual care arm were allocated to activity monitoring for 7 days at baseline and 7 days prior to end of study visit. Two RWEs reported limited data.

Abbreviations: CAT – COPD Assessment Test; COPD – Chronic obstructive pulmonary disease; EAC – External Assessment Centre; HRQoL – Health-related quality of life; MRC - Medical Research Council; N/A – Not applicable; PAM – Patient Activation Measure; PR - Pulmonary rehabilitation; RCT – Randomised controlled trial

2 Overview of the technology

As described in section 2.1 of the company submission, myCOPD is a digital tool designed to enable people to self-manage their chronic obstructive pulmonary disease (COPD). The platform is designed to allow shared decision making between patient and clinician to promote self-efficacy and beliefs that the patient can self-manage effectively with the support of myCOPD. The goal is preventing disease progression and promoting behavioural change, leading to improved clinical and patient outcomes, and reducing healthcare visits. People with COPD at any stage of disease progression can use the tool provided they have access to a device with an internet connection such as a smart phone or tablet.

MyCOPD incorporates multiple elements of care including patient education, self-management tools, symptom tracking, and pulmonary rehabilitation (PR) into a single system. Educational resources (for example inhaler technique videos and online tutorials on smoking cessation) allow people to learn more about their condition and how they can manage it, while a digital self-management plan reminds them which medications to take and when as well as checking any conflicts in prescribed medications. Users can report their symptoms daily and periodically undertake a COPD assessment test (CAT). With the user's permission, clinicians can access the results of these assessments and patient medication records, meaning that monitoring and management (for example suggesting a change to inhaler prescriptions) can be undertaken remotely.

The PR element of the tool is a 6-week online course comprising incremental exercise training and education sessions promoting effective self-management of COPD. This is done entirely remotely, meaning that people who would not be able to attend face-to-face sessions can still receive PR. This element was previously called myPR. Within this report the EAC refers to myCOPD or myPR as per the study being described at first use and then myCOPD thereafter.

The company advises the platform is intended for use in a shared care process, with clinicians and patients having access to the same real-time information on:

- symptoms as updated by patients
- management plans as updated by clinicians.

(See correspondence log).

In the company's submission, it notes that health information provided in the tool is aligned with current British Thoracic Society (BTS) guidelines on the management of COPD and content is updated as needed by specialists in the field. The BTS follows NICE guidelines on the diagnosis and management of COPD and uses the NICE Quality Standards (National Institute for Health and Care Excellence 2016). The guidelines are described more fully in section 3. This suggests that the information provided in the tool is accurate and appropriate to the UK clinical setting. This was confirmed by the clinical experts (see correspondence log).

MyCOPD incorporates an element of safeguarding by ensuring that only healthcare professionals to whom the user grants permission are able to access their data. Nonclinical healthcare staff (for example managers) can only view data reporting usage of the tool on an anonymised aggregated level.

MyCOPD incorporates multiple elements that encourage behaviour change including tutorials on smoking cessation and physical exercise, inhaler technique videos and tools promoting medication adherence.

The company has provided a theoretical framework and evidence base underpinning the behavioural change aspects within myCOPD. These draw on the Behavioural Change Wheel (see correspondence log).

MyCOPD received CE marking as a Class 1 device in 2016 following its commercial release in December 2015. In March 2020 myCOPD was classified as CE marked Class 1 medical device under the Medical Device Regulation. According to the advice from the Medicines and Healthcare products Regulatory Agency (MHRA) following Brexit, the CE marking will continue to be recognised in Great Britain until 20 June 2023. The CE mark certificate was included in the company submission.

The platform is constantly being updated, with a change log published on the website, providing a summary of each change, together with its date of release. Updates to the technology typically aim to improve functionality and performance. Recent changes include enhancing training for healthcare professionals (HCP) using an eLearning platform and simplifying the login process. The company states that the company has now developed a real time database and user interface which enables prospective review of aggregated, anonymised data on app registration, app access and clinical outcomes (my mhealth Ltd 2021b).

Under the NICE evidence standards framework (ESF) for digital health technologies (National Institute for Health and Care Excellence 2019b),

myCOPD is classified as Tier 3b because it includes active monitoring and is designed to provide and guide treatment. This means that evidence from high-quality comparative studies is needed to demonstrate its effectiveness and appropriate use in the NHS.

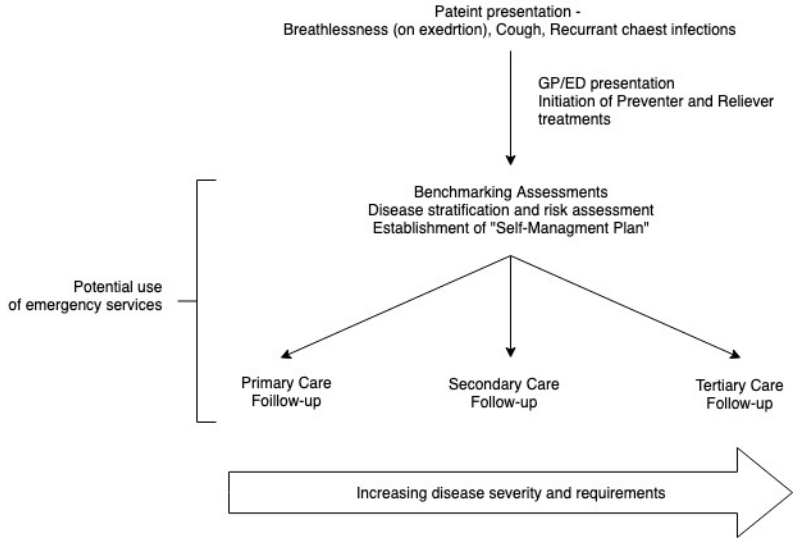
Since it was released in 2015, myCOPD now has over 11,000 users across the UK, all of whom were provided with access in order to improve the self-management of their COPD.

3 Clinical context

Company description of the clinical context

A description of the clinical context of the technology (that is its place in the current care pathway) is provided in section 3.1 of the company's submission and in additional submission information from the company (my mhealth Ltd 2021b). Figure 3.1 presents the company's presentation of the current pathway.

Figure 3.1: Pathway of care (from company)



The EAC considers that this description is relevant to the management of COPD in the NHS and, therefore, to the decision problem under consideration. The following EAC summary is intended to add to the detail provided by the company.

NICE Guideline on COPD

The NICE guideline on COPD in over 16s: diagnosis and management (NG115) recommends that people with a diagnosis of COPD are offered treatment and support to stop smoking in the first instance. All people with COPD should also be offered pneumococcal and annual flu vaccinations (National Institute for Health and Care Excellence 2019a).

Diagnosis of COPD is usually confirmed in secondary care, with subsequent management of people split between primary and secondary care. Those with severe symptoms are at greater risk of frequent exacerbations meaning that they are more likely to be admitted to hospital and receive care there, while people with mild to moderate symptoms are mostly managed in primary care, including by community pharmacists. All elements of standard care reported in NG115 are now reported.

Education

NG115 emphasises the importance of education for all people with COPD. This should be relevant to the person’s stage of disease, tailored to their individual needs and available on an ongoing basis throughout the care pathway. Such education is generally provided at face-to-face review appointments and includes written information and the opportunity to discuss the condition with an experienced healthcare professional (typically in primary care).

NG115 states that the information provided should cover the following at a minimum:

- an explanation of COPD and its symptoms
- advice on quitting smoking (if relevant) and how this will help with the person's COPD
- advice on avoiding passive smoke exposure
- managing breathlessness
- physical activity and PR
- medicines, including inhaler technique and the importance of adherence.
- vaccinations
- identifying and managing exacerbations
- details of local and national organisations and online resources that can provide more information and support

- how COPD will affect other long-term conditions that are common in people with COPD (for example hypertension, heart disease, anxiety, depression, and musculoskeletal problems).

Self-management

NG115 recommends that clinicians work with each COPD patient (and family members/carers if appropriate) to develop an individualised self-management plan. This should be reviewed regularly and updated as necessary. A self-management plan includes actions that the patient should take when experiencing exacerbation symptoms such as adjusting their short-acting (SABA) inhaler use, telling a healthcare professional, and self-administering oral antibiotics, corticosteroids, or both.

Pharmacological treatments

Pharmacological COPD treatments are provided in response to symptoms. Inhaled therapy is commonly prescribed to relieve breathlessness and exercise limitation. This includes the use of short and long-acting beta2 agonists (SABA and LAMA), inhaled corticosteroids (ICS), and combination therapies. People with COPD should be trained to use their inhalers before they are prescribed, and this ability should be assessed regularly and corrected if necessary.

NG115 also recommends that oral therapies are prescribed in some cases in response to symptoms. For example, oral corticosteroids and antibiotics may be used to manage exacerbations of COPD. For those with severe airflow obstruction, supplemental oxygen therapy may be necessary.

Pulmonary rehabilitation

PR should be offered to all people who view themselves as functionally disabled by their COPD. This is usually breathlessness equivalent to Medical Research Council (MRC) grade 3 dyspnoea or above (generally moderate to severe COPD). People often receive PR after being hospitalised for an acute exacerbation.

PR is a multidisciplinary programme of care with multiple elements that should be tailored to the individual. The aim is to minimise COPD symptoms, improve health related quality of life (HRQoL), increase physical involvement in day-to-day life, and improve mental health. In the current pathway of care PR is delivered face-to-face, often in a hospital setting, and includes exercise

training, disease education and nutritional, psychological, and behavioural counselling. Programmes last from 6 to 12 weeks.

NG115 does not give detailed recommendations on the specific content of PR programmes. However, a BTS Quality Standards for Pulmonary Rehabilitation in Adults was published in 2014 (British Thoracic Society 2014). This details that people with COPD and self-reported exercise limitation should be offered PR and receive it within 3 months of referral, while those discharged from hospital after an acute exacerbation should be offered PR and receive it within 1 month of discharge. Programmes should run for at least 6 weeks, with a minimum of twice weekly supervised sessions. Assessment sessions at baseline and on completion are in addition to this. Individualised aerobic and resistance training, together with a structured and comprehensive programme of education, should be delivered by competent professionals.

Monitoring

People with COPD should be followed up regularly in primary care. The frequency of follow-up depends on the person's severity of disease. People with mild, moderate, or severe COPD should attend a review at least once a year and undergo clinical assessment including smoking status, symptom control, inhaler technique, effectiveness of pharmacological treatment, and need for PR. For those with very severe COPD, reviews should be done at least twice a year and include additional assessments such as nutritional status, mental health, and need for supplemental oxygen therapy.

COVID-19 guideline

Subsequently, NICE issued a COVID-19 rapid guideline on community-based care of patients with COPD [NG168] (National Institute for Health and Care Excellence 2020). The guideline advised patients with COPD are at increased risk of severe illness from COVID-19. It recognised the need to reduce face-to-face contacts, recommending patients access online resources such as:

- the British Thoracic Society pulmonary rehabilitation resource pack, covering self-management, home exercise and educational materials
- a video on correct inhaler technique.

The guideline also advised that changes to care should take into account digital access and digital literacy issues to avoid inequalities of access. This guideline is relevant while the COVID-19 pandemic poses risks to the safety of patients and staff.

The company advised that many NHS services have used myCOPD to support patients during the COVID pandemic, with the platform replacing face-to face meetings. Usage accelerated during periods of lockdown. Hence in January 2020 there were about 1,000 new users a month, rising to over

2,500 new users in July 2020, with the initial lockdown; the current rate is around 2,000 a month.

Adherence to guidelines

Clinical experts noted that elements of NG115 are typically followed within the NHS but there is widespread variation in patients' access to services (see correspondence log). Key aspects were:

- Early access to education on the disease and its management (for example inhaler techniques) was the key to effective self-management.
- There is a lack of training for patients when self-management is first broached by HCPs.
- This is often not delivered until patients attend secondary care or receive PR.
- There is considerable variation in access to services, with many patients experiencing long delays in accessing services along the pathway from diagnostics to PR; for example, some 85% to 90% of patients may never be offered PR.
- About half of patients need reminders of the correct inhaler technique at the next visit following an HCP delivering such education.
- Causes of the access problems include the limited finite resources available; sometimes these patients are poor at advocating for their own needs; and exacerbations are most frequent in winter when the NHS is managing peak demands.
- In summary, all experts agreed patients would benefit from easy access to discrete and early interventions and this does not happen now.

Proposed pathway of care with the technology

The experts and company advise that the adoption of myCOPD in the NHS is unlikely to substantially change the care pathway for people with COPD. Face-to-face appointments are likely to remain the gold standard of care. The company reports in its submission that some clinical commissioning groups (CCGs) have already adopted myCOPD alongside existing care pathways. This is consistent with the views of the experts being that myCOPD enables services to offer a blended service, combining access to digital tools with face-to face support. Hence myCOPD can respond to patients' preferences and to service availability. This means that when face-to-face services cannot be delivered at a time when patients need the service, myCOPD may be substituted.

The company suggested that, in future, it is possible that myCOPD could replace some elements of the existing care for some people with COPD. For example, PR delivered by myCOPD could replace face-to-face programmes. This would reduce the NHS resources needed for PR. Similarly, use of the app's monitoring features by clinicians could possibly replace some face-to-face healthcare appointments (for example appointments where inhaler use, or the self-management plan is reviewed). Again, this could lead to a reduction in resource use.

Within the next few months, the company hopes to go live with links to the GP systems, SystmOne and EMIS. Interoperability will also be enhanced once planned developments are delivered which aim to integrate the platform with electronic health records. Such automation across systems should reduce data entry for items such as self-management plans and enable HCPs to, for example, upload symptoms information for tracking.

Equality issues

The NICE scope highlights that only people who have and can use a device with an internet connection (for example a smartphone or tablet) are able to use myCOPD (National Institute for Health and Care Excellence 2019c). The tool would likely be unsuitable for people with impaired manual dexterity, learning disabilities or visual impairments. Disability is a protected characteristic under the Equality Act.

It is noted in the company submission that use of the tool does not depend on being able to attend face-to-face appointments, which some people with myCOPD could struggle with either because physical disability or because of the availability and cost of transport. However, the company does not directly address any of the equality issues presented in the scope in its submission.

The NICE COVID-19 guideline identified that a decision to change usual care to digital only access could create access inequalities, exampling those with limited internet access, but inequalities could also arise for those with poor access to digital resources or poor digital literacy. A further inequality could arise because the app is only available in English, disadvantaging those with English as a second language (National Institute for Health and Care Excellence 2020).

No areas for improvement in access to healthcare for hard-to-reach populations were identified in the submission.

4 Clinical evidence selection

4.1 *Evidence search strategy and study selection*

Literature search

No literature search was reported in the submission. It was, therefore, not possible to assess whether the search methodology was appropriate. Because the EAC was unable to replicate or assess any search done by the company, the EAC conducted a *de novo* literature search to identify evidence.

The EAC search was conducted in a range of resources containing details of published, unpublished and ongoing research. The search was originally conducted in October 2019, then repeated in January 2021.

The October 2019 EAC search retrieved 3,168 records, with 2,133 records remaining after deduplication. The January 2021 EAC search retrieved 4,593 records, with 1,147 records remaining after deduplication (within-set and against the 2019 results). From the 2019 and 2021 searches, 7,761 records in total were retrieved, with 3,280 remaining after deduplication for assessment. The 2021 search result numbers include 1 study that became available as a pre-print after the search date. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Flow Diagram is provided in appendix A. Full details of the EAC's *de novo* search methods are provided in appendix A.

Study selection

The company did not provide information on the selection criteria and the process used to identify relevant studies in its submission report. Hence, it was not possible to critique the company's study selection process.

The EAC adopted a PICO (Population, Intervention, Comparator, Outcomes) framework for study selection. Details of the eligibility criteria are presented in appendix A. In summary, the population, and outcomes used were in line with the scope specified by NICE. However, the EAC adopted a broader approach to the intervention and comparators and included studies of myCOPD alone or in combination with 'standard care' vs. 'any intervention' or 'none' to reduce the risk of excluding relevant studies in which 'standard care' was not defined or explicit.

4.2 *Included and excluded studies*

Clinical studies

The company provided 5 documents on 4 completed studies (3 RCTs and 1 observational study) and 1 ongoing study. These included:

- 3 documents on 3 RCTs: TROOPER (Bourne et al. 2017), RESCUE (North et al. 2020) and EARLY (Crooks et al. 2020).
- 1 document on an observational study (North et al. 2014) but this study was not reported in company's submission document.
- 1 document on an ongoing study by Chmiel et al. (2020), which has not been peer reviewed (see section 8.2) (Chmiel et al. 2020).

The EAC's search did not identify any additional clinical study that was not stated in the company's submission. The EAC's search identified 11 documents on the 4 clinical studies. The 11 documents included 4 documents provided by the company and 7 additional documents. The 11 documents identified by the EAC's search were as follows: 3 documents on TROOPER (Bourne et al. 2017, Wilkinson et al. 2017, My mhealth Ltd 2015a), 3 documents on RESCUE (North et al. 2018, My mhealth Ltd 2015b, North et al. 2020), 2 documents on EARLY (Crooks et al. 2020)(My mhealth Ltd 2015a) and 3 documents on the observational study (North 2015, North et al. 2014, The Health Foundation 2014).

Apart from the full text of the ongoing study by Chmiel et al (2020), all documents provided by the company were identified by the EAC's search.

The EAC used evidence from 5 documents on the 4 studies (TROOPER (Bourne et al. 2017, Wilkinson et al. 2017, My mhealth Ltd 2015a), RESCUE (My mhealth Ltd 2015b, North et al. 2018, North et al. 2020), (Crooks et al. 2020)) and the observational study (North 2015, North et al. 2014, The Health Foundation 2014) to inform this report because the remaining associated documents did not provide any additional information.

Further details of the included studies are presented in Table 4.1. The colour coding in the table relates to whether the study matches the scope fully (green dots), partially (orange dots) or not at all (red dots).

Table 4.1: Clinical studies included by the EAC as the evidence base

Study name (acronym)	Design and intervention(s)	Participants and setting	Follow-up	Outcomes	Withdrawals	EAC Comments
Comparative studies: Randomised controlled trials						
TROOPER (Bourne et al. 2017) UK Published as full text, abstract and clinical trial record	**Design**: single site prospective, parallel group, single blind, 'non-'inferiority RCT. **Intervention**: 'myPR' – the PR elements of myCOPD. Referred to as myCOPD going forward. **Comparator:** face-to-face class-based PR programme for 6 weeks, delivered in a conventional community setting. Twice weekly supervised sessions with additional home-based exercises (3 times weekly	**Participants**: People aged ≥40 years with a diagnosis of COPD as defined by the NICE COPD guidelines with a modified MRC dyspnoea of grade ≥2 and referred for PR, with internet access and ability to use a web platform. Note that this is a subgroup of the overall COPD population. **Baseline characteristics** **myCOPD**: 64 participants **Age,** mean (SD): 69.1 (7.9) **Male,** n(%): 41 (62) **Smoking status,** n (%): Current: 9 (14) Former: 55 (86) **Severity of COPD,** n (%) Mild:15 (23) Moderate: 26 (41) Severe: 17 (27) Very severe: 6 (9). **Duration of disease**: Not reported. **Face-to-face PR**: 26 participants **Age,** mean (SD): 71.4 (8.6) **Male**, n(%): 18 (69)	Outcomes were measured at baseline and within 1 week of completion of the 6 week long PR programme. Adverse effects were captured at the start of each supervised session in the face-to-face group, and during a weekly phone call from the study clinical team in the myCOPD group, and at final assessment. The study did not have any long-term follow-up.	●Performance assessment using 6MWD test (best performance over a 30 m course) according to national standards (BTS quality standards 2014) ● Impact on health status: COPD symptoms assessment using CAT score ● SGRQ to assess respiratory QoL ● HADS to assess anxiety and depression	myCOPD [n(%)]: Lost to follow up: 4(6) Withdrawals: 11 (17) Exacerbation: 3(5) Face-to-face PR: Lost to follow up: 2(8) Withdrawals: 3 (12) Exacerbation: 0	Single centre study in UK Study partially matches scope. The name of the technology (myPR) is different from the one mentioned in the scope (myCOPD). Patients in myCOPD arm did not receive all components of usual care as in the comparison arm. This was a 'non-'inferiority trial which needs fewer participants than a superiority or equivalence study. Participants were randomised 2:1 to online and conventional PR. Minor imbalances between groups in baseline characteristics, most notably in smoking status with a higher proportion of current smokers in the face-to-face group compared with the online group (23% vs 14%). The number of participants with anxiety or depression at baseline was not reported despite these being

Study name (acronym)	Design and intervention(s)	Participants and setting	Follow-up	Outcomes	Withdrawals	EAC Comments
	requested). **Funding**: SBRI grant from NHS England.	**Smoking status,** n (%): Current: 6 (23) Former: 20 (77) **Severity of COPD,** n (%) Mild: 5 (19) Moderate: 13 (50) Severe: 7 (27) Very severe 1(4) **Duration of disease**: Not reported. **Setting**: Single centre; UK myCOPD: participants' home Face-to-face PR: Local rehabilitation facility		● Modified MRC Dyspnoea score ● Incidence of AE ● Adherence to PR		outcomes assessed. The authors noted the study was relatively short, although in line with the current clinical model of 6- to 12-week clinical PR courses. Results might not generalise to other settings as practice may differ across providers and regions. Trial registered as NCT02706613
RESCUE (North et al. 2020) Published as full text, abstract and clinical trial record	**Design**: single site, single-blind, parallel arm feasibility RCT. **Intervention**: myCOPD **Comparator:** Usual care with additional written support (education booklet plus self-management plan) for 3 months	**Participants**: People aged >45 years) with a primary COPD diagnosis as defined by the NICE guidelines, using an inhaled device and a current or ex-smoker for over 10 years. Included patients who had been admitted to a single NHS Acute Trust or managed by the local COPD Admission Avoidance Team in a home-based environment with an acute exacerbation of COPD. Internet access and ability to use a web platform, use a written action plan, or both, was also needed. Note that this is a subgroup of the overall COPD population.	Effectiveness outcomes were measured at baseline and after 3 months of commencing the study. All participants were contacted at 30, 60 and 90 days to record CAT score and collect adverse and serious adverse events. The numbers of COPD	●Recovery rate of symptoms, as measured by the CAT score at study completion (90 days) ● Inhaler technique ● SGRQ ● PAM ● HADS Questionnaire ● VSAQ ● WPAI ● Number of	myCOPD [n(%)]: Withdrawals: 3 (15) Usual care [n(%)]: Withdrawals: 3 (14)	Single centre study in UK Study partially matches scope. Patients in myCOPD arm did not receive all components of usual care as in the comparison arm. This was a feasibility trial with a relatively small sample size (<50 participants). The 2 groups were broadly comparable in terms of the participants' baseline characteristics with a few exceptions. The myCOPD group contained higher proportions of

Study name (acronym)	Design and intervention(s)	Participants and setting	Follow-up	Outcomes	Withdrawals	EAC Comments
	Funding: SBRI grant from Innovate UK.	**Baseline characteristics** **myCOPD**: 20 participants **Age,** mean (SD): 65.1 (6.3) **Male,** n(%): 13 (65) **Smoking status,** n (%): Current: 7 (35) Former: 13 (65) **Severity of COPD,** n (%) Moderately severe: 4 (20) Severe: 11 (55); Very severe: 5 (25) **Duration of disease:** Not reported. **Usual care:** 21 participants **Age,** mean (SD): 68.1 (7.4) **Male,** n(%): 11 (52) **Smoking status,** n (%): Current: 5 (24) Former:16 (76) **Severity of COPD,** n (%) Moderately severe: 10 (48) Severe: 6 (29) Very severe: 5 (24) **Duration of disease**: Not reported. **Setting**: Single centre; UK myCOPD: participants' home Conventional care: Not stated. Study visits took place in the	exacerbations and readmissions to hospital for COPD during the 3-month study period was recorded during monthly phone calls and at the end of study visit. The study did not have long-term follow-up of the participants.	treated COPD exacerbations ● Number of hospital readmissions for COPD ● Adverse events and serious adverse events These were not reported by COPD severity.		participants with severe COPD (55% vs 29%), male participants (65% vs 52%), and current smokers (35% vs 24%) than the usual care group. There was no statistical analysis of these differences. The prevalence of comorbidities such as anxiety and depression was not reported. The authors noted the study was small and limited in power to demonstrate effects on all measured outcomes. In addition, the study was unable to capture all data for myCOPD usage, which individual components were accessed and were beneficial. The study population was recruited from a single UK centre where English was the predominant spoken language and lower socioeconomic status was ubiquitous. The results might not generalise to other cultures and social backgrounds, in addition to other settings as practice may differ across providers and regions.

Study name (acronym)	Design and intervention(s)	Participants and setting	Follow-up	Outcomes	Withdrawals	EAC Comments
		hospital research centre at Portsmouth Hospital NHS Trust or in a participant's home.				Trial registered as NCT027066000
EARLY (Crooks et al. 2020) Published as full text, abstract and clinical trial record	**Design**: multiple sites, open label, parallel arm RCT. **Intervention:** myCOPD **Comparator:** Usual care for 3 months **Funding:** UKRI Innovate UK Grant to my mhealth	**Participants:** Patients aged 40 to 80 years with either mild to moderate COPD (FEV1 >50% predicted and FEV_1/forced vital capacity ratio <70%) or COPD of any severity diagnosed within the past 12 months. Patients were also current or ex-smoker. Internet access and ability to use a web platform was also needed. **Baseline characteristics:** **myCOPD:** 29 patients **Age,** mean (SD): 65.9 (7.3) **Male,** n(%): 11 (37.9) **Smoking status,** n(%): Current: 7 (24.1) **Years of smoking,** mean (SD): 39 (11) **Years since COPD diagnosis,** mean (SD): 7.9 (6.9) **Severity of COPD**, n(%): Mild:7 (24.1) Moderate: 22 (75.9) **⩾1 exacerbation** (past 3 months), n(%): 11 (37.9). **Standard care:** 31 patients	CAT scores, exacerbations, PAMS and SEAMS were recorded at baseline month 1, month 2 and end of the 3 months study period. All other outcomes were collected at baseline and at the end of the study. Activity monitoring was undertaken n in a subgroup for a 7-day period at baseline and then for 7 days prior to the end of study visit. The study did not have long-term follow-up of the participants.	●Recovery rate of symptoms, as measured by the CAT score ●Compliance average cause effect ● Inhaler technique ● PAM ● SEAMS ● EQ5D 5L ● Activity monitoring using Fitbit ● Number of treated COPD exacerbations ● Adverse events	myCOPD [n(%)]: Incomplete follow up: 5 (17.24) [this includes: withdrawn no reason (n=1); withdrawn as too unwell (n=1); withdrawn and re-entered (n=1); lost to follow-up (n=2)] Standard care [n(%)]: Incomplete follow up: 1 (3.2) [withdrawn no reason)	3 UK primary care centres. Study fully matches scope. All patients received same standard care. This was a superiority trial but had a small sample size (60 participants). The 2 groups were broadly comparable for some characteristics including COPD severity, age and smoking status. However, there was imbalance in others. The proportion of patients with at least 1 exacerbation in the past 3 months was greater in myCOPD than the standard care (37.9% vs 9.7%). myCOPD group contained lower proportion of men than standard care (37.9% vs 64.5%). Baseline scores were different between myCOPD and standard care groups [mean (SD)] for CAT [21.8 (8) vs 19.8], PAM [59.9 (15.9) vs 69 (13.8)] and the proportion of participants with highest PAM level (20.7% vs

Study name (acronym)	Design and intervention(s)	Participants and setting	Follow-up	Outcomes	Withdrawals	EAC Comments
		Age, mean (SD): 66.4 (7.3) **Male,** n(%): 20 (64.5) **Smoking status,** n(%): Current: 9 (29) **Years of smoking,** mean (SD): 38.6(12.5); **Years since COPD diagnosis,** mean (SD): 6.1 (5.9) **Severity of COPD**, n(%): Mild: 7 (22.6) Moderate: 24 (77.4) **≥1 exacerbation** (past 3 months), n(%): 3 (9.7). **Setting:** Primary care, three centres; UK (Hull University Teaching Hospitals; NHS Trust Hampshire Hospitals NHS Foundation Trust; Central London Community Healthcare NHS Trust) MyCOPD: Patients' home Conventional care: NR Study visits involved two sites visits and one telephone contact.				41.9%). There was no statistical analysis of these differences. The prevalence of comorbidities such as anxiety and depression was not reported. The authors advised the 2 groups were not similar because of the small sample size. MyCOPD group were predominantly female with a high baseline symptom burden, had a lower physical activity level and a higher proportion of patients in the lowest activation levels. The authors added the study was underpowered to demonstrate significant effects in the primary outcomes at 90 days. The study population was recruited from and included patients with mild to moderate COPD. Participants in the myCOPD group received no coaching or encouragements from researchers to use the app. This may increase the generalisability of the results. However, the small size of the study makes it difficult to generalise the results to other

Study name (acronym)	Design and intervention(s)	Participants and setting	Follow-up	Outcomes	Withdrawals	EAC Comments
						settings as practice may differ across providers and regions Trial registered as NCT03620630
Comparative studies: Observational studies						
(North 2015) UK Published as an abstract, a narrative article and a service evaluation	**Design**: single site, observational (cohort) study. **Intervention**: 'myCOPD' followed for 3 months. **Comparator:** Usual care consisting of the conventional paper-based self-management system for 3 months. Under current practice, patients are allotted time with a specialist nurse to learn the correct use of inhalers and some simple exercises.	**Participants**: People with a confirmed COPD diagnosis who were recruited through a request for volunteers in a local newspaper. Baseline characteristics **Overall:** 36 participants. Age range: 50 to 85 years. Duration of disease: Not reported. **myCOPD**: 27 participants Baseline characteristics not reported. **Paper-based system:** 9 patients Baseline characteristics not reported. **Setting**: Single centre; UK myCOPD: participant's home Paper-based system: During clinic, after an admission or during the participant's annual review.	Effectiveness outcomes were assessed at the beginning and end of the project (3-month programme). The study did not have long-term follow-up of the participants.	●Impact on quality of life, as measured using the CAT ● Inhaler technique from a video recording	myCOPD [n(%)]: Withdrawals: 5 (18.5) Paper-based system [n(%)]: Withdrawals: 4 (44.4)	Single centre study in UK Study partially matches scope. Patients in myCOPD arm did not receive all components of usual care as in the comparison arm. The online system contains exactly the same information as the paper-based system, but in a different format. The written group were allocated by default, as the technology needed to access the online system was not available to them. Small study (<50 patients). The brief article had limited details of the study methods. Apart from the age range, baseline characteristics of participants were not reported. The study was reported to involve participants from all socioeconomic backgrounds. The study was limited in the outcomes it measured, with selective and poor reporting of the outcome data.

Study name (acronym)	Design and intervention(s)	Participants and setting	Follow-up	Outcomes	Withdrawals	EAC Comments
	At the end of the study participants in both arms were offered access to myCOPD platform for life **Funding**: SBRI for Healthcare contract.					This study was undertaken to explore the efficacy of the online system compared with the conventional paper-based system. The authors stated that, based on the success of this project, they had been awarded funding to complete 2 clinical trials. The results might not generalise to other settings as practice may differ across providers and regions. Trial registered as NCT027066000

Abbreviations: 6MWD – 6-minute walking distance; AE – adverse event; BTS - British Thoracic Society; CAT – COPD assessment test; COPD - Chronic obstructive pulmonary disease; EAC – External assessment centre; FEV_1 – Forced expiratory volume in 1 second; HADS – Hospital Anxiety & Depression Scale; MRC - Medical Research Council; NICE – National Institute for Clinical Excellence; NHS – National Health Service; NR – not reported; PAM – Patient activation measure; PR – Pulmonary rehabilitation; RCT – Randomised control trial; SBRI – Small business Research Initiative; SD - Standard deviation; SEAM – social-emotional assessment/evaluation measure; SGRQ – Saint Georges Respiratory Questionnaire; UKRI – UK Research and Innovation; VSAQ - Veteran specific activity questionnaire; WPAI: Work Productivity Activity Impairment Questionnaire.

Real world evidence

The company submitted:

- 6 published real world evaluations (RWE) of myCOPD
- 9 unpublished RWE of myCOPD
- Usage information for myCOPD as at January 2021 (my mhealth Ltd 2021b)
- Unpublished responses from 6 clinicians to a company questionnaire (My mhealth Ltd. 2020).

A further 5 published evaluations were identified by the EAC's searches. Hence the evidence base comprised of 22 documents. Several of these were under a page in length and thus had limited evidence (for example from Kent Community Health NHS Foundation Trust (CHFT) or were a poster (for example from NHS Grampian). Many were interim evaluations designed to inform commissioning decisions or service developments. Publications were not in peer-reviewed journals but usually on local websites.

The 10 settings for the studies were: Southend CCG (5 documents), NHS Grampian evaluation (2 documents), NHS West Lothian (3 documents), NHS Highland (3 documents, note data is extracted from the most recent document only following advice from the study author that comprises the most accurate data), Leeds community evaluation, Coventry primary care, Ipswich and East Suffolk (meeting presentation and staff survey), Mid and South Essex case study, Kent CHFT and Dorset CCG evaluation. Table 4.2a contains details extracted from these evaluations.

The company also provided information which it had downloaded from the system on all users of the app as at January 2021 (my mhealth Ltd 2021b). The report details user characteristics, the content accessed and for how long and attrition rates over time (see Table 4.2b). Responses from 6 clinicians are provided in section 5.3 (My mhealth Ltd. 2020).

Table 4.2a: Real world evidence (RWE) included by the EAC as the evidence base

Study name (acronym)	Design and intervention(s)	Participants and setting	Follow-up	Outcomes	Comments
myCOPD Leeds evaluation [published] myCOPD in Leeds Author: R Benn. Digital Inclusion Coordinator at Leeds City Council Date: unknown (Benn 2021)	Interim evaluation of the key benefits, challenges, opportunities, and next steps of using the myCOPD app in a Leeds community setting.	**Participants:** People with a confirmed COPD diagnosis in Leeds, using myCOPD in primary care and attending Breathe Easy group meetings. Number of participants NR Baseline characteristics NR **Setting**: Breathe Easy group meetings	NR	Key benefits • The Mindfulness component helped calm a client's breathing during bouts of anxiety and depression after the loss of his wife. • The inhaler videos helped a client correct her inhaler technique, which she shared with group members who also improved their technique. Key challenge: remembering to use the app daily. Key opportunities: medication log, enabling users to remember what medication has been taken daily and PR course. This enabled clients to access it at home rather than join a waiting list.	This is a qualitative evaluation. Key next steps are to measure impact on GP visits/visits to A&E and identify the features patients find vital in self-managing their condition. No patient data/demographics are reported. The report uses only a small number of examples.
NHS Grampian (2 x docs): NHS Grampian evaluation MMH-E04 [published] Local evaluation Poster ID 2018 Aberdeenshire HSCP myCOPD	A supported self-management evaluation of COPD patients in general practice in NHS Grampian	**Participants:** Primary care COPD patients **Overall: 23** Average age: 70 (range 40 to 86) 14 to 20% of the COPD patient register in each practice agreed to participate in the project	5 months	• Improvement in mean CAT score of -2.1 • Mean reduction in rescue inhaler use from 3.17 to 2.13. Good inhaler technique practice increased from 48 to 91%. • 20 (19%) fewer unscheduled GP appointments (reduction range of 105 to 85), and hospital admissions dropped from 6 to 0 compared with patient data prior to myCOPD. • Patient feedback reported that those describing their ability to manage exacerbations very well rose from 29% to	The report has a small sample size, with no information on patient clinical baseline. It is not clear why 43 patients from Stonehaven were selected for the interim review.

Study name (acronym)	Design and intervention(s)	Participants and setting	Follow-up	Outcomes	Comments
[published] Authors: McLaughlin et al.; GP Stonehaven, Clinical Lead Date: 2019 (McLaughlin and Skinner 2018, McLaughlin and Skinner 2020)		**Interim review patients selected**: 43 patients were selected for the interim review from Stonehaven **Interim review patients included:** 23 of the above 43 who returned for clincal review **Setting**: Multi-centre (3 GP practises), UK NHS Grampian, 2019		55%, and those who felt confident using an inhaler rose from 76% to 90%. • The proportion reporting exacerbations every other day reduced from 28% before using myCOPD to 22% six months after.	
Coventry community project Evaluation [unpublished] Use of the my mHealth myCOPD platform by the Coventry Community COPD Service during the Covid-19 pandemic Author: [redacted] Date: [redacted] (Heritage 2020)	Evaluation of the use of myCOPD by Coventry community COPD service during the Covid-19 pandemic	**Participants:** [redacted] Data collection from [redacted] **Overall:** [redacted] Age: [redacted] males ([redacted]) females ([redacted]). COPD Severity [redacted]	Use of app: [redacted] CAT score: [redacted]	• Frequency of app use: [redacted] • Accessed inhaler videos: [redacted] • CAT scores [redacted] • 1-minute sit to stand test [redacted] • Self-reported CRQ: [redacted] • Patient feedback [redacted]	[redacted]

Study name (acronym)	Design and intervention(s)	Participants and setting	Follow-up	Outcomes	Comments
		[redacted] **Setting**[redacted]			[redacted]
NHS Highland (3x docs included, data extracted from most recent paper): NHS Highland narrative data summary [unpublished] Author: unknown Date: 2019 Note superseded by 2021 paper NHS Highlands evaluation of myCOPD Abstract [published] Author: Cooper et al.	Evaluation of the myCOPD by NHS Highland Test of Change in a predominantly remote and rural population	**Participants:** Patients enrolled on myCOPD. **Narrative summary: 120** patients (113 analysed as 7 died during the study) Mean age: 69.3 years Female: 51.3% COPD severity (based on GOLD score): Moderate/severe = 61.1% (n=69/113) Very severe = 20.4% (n=23/113) **Setting**: 65% were recruited in the community, 35% through outpatient departments.	12 months	**Narrative summary:** • 79% of patients activated myCOPD. • 56% activitated on the day of enrolment and 90% within 1 month. • 70% recorded their symptom score at least once, 57% recorded their CAT score, 54% initiated PR training, 24% viewed educational material and 10% watched at least 1 inhaler technique video. • No association between myCOPD use and participant demographics. • No statistically significant differences in hospital admissions, inpatient bed days, or other health service utilisation before and after myCOPD activation. Modest increase in home visits. • Subgroup analysis found individuals with the greatest engagement either by frequency of symptom scoring or by numbers of modules used did show a reduction in bed days.	No data on clinical outcomes were reported. Different amount of data was collected before and after myCOPD activation due to COVID-19 pandemic. No associations were found in patient demographics and outcomes, excluding the subgroup of most engaged users, who were found to

Study name (acronym)	Design and intervention(s)	Participants and setting	Follow-up	Outcomes	Comments
Date: 2020 Note superseded by 2021 paper Evaluation of myCOPD, a digital self-management technology, in a remote and rural population [preprint] (publication of 2020 evaluation) Author: Cooper et al. Date: 3rd June 2021 (NHS Highland 2019, Cooper et al. 2021b, Cooper et al. 2021a)					have significantly less bed days.
NHS West Lothian (3x docs): NHS West Lothian project evaluation [unpublished] West Lothian Scottish Thoracic Society presentation [unpublished]	[redacted]	**Participants:** [redacted] Median age: [redacted] **Overall:** [redacted]	[redacted]	**Interim evaluation based on sample from** [redacted] **Interim evaluation** [redacted]	[redacted]

Study name (acronym)	Design and intervention(s)	Participants and setting	Follow-up	Outcomes	Comments
West Lothian myCOPD Poster A9263581 [unpublished] Author: [redacted] Date: [redacted] (Maguire 2018, Maguire and Noble 2018, NHS Lothian 2018)	[redacted]	[redacted] **Setting**: [redacted]		[redacted]	[redacted]
Ipswich and East Suffolk evaluation (2 x docs): Ipswich and East Suffolk meeting presentation [published] Author: Dr Harry Thirkettle; Senior Medical Advisor	Evaluation of the ongoing Ipswich and East Suffolk myCOPD project	**Participants:** Patients with severe and very severe COPD via Secondary Care and Community Team **Overall**: **348** patients that initially registered to use myCOPD **Setting**: Home based, Ipswich and East Suffolk, UK	18 months	Usage metrics: • 127 activated the app (37%). • Average of 22.2 per patient • 48 (38% of those activating) became engaged users (≤5 log-ins). • 31(24%) logged in ≤10 times. Average usage was 7 months. • 15 patients (12%) became super users; logging in ≤50 times, with 10 (8%) of these logging in ≤100 times. Engagement metrics: • CAT scores completed 1041 times	It is stated the next steps are for the digital health advisors to provide training to clinician and admin staff on the app and its use in primary care and home PR. They will also offer to provide remote activation of the app to increase the

Study name (acronym)	Design and intervention(s)	Participants and setting	Follow-up	Outcomes	Comments
Date: November 2019 Ipswich and East Suffolk Staff survey evaluation [unpublished] [redacted] ([redacted])		**Staff survey:** [redacted] [redacted] Length of time using myCOPD: 0 to 3 months: 33.3%, 6 to 12 months: 50.0% > 12 months: 16.7% Number of patients logging on: 15 patients (12%) logged in > 50 times, with10 (8%) logging in > 100 times.		• 489 PR exercise videos watched for a total of 6,901 minutes. • 328 Education videos watched, a total of 641 minutes. • 91 inhaler videos watched. • Mean usage per activated patient of 1.2 hours of video content. Other outcomes • Over 80% would likely or highly recommend the app. • Over 90% rated their experience with the app good or very good, with the balance scoring it as neither good or bad. • Of those completing the PR component, CAT scores declined by 3.1. • Capacity increased by 113%. Staff evaluation survey: [redacted]	proportion of users.

Study name (acronym)	Design and intervention(s)	Participants and setting	Follow-up	Outcomes	Comments
				• [redacted] .	
Southend CCG (5 x docs): Southend myCOPD Enhanced Home-Based Pulmonary Rehabilitation Evaluation MMH-E03 [published] Author and date unknown Southend CCG: 3-armed study into the use of myCOPD in pulmonary rehabilitation. [published] Author and date unknown Southend CCG Pulmonary rehab overview [unpublished]	A service evaluation using myCOPD to support home-based PR	**Participants:** Home-based patients awaiting pulmonary rehabilitation at Southend University Hospital **Overall**: **88** **myCOPD**: 59 (67%) of whom **myCOPD only**: 15 (17%) **myCOPD + written information and DVD:** 44 (50%) **Written information and DVD**: 29 (33%) Baseline characteristics NR **Setting**: Southend University hospital launched the home-based service in 2018	6 weeks	Home-based PR • 52.5 % using myCOPD at home completed the full PR programme vs. 24.1% of group not using the app. • Greatest reduction in CAT score -3.7 with myCOPD only; -3.6 to -1.9 across other groups. Hybrid PR: • Completions rates increased from 40% (usual care) to 72%. • 6 MWT increased by 105m. • CAT score decreased by 4.2. • Capacity increased by 113%.	This was a 3-armed study to assess the integration of myCOPD in PR. No patient demographics or clinical baseline reported. Study is still ongoing. It is stated this report supports the TROOPER study.

Study name (acronym)	Design and intervention(s)	Participants and setting	Follow-up	Outcomes	Comments
Author and date unknown Southend CCG Home programme report Author and date unknown Southend CCG/Castlepoint & Rochford CCG [unpublished] Author: Lisa Ward, Lead Respiratory Nurse, Southend Hospital Date: Jan 2019 (Southend CCG 2019b, Southend CCG 2019a, Southend University Hospital 2021a, Southend University Hospital 2021b, Ward 2019)					
Kent CHFT evaluation	A service pilot evaluation of myCOPD	**Participants:** COPD patients aged ≥18 years who were referred into the	6 weeks	• 49 (68%) completed the 6-week course compared with a national average for	A brief report, but results show that clinical use of

Study name (acronym)	Design and intervention(s)	Participants and setting	Follow-up	Outcomes	Comments
A digitally enhanced pulmonary rehabilitation approach for COPD during COVID-19 using myCOPD [unpublished] Author: J Stokes et al. Date: 2021 (Stokes and Savage 2021)		service, and who had an internet connected device. Patient demographics NR. **Overall**: **72** patients chose to use myCOPD for PR **Setting**: Patients were enrolled for a period of 6 weeks in digital supported PR between June to October 2020		completion of conventional PR of 62% (1). • 49 of 72 patients (68%) had their exercise capacity measured • 33 (67%) patients achieved an overall improvement in the test compared with the national average of 65%, and 60% for remote delivery. • 70 (97%) distinct users entered 235 CAT scores ranging from 1 to 29 per user. • These initial results prompted an increase in patients having access to the app, now 103 patients use it • Of these 103, 102 (99%) have accessed educational video content with a total of 2,788 watches, and 85 patients (83%) have accessed the PR course with 1,286 views.	myCOPD can address both current and pre-COVID-19 service challenges.
myCOPD Mid and South Essex evaluation [published] myCOPD Mid and South Essex Case Study Author and date unknown (Mid and South Essex STP 2021)	Evaluation of a case study into myCOPD clinical integration.	**Participants:** patients undergoing PR. Patient demographics NR. **Setting:** patients could complete either home-based or centre-based	NR	myCOPD home-based PR showed improvements in: • 6 MWT of 58m • 3.7 in CAT scores Both gains are above the minimal clinically important difference for PR.	This is a brief report with minimal details of the study, and patient demographics. It is stated that a primary care roll-out is now planned to provide access to broader range of patients.
Dorset CCG evaluation	An independent mixed methods	**Participants**:	~12 months	**Working groups data:**	Data are from 207 users, with 125 in

Study name (acronym)	Design and intervention(s)	Participants and setting	Follow-up	Outcomes	Comments
Dorset CCG independent evaluation of My mHealth [published] Author: Catherine Matheson-Monnet et al. Date: March 2019 (Matheson-Monet 2019)	evaluation of the Proof of Concept pilot roll out of My mHealth, (including myCOPD, myHeart, and myDiabetes)	'Non-participant' observation of 19 working group meetings 7 focus groups with clinicians: 7 Survey responses from clinicians: 14 Interviews with clinicians who distributed My mHealth to patients: 9 Survey responses from patients: 8 Interviews with patients: 3 **Setting**: Roll out was via Dorset CCG		• myCOPD is beneficial for regularly users who are satisfied using it. • Restricting factors were; additional staff time needed and not being able to easily follow up patient engagement. • Improvements included a simplified password procedure, promotion at a primary care flu clinic, and redesigning of content to help resolve app errors. **Patient data:** • Some did not enter data regularly but used the app to refresh knowledge. • Agreed online training module was easy to follow, but less so that it was useful. • Agreed they were supported by healthcare staff and valued the app on their daily/weekly routine practice. • Had the greatest agreement that the app enabled them to manage their condition. • Agreed they would recommend the app to family and friends. **Findings from clinicians:** • Clinicians agreed myCOPD could be integrated into annual and other reviews and they had access to information about the impact of my mHealth – but disagreed that they use the app to check on patients remotely. • Because of lack of patient engagement and hence insufficient evidence, clinicians disagreed that my mHealth improved the quality of patients' experience or empowered them to	secondary care and 82 in in primary care. Data reported is for My mHealth as a whole, and so may not be specific to myCOPD. The patients surveyed and interviewed were stated by the authors to be highly motivated, knowledgeable and confident about self-management, and the condition of their health was important to them. Hence findings have limited generalisability.

Study name (acronym)	Design and intervention(s)	Participants and setting	Follow-up	Outcomes	Comments
				manage Long Term Conditions alongside traditional models of care or had helped reduce the cost of healthcare. • Clinicians estimated between 5% to 10% of registered patients entered data into myCOPD daily or weekly.	

Abbreviations: 6 MWT – 6-minute walking test; CAT – COPD assessment test; CCG – clinical commissioning group; COPD – chronic obstructive pulmonary disease; CRQ – chronic respiratory questionnaire; HSCP – health and social care partnership; MCN – managed clinical network; MRC – Medical Research Council; NR – not reported; PR – pulmonary rehabilitation; SWOT – strengths, weaknesses, opportunities and threats; UK – United Kingdom.

Table 4.2b summarises usage information downloaded from myCOPD for 11,017 users who had activated the app by 11 January 2021. These provide an overview of the range of information available from the app and the types of reports which can be extracted. The key data relate to usage over time and the components of the app which users are engaging with.

Table 4.2b: myCOPD Supplementary usage information (my mhealth Ltd 2021b)

Study name (acronym)	Participants and setting	Follow-up	Outcome	Comments
myCOPD Supplementary information 20210117 Author: My mHealth Date: 2021	**Participants:** [redacted]	[redacted]	Uses of myCOPD	[redacted]

Study name (acronym)	Participants and setting	Follow-up	Outcome	Comments
	[redacted]		Patient retention	[redacted]
			CAT scores on [redacted]	[redacted]
			Exacerbations	[redacted]
			Regional usage	[redacted]

Study name (acronym)	Participants and setting	Follow-up	Outcome	Comments
				[redacted]

Abbreviations: CAT – COPD assessment test; CCG – clinical commissioning group; PR – pulmonary rehabilitation

5 Clinical evidence review

5.1 *Overview of methodologies of all included studies*

Evidence from 3 RCTs

The company did not report details of the methodology of the 3 included RCTs (TROOPER, RESCUE and EARLY) in its submission. The EAC has extracted information on the patients and study methodologies from 3 RCTs and the additional observational study (Table 4.1).

The TROOPER study was a 'non-'inferiority RCT that compared myCOPD with a 'face-to-face' PR programme. Five online sessions a week were suggested for myCOPD. Because of the use of the older version of myCOPD (myPR) it is unclear if the intervention is fully aligned with the version of myCOPD available today. The RESCUE study was a feasibility RCT and compared myCOPD with 'usual care with additional written support'. The EARLY study was a superiority RCT and compared myCOPD with usual care.

The EAC noted that, in TROOPER and RESCUE trials, participants in the intervention arm received usual care, but that this was not fully aligned with usual care in the comparator arm. In TROOPER those in the comparator arm received additional face-to-face PR and in RESCUE they received additional written action plans. According to the scope of the decision problem, the only difference between the 2 arms should be myCOPD. For this reason, the EAC concluded that the intervention partially matches the scope for these two trials. The EARLY study compared myCOPD with usual care. Details of usual care were not reported, but the company confirmed that participants in the myCOPD arm received the same usual care as the comparator arm. Hence, the EAC concluded that the intervention fully matches the scope for this trial. Participants used the myCOPD app as they wished and did not receive coaching or encouragement from researchers during the study.

The comparator varied across the RCTs but was generally aligned with the scope in that it was "standard care", noting that standard care is likely to differ across settings. In TROOPER, the face-to-face PR programme included twice weekly supervised sessions delivered in a conventional community setting with additional home-based exercises. In RESCUE, the comparator was usual care with additional written support, which included education booklet plus self-management plan. No further details were provided. The EARLY study did not provide any information on the components of standard care, but it was stated to be aligned with current NHS management based on national

and local guidelines. In EARLY, at the end of the study participants in both arms were offered access to the myCOPD platform for life.

Studies were small with 41 participants in RESCUE, 60 in EARLY and 90 in TROOPER. The number of participants were balanced across the treatment arms in RESCUE and EARLY but in TROOPER, participants were randomised in the ratio of 2:1 to myCOPD and face-to-face PR respectively to reduce the numbers of participants in the more costly face-to-face intervention while maintaining the power. Studies used a stratified approach to ensure even distribution of severity of COPD in both arms. Disease severity (FEV1% predicted) was defined by the global initiative for obstructive lung disease (GOLD) classification of COPD severity in RESCUE and TROOPER studies but not defined in EARLY.

Each RCT recruited adults (>40 years in TROOPER, >45 years in RESCUE and 40 to 80 years in EARLY), with a primary COPD diagnosis as defined by the NICE guidelines which is aligned with the scope. Participants needed to have access to the internet and the ability to use a web platform. In TROOPER, participants were recruited from outpatient respiratory clinics and needed to have a modified MRC dyspnoea of grade ≥2 and were referred for PR. In RESCUE, patients with acute exacerbation of COPD were recruited following a hospital admission or if they had been managed by the local COPD Admission Avoidance Team in a home-based environment. RESCUE also needed participants to be current or ex-smokers for over 10 years and to be using an inhaled device. All of the participants in RESCUE had moderately severe to very severe COPD. EARLY recruited patients who had either mild to moderate COPD or COPD of any severity diagnosed within the past 12 months. Participants in EARLY were also needed to be either current or ex-smokers. All of the participants in EARLY had mild to moderate COPD.

Details on a number of characteristics at baseline were reported in the studies but no statistical analyses of the differences in these characteristics was done. In TROOPER and RESCUE the groups were broadly comparable for most of the participants' baseline characteristics with a few exceptions. In TROOPER, there was a higher proportion of current smokers in the face-to-face group compared with the myCOPD group (23% vs 14%). In RESCUE, the myCOPD group contained higher proportions of participants with severe COPD (55% vs 29%), male participants (65% vs 52%), and current smokers (35% vs 24%) than the usual care group. In EARLY, the myCOPD group were predominantly female with a high baseline symptom burden, significantly lower physical activity levels and had a higher proportion of patients in the lowest activation levels This was because in EARLY, the myCOPD group contained a higher proportion of participants with at least 1 exacerbation in the past 3 months (37.9% vs 9.7%), lower proportion of male (37.9% vs

64.5%), higher CAT score [mean (SD): 21.8 (8) vs 19.8], lower PAM score [mean (SD): 59.9 (15.9) vs 69 (13.8)] and lower proportion of patients in highest PAM level (20.7% vs 41.9%) compared with usual care. The prevalence of comorbidities such as anxiety and depression at baseline and duration of disease was not reported in any of the three studies.

The studies used a number of different questionnaires to assess HRQoL, anxiety and depression, activity impairment, work productivity impairment using measures that were not specified in the scope. EARLY also analysed the effect of compliance with myCOPD app on CAT score (compliance average cause effect) and self-efficacy for appropriate medication use. One outcome specified in the scope was not reported in any of the studies. This was number of consultations with healthcare professionals in primary and secondary care.

Outcomes were measured at baseline and 1 week after completion of a 6-week PR programme in TROOPER and at 3 months in RESCUE and EARLY. The studies did not have any longer term follow up.

Details of power calculations were reported in TROOPER and EARLY. In RESCUE, the authors noted that the study was small and limited in power to demonstrate effects on all measured outcomes. However, they considered it suitable for the main objective of their pilot study; to determine the feasibility of using a digital platform to support participants with COPD after a significant clinical event such as exacerbation.

TROOPER and RESCUE were done in a single centre and EARLY was done in 3 centres; all were done in English NHS settings. Funding for TROOPER was by a Small Business Research Initiative (SBRI) grant and RESCUE and EARLY were funded by grants from Innovate UK.

Evidence from 1 comparative observational study

The EAC identified 1 comparative observational study (North 2015), which was published as a full text. The company also identified this study (as an abstract) (North et al. 2014) but did not mention it in its submission. North 2015 (North 2015) was a service development project undertaken to explore the efficacy of the online system ‘myCOPD’ compared with the conventional paper-based system for PR. The online system contained the same information as paper-based system but in a different format. Participants accessed myCOPD in their home and the paper-based system was accessed during clinic, after an admission or during a participant’s annual review. In both arms participants received usual care, with the difference between arms consisting of myCOPD or paper-based PR.

North 2015 was small (n=36) and had 3 times more participants in the intervention (n=27) than the comparator group (n=9). The study matched the scope of the decision problem in terms of its populations, recruiting people with a confirmed diagnosis of COPD. The study was reported as a brief article with limited details of the study methods. Aside from the overall age range (50-85 years), baseline characteristics of the participants were not reported.

The study was limited in the outcomes that it measured, but those that were reported aligned with the scope. Outcomes assessed were (i) impact on HRQoL measured using the CAT and (ii) inhaler technique. The programme was followed for 3 months, and outcomes were assessed at the beginning and end of the study. The study did not have any long-term follow up of the participants.

The study did not report power calculations given that it was a pilot study. The authors stated that, based on the success of this pilot, they had been awarded second-phase funding to complete 2 clinical trials. The study was done in a single centre in the UK and was funded by a SBRI grant.

Evidence from real world evidence studies

In the evaluation of myCOPD, RWE can identify key factors influencing effectiveness such as if patients found the app useful in managing their condition, whether they activated it and used it over a sustained period and if they would recommend it to others. Other more direct indicators of success include whether patients have successfully changed behaviours or exhibited clinical improvement while using the app. However, evaluations were usually too short, too small and not sufficiently well-resourced to measure aspects such as behavioural changes or changes to clinical outcomes.

The RWE focused on user acceptance and adherence. Several report only on the PR component of the app. Many were pilot studies using the results to inform decisions on whether to commission the app more widely and aspects such as the service developments required to encourage greater user and clinical engagement and hence effectiveness. Thus, many are interim evaluations, with the sites continuing to use the app, whilst addressing concerns identified by the evaluation, and, importantly, continuing to monitor its use.

Of the 10 settings publishing RWE, 1 was based in secondary care (myCOPD Mid and South Essex evaluation), 1 in primary care (NHS Grampian evaluation), 3 in community care (myCOPD Leeds, Coventry community evaluation, Kent CHFT evaluation), with the remainder combining patients managed in the community or at outpatient clinics (Ipswich and East Suffolk, Southend CCG, NHS West Lothian, Dorset CCG and NHS Highland).

Only the Dorset CCG evaluation, conducted by academics at the University of Southampton used a robust theoretical approach, applying the Normalisation Process Theory (Matheson-Monet 2019). This study also used focus groups, observed working group meetings and conducted interviews to identify the views of staff on the app.

The main methodological approach taken in the other studies was to use surveys. This raises issues regarding selection bias. For example, in the NHS Grampian evaluation, there was a total of 64 patients, but 43 were selected to take part in an interim evaluation, of whom only 23 responded. It is not clear why these patients were selected. Additionally, response bias is common with the use of surveys. For example, the Dorset evaluation reported that the patients who responded were the individuals who were most engaged with the app and were confident, active, users. Therefore, this may not be a representative sample.

Though there were limited details of patients' clinical history and background, there was nothing to suggest the characteristics of the patients included in the RWE are not representative of COPD patients across the UK (other than level of engagement as noted above).

Generalisability outside these settings is difficult to gauge. In part because some settings were early adopters by enthusiasts and hence their experience may differ from later sites. Moreover, the suspension of face-to-face services because of COVID-19 has prompted some services to use the app. How relevant the results from a pre-COVID world are to the services post-COVID remain to be seen. Also, the knowledge gained from these early evaluations has informed service developments with, for example, several services now engage actively with users to encourage activation or use remote activation.

Nevertheless, the studies do give a good overview of how myCOPD has been used in a variety of services and its impact on users in the first few weeks and months of using the app.

5.2 *Critical appraisal of studies and review of company's critical appraisal*

The company did not conduct a critical appraisal of the included studies. Hence the EAC undertook its own critical appraisal for each of the studies. The checklists used by the EAC were the criteria proposed by the Centre for Reviews and Dissemination for the RCTs and the CASP checklist for cohort studies for the comparative observational studies (Khan et al. 2001, CASP UK 2013).

A summary of the critical appraisal focusing on the internal and external validity of the studies in relation to the decision problem is presented in Table 5.1 while the detailed completed checklists for both study designs are provided in appendix B.

Clinical studies

For RCTs, to determine whether a study adequately addressed the criteria (that is yes, no or not clear), guidance from the Cochrane Handbook for Systematic Reviews of Interventions was used to apply a judgement (Higgins et al. 2011). For observational studies, the EAC has provided explanatory notes for key questions in the checklist at the bottom of the corresponding detailed appraisal table (appendix B).

Three RCTs and 1 comparative observational study have been critically appraised by the EAC.

Table 5.1: Summary of critical appraisal in relation to decision problem

Study	Internal validity[1]	External validity[2]
Randomised controlled trials		
TROOPER	**Acceptable** Sequence generation, allocation concealment was acceptable. Outcome measurement was unclear. Participants and PR providers were not blinded given nature of treatments; study personnel and outcome assessors were blinded. Groups were broadly comparable in baseline characteristics and imbalances in drop-outs. ITT analysis and appropriate methods used to account for missing data.	**Acceptable** Patients (adults with COPD as defined by NICE COPD guideline) and comparator (face-to face PR) in line with scope. Intervention (myCOPD) partially met the scope as participants did not receive all components of usual care as in comparison arm. Relevant for outcomes reported in the scope. No subgroup analysis done. UK setting
RESCUE	**Acceptable** Sequence generation was acceptable. Allocation concealment and outcome	**Acceptable** Patients (adults with COPD as defined by NICE COPD guideline) were recruited following

Study	Internal validity[1]	External validity[2]
	measurement were unclear. Patients and PR providers were not blinded given nature of treatments; study personnel and outcome assessors were blinded. Groups were broadly comparable in baseline characteristics and imbalances in drop-outs. ITT analysis was done but it was unclear how missing data were handled.	hospitalisation for an acute exacerbation or if they had been managed by the local COPD Admission Avoidance Team in a home-based environment with an acute exacerbation of COPD. All participants had moderately severe to very severe COPD. Patients and comparator (usual care with additional written support) were broadly in line with scope. Intervention (myCOPD) partially met the scope as participants did not receive all components of usual care as in comparison arm. Relevant for outcomes reported in the scope. No subgroup analysis done. UK setting
EARLY	**Acceptable** Sequence generation was acceptable. Allocation concealment and outcome measurement were unclear. Patients were not blinded given the nature of treatments; study personnel and outcome assessors were also unblinded. The only exception was that inhaler technique was assessed by a blinder assessor at the end of the study. Groups were comparable only for few baseline characteristics and there were imbalances in dropouts. Modified ITT analysis was done, and methods used to handle missing data were reported. Some outcomes needed complete data set for the analysis and included only participants who were present at the final study visit.	**Acceptable** Population aligned with the scope as the study recruited adults with either mild to moderate COPD or COPD of any severity diagnosed within the last 12 months. Intervention (myCOPD) and comparator (usual care) were also broadly in line with scope (company confirmed that patients in the myCOPD arm received the same usual care as in the comparator arm). Relevant for outcomes reported in the scope. A subgroup of participants in the myCOPD and usual care arm were allocated to activity monitoring for 7 days at baseline and 7 days prior to end of study visit. UK setting
Comparative observational studies		
North 2015	**Low** Cohort recruitment was not acceptable. Unclear/limited reporting of exposure, outcome measurement, and precision. No information on confounding factors. Imbalance in patient numbers between groups (27 intervention vs 9 control). All patients followed-up for the study duration of 3 months.	**Acceptable** Patients (adults with COPD as defined by NICE COPD guideline) and comparator (paper based self-management system) in line with scope. Intervention (myCOPD) partially met the scope as participants did not receive all components of usual care as in comparison arm. Relevant for 2 outcomes reported in the scope. No subgroup analysis done. UK setting
Real world evidence: no critical appraisal undertaken. All evidence has low internal validity but acceptable external validity		

1: Overall internal validity for each study has been assessed as 'High', 'Acceptable' or 'Low'.
For RCTs:
A rating of 'High' was assigned if ≥3 key criteria (sequence generation, allocation concealment, blinding) were met and ≤1 of all other criteria were unclear/not met.
An 'Acceptable' rating was assigned to those reporting met/unclear judgements for most of the criteria.
A 'Low' rating was assigned if ≥2 key criteria (sequence generation, allocation concealment, blinding) or most of all criteria were not met.

For observational studies:
A 'High' rating was assigned if all 3 key criteria (patient group, measurement of exposure, measurement of outcome) were met and established guidelines were used in both groups.
An 'Acceptable' rating was assigned to those with established guideline use and ≥1 criterion met.
A 'Low' rating was assigned if ≥2 key criteria and the need for use of established guidelines were unclear/not met.

2: Overall external validity for each study has been assessed as 'Acceptable' or 'Not acceptable'.
'Not acceptable' has been assigned if there is any uncertainty in the relevance of the patients, intervention, comparator, or outcomes in relation to the scope, or the study report is an abstract/poster with limited information.
All others have been rated as 'Acceptable'.

Abbreviations: COPD - Chronic obstructive pulmonary disease; ITT – Intention-to-treat; NICE – National Institute for Clinical Excellence; PR – Pulmonary rehabilitation; RCT – Randomised control trial.

Randomised controlled trials

The EAC found prospectively registered trial protocols for TROOPER, RESCUE and EARLY on the online, international clinical trials registry database, ClinicalTrials.gov. This aids in research transparency and reduces the potential for publication bias. Studies were funded by SBRI and UKRI Innovate UK grant. The EAC notes that Mr Bourne, a key author of TROOPER and RESCUE, is the CEO, co-founder and part owner of the my mhealth company that developed the 'myCOPD' app. Authors of the EARLY study includes 2 employees (M. North and A. Blythin) and the founder and director (T. Wilkinson) of my mhealth. Given this involvement there is the potential for a bias towards myCOPD, particularly if the outcome assessors were not blinded to the treatment allocation. The company advises that the authors were not involved in reviewing the data or performing analysis and that this was undertaken by Imperial College London clinical trial unit in order to reduce such biases.

The randomisation procedure (permuted blocks via an online randomisation system) described by the studies should produce comparable groups of participants allocated to each treatment. TROOPER carried out randomisation in the ratio of 2:1 and had more participants in the intervention than the

comparator arm. Investigators used an online system to conceal the allocation sequence from participants and clinical personnel. The use of an online system to carry out randomisation was also mentioned in RESCUE and EARLY, but it was unclear if it was used to conceal treatment allocation as well.

Blinding of the participants and the providers of the PR was not possible given the nature of the interventions being compared. Participants not being blinded to intervention allocation could lead to performance bias as most of the outcomes were assessed using questionnaires, which are subjective by their design. However, in TROOPER and RESCUE, the study personnel were divided into 2 teams to ensure they remained blinded to treatment allocation: 1 team was responsible for the initial assessment and randomisation of participants onto the study, while the other team was responsible for subsequent assessment. Outcome assessors were blinded to the treatment allocation and participants were requested not to mention their group assignment during assessment. These measures are likely to reduce the risk of performance and detection bias in these two studies. The risk of bias was higher in EARLY, which was an open label RCT. In EARLY, the study personnel and the outcome assessors were not blinded to treatment allocation. Only inhaler technique was assessed by a blinded assessor at the end of study.

The groups in TROOPER and RESCUE studies were reasonably well matched at baseline for a number of characteristics. However, some differences were noted. There were more current smokers in the myCOPD arm in both studies. RESCUE also had more male participants and people with severe COPD in the myCOPD than the usual care arm. However, no statistical analysis was undertaken to determine the significance of the differences. In EARLY, the two groups were comparable for a few baseline characteristics (like COPD severity, age and smoking status). They differed in several characteristics which resulted in the myCOPD group having predominantly female patients with a high baseline symptom burden, significantly lower physical activity level and a higher proportion of patients in the lowest activation levels.

All 3 studies presented Consolidated Standards of Reporting Trials (CONSORT) flow diagrams depicting the patient flow through the study. Drop-out levels between the treatment groups were similar in RESCUE and it was unclear whether the differences noted in TROOPER (n=7/64 with myCOPD and n=5/26 with face-to-face PR) and EARLY (n=5/29 with myCOPD and n=1/31) increased the risk of bias. Analyses were reported to be done on the intention-to-treat (ITT) population in both the studies, which would decrease the risk of attrition bias. In EARLY ITT analysis did not include all the

randomised participants and was modified to include only those with at least 1 post-baseline measurement. Moreover, for some analysis that needed complete data sets, only participants who were present at the final study visit were included. TROOPER and EARLY reported data imputation methods for handling missing data. In RESCUE authors calculated the proportion of missing data by timepoint for key study variables, but it was unclear how they were taken account of in the analyses.

Power calculations were done for TROOPER and EARLY. In TROOPER these were based on the non-inferiority threshold of -40.5 for the lower bound of the 95% confidence internal (CI) for the 6MWD test, and 1.8 for upper bound of the 90% CI for the CAT scores. In EARLY these were based on estimating 95% CI with precision of ±4.3 for the CAT scores. The authors of RESCUE acknowledged the small sample size was a limitation of their study but considered it sufficient for the purpose of a feasibility study.

TROOPER, RESCUE and EARLY demonstrated acceptable levels of external validity and are considered applicable to the scope. The studies reported participants in line with the scope and presented data on several relevant outcomes. The EAC notes that the intervention myCOPD partially met the scope in TROOPER and RESCUE, but it fully met the scope in EARLY. Although the comparator met the scope of the decision problem it was different in all three RCTs. TROOPER included face-to-face PR for 6 weeks, RESCUE included usual care with additional written support for 3 months and EARLY included usual care in line with national and local guidelines. This shows the variation in the definition of standard care, not just on a national basis, but also at the local level and within different care settings and, therefore, across studies, which will impact on generalisability. In addition, studies did not provide details of the standard care programmes, and it was not entirely clear whether all participants received exactly the same programme, or a more individualised approach tailored to the participant's need. As such, the components of standard care might not always be aligned with those described in the scope.

EARLY was based at 3 sites and TROOPER and RESCUE were based at single-site, which will further limit their generalisability. However, as the studies were done in the UK and met most of the criteria specified in the scope, the EAC considered that the results from TROOPER and RESCUE were generalisable to people with COPD, who have been referred for PR or recently hospitalised for an acute exacerbation. Results from EARLY would be generalisable to patients with mild or moderate COPD.

The RCTs had an acceptable level of internal validity.

Comparative observational studies

The EAC included and appraised 1 observational study (North 2015). The study received funding from SBRI. Although the study did not declare any conflicts of interest the primary author of the study, Mr M. North, developed myCOPD through collaboration with 2 senior respiratory consultants.

Cohort recruitment was not considered acceptable because the eligibility criteria were not described in enough detail and participants were recruited through a request for volunteers in the local newspaper. The groups were not balanced with the myCOPD arm including 3 times the number of participants than the comparison arm. Participant demographics at baseline were also not reported. The authors did not mention potential confounding factors and their possible impact on outcomes. However, the study was a service development project to explore the efficacy of the online self-management system compared with the paper-based system and was most likely not designed or done to enable full analysis of the outcomes.

Information relating to both exposure and outcome measurement and outcome definitions, were deemed too unclear/limited to inform an assessment by the EAC. North 2015 did not report the method (criteria or guidelines) used to diagnose COPD. The CAT score was used to measure the impact on participant's quality of life, but the methods used to assess inhaler technique from a video recording were not reported. The participants undertook a 3-month programme and no further follow-up was planned. Results were scant and limited in nature and were not reported on a similar basis in both groups. Precision of the results was unclear and standard deviations, confidence intervals, or other statistical analysis of the results were not reported.

The study was considered to have a low level of internal validity but acceptable levels of external validity and was applicable to the scope. The patients and comparator were relevant to the scope and limited data for 2 relevant outcomes were reported. The intervention partially met the scope as participants did not receive all components of usual care as in comparison arm. However, the study was a single site service development project done in the UK with limited information on its methodology and poor reporting of results. These factors will impact generalisability and the overall usefulness of the study to the decision problem.

Real world evidence

There are no validated checklists to critically appraise this type of evidence. Indeed, grading real world evidence does not fit comfortably into the traditional hierarchies of clinical evidence. Judged under the traditional hierarchy of evidence, most of the studies are poor quality, with many not reporting the methodology, patient numbers or characteristics, risk of bias, clinical outcomes, follow-up period and statistical methods used to report results.

In this context, contributors to a forum on RWE, done by the Academy of Medical Science (2018), agreed that the traditional concepts of hierarchies of evidence should be replaced by selecting evidence based on the research question and what is most relevant and useful for answering that (Academy of Medical Sciences 2018).

The real-world evidence on the use of myCOPD by over 800 patients with COPD was included despite these internal validity problems. This reflects that it should have reasonable external validity. However, using such data sources results in more uncertainty when used as evidence to inform outcome measures.

The company advised that sites receive no funding to conduct evaluations, but they can access their own dashboard for data and request specific reports but there is a cost for these. They can also get advice from the company's research team. The app was provided free under the Innovation and Technology Tariff 2017/19.

5.3 *Results from the evidence base*

The company reported limited results on a few outcomes for each RCT. Because of the paucity of data reported therein, the EAC did its own data extraction of the 4 included studies and summarised the results below.

COPD symptoms assessment (CAT score)

The effect of the interventions on COPD symptoms was assessed using CAT scores in all 4 studies. A difference of 2 points or more in a CAT score suggests a clinically important change in health status. A reduction in CAT score indicates an improvement in COPD symptoms (North 2015). All 4 studies showed a greater improvement of COPD symptoms in the myCOPD compared with the usual care group (Table 5.3).

Table 5.3: COPD symptoms assessment: change from baseline in CAT score (a reduction in CAT score indicates an improvement in COPD symptoms)

Study	Intervention	Number of patients analysed	Timepoint	Baseline CAT score Mean (SD)	Follow-up CAT score Mean (SD)	Adjusted mean difference (SD)
RCT						
TROOPER	myCOPD	64	7 weeks	18.1 (7.9)	14.9 (7.0)	−1.0 (95% CI −2.9 to 0.86, p=0.373)
	Face-to-face PR	26		17.3 (6.7)	16.2 (6.7)	
RESCUE	myCOPD	20	3 months (90 days)	26 (8.5)	20.7 (7.35)	-2.94 (95% CI -6.92 to 1.04, p=NR)
	Usual care	21		28 (5.8)	25.1 (7.24)	
EARLY	myCOPD	28	3 months (90 days)	21.5 (8.0)	19.2 (9)	-1.27 (95% CI -4.47 to 1.92, p=0.435)
	Usual care	30		19.8 (5.3)	19.8 (7.5)	
Observation study						
North (2015)	myCOPD	22	3 months	NR	Decrease in score: 4 (2.8)	p<0.001 for change from baseline
	Paper-based system	5	3 months	NR	Increase in score: 2.4 (1.0)	NR

Abbreviations: CAT – COPD assessment test; COPD - Chronic obstructive pulmonary disease; NR – Not reported; PR – Pulmonary rehabilitation; RCT – Randomised control trial; SD – Standard deviation.

RCT evidence

In TROOPER, the mean reduction in the CAT score from baseline to week 7 was greater and clinically significant in the myCOPD group (CAT score -3.2) compared with the 'face-to-face' PR group (CAT score -1.1). However, the adjusted mean difference (adjusted for disease severity measured by FEV1% predicted and baseline 6MWT between the 2 groups was -1 (95% CI -2.9 to 0.86, p=0.373) which, although in favour of myCOPD, was not statistically significant. The per-protocol analysis was consistent with the ITT analysis with a mean difference of −0.64 (95% CI −2.5 to 1.2, p=0.569) between the 2 groups.

In RESCUE, the reduction in the mean CAT score from baseline to end of 90 days was clinically significant in both groups but the reduction was greater in the myCOPD group (CAT score -5.3) compared with the usual care group (CAT score -2.9). The proportion of participants who showed a clinically significant improvement in CAT score at any point during the study period was greater in the myCOPD arm (90%) than the usual care arm (81%).

At the 3 month timepoint, the mean CAT score difference (adjusted for COPD severity and smoking status) was -2.94 (95% CI -6.924 to 1.05) in favour of myCOPD, but the result was not statistically significant. This was not an ITT analysis, including only participants who had completed the study (n=35). A longitudinal analysis which included all randomised participants (n=41) at all timepoints over 3 months study period showed that the average treatment effect for CAT score was -4.49 (95% CI -8.41 to -0.58; p=0.025) in favour of myCOPD compared with the usual care arm. The result was statistically significant.

In EARLY, the reduction in the mean CAT score from baseline to the end of 90 days for participants who attended the final study visit (n=54) was greater in the myCOPD group (CAT score -1.8) compared with the 'face-to-face' PR group (CAT score 0.03). However, this reduction was not clinically significant. The adjusted mean difference (adjusted for disease COPD severity, baseline values and centre) between the 2 groups was -1.27 (95% CI -4.47 to 1.92, p=0.435) favouring myCOPD but it was not statistically significant (modified ITT analysis, n=58).

EARLY study also did compliance average cause effect (CACE) analysis to estimate the effect on CAT scores in those using the myCOPD app. To conduct CACE analysis, 6 adherence definitions were constructed based on how many times participants interacted with the app during the study (total use definition) and the patterns of use during the study (sustained use definition). The participants in usual care were assumed not to have used the

app under all definitions. The CACE analysis was adjusted for baseline CAT score, COPD severity and study site and included only those participants who were present at the final study visit. Both total and sustained myCOPD use definitions were associated with greater reductions in CAT score and it exceeded minimum clinically important difference (≥2 scores) in those using the app on >30 days (total use) or those using it for at least 50% of the trial weeks (sustained use). However, this was not statistically significant. There was an estimated −0.22 (95% CI −0.74 to 0.31) decrease in CAT score for every 7-day increase in app use. The results of the CACE analysis is provided in Table 5.4.

Table 5.4: CACE analysis

Usage definition	Active users	Adjusted treatment estimate
Total usage		
Activated the app and had at least 1 activity	18	−1.63 (95% CI −5.56 to 2.30)
Accessed the app on >30 day	12	−2.47 (95% CI −8.46 to 3.53)
Accessed the app on ≥60 day	7	−4.28 (95% CI −15.00 to 6.43)
Sustained use		
Had an activity in the app in at least 50% of trial week	14	−2.13 (95% CI −7.24 to 2.98)
Had an activity in the app in at least 75% of trial week	12	−2.47 (95% CI −8.46 to 3.53) n=12
Had an activity in the app in at least 90% of the weeks in the first half and 90% of the weeks in the second half of the trial	10	−2.93 (95% CI −9.97 to 4.10)

Abbreviations: CI – confidence interval

Observational evidence

In North (2015), 21 of the 22 participants who used myCOPD reported a mean decrease in their CAT score of 4 (SD=2.8)[1] at the end of the 3 month study period. Five participants in the paper-based group reported an increase in mean (SD) CAT score of 2.4 (SD=1.0)[1]. There were insufficient data reported to calculate the difference in change of mean scores between the 2 groups.

Real-world evidence

In the Southend CCG evaluations, a reduction of 3.7 in CAT score was reported in patients using myCOPD only (n=15), scores ranged from -3.6 to -1.9 across other groups (n=44/n=29). Time of follow up was not reported. In the hybrid arm (centre-based PR as well as home-based myCOPD PR) CAT scores decreased by 4.2 at 6 weeks. The NHS Grampian evaluation

[1] These results are taken from the ERS 2014 abstract as they had reported SD and p values.

demonstrated an overall improvement in mean CAT scores of -2.1 at 5 months. The Coventry community project evaluation assessed CAT scores, [redacted]. The myCOPD Mid and South Essex evaluation found that [redacted]

Acute exacerbation

RCT evidence

Two RCTs (RESCUE and EARLY) reported data on acute exacerbation of COPD symptoms. No detail was provided on how the acute exacerbation was measured.

In RESCUE both groups demonstrated a reduction in acute exacerbations of COPD symptoms compared with baseline. The decrease in number of exacerbations per person (mean [SD]) was slightly greater in the myCOPD group (baseline: 2.9 [1.6], 90 days: 1.06 [0.83]) compared with the usual care group (baseline: 3.2 [2.0], 90 day: 1.88 [1.84]). After adjusting for the number of exacerbations at baseline, the rate ratio comparing the 2 arms showed that people in the myCOPD arm had 0.58 (95% CI 0.32 to 1.04) times exacerbations compared with usual care arm in the study period. This reduction was not statistically significant.

In EARLY both groups demonstrated an increase in acute exacerbation of COPD symptoms during the study compared with baseline, and more exacerbation events were recorded in myCOPD group. There were 18 events recorded in 13 participants in myCOPD group and 11 events recorded in 8 participants in usual care group during the 3-month study period. This was higher compared with the number of exacerbations recorded 3 months prior to the study baseline (myCOPD: 12 events in 11 participants; usual care: 3 events in 3 participants). The rate ratio (adjusted for disease COPD severity, baseline values and centre) showed that people in the myCOPD arm had 2.55 (95% CI 1.17 to 5.54) times the exacerbations compared with usual care arm in the study period. This was not statistically significant. Three exacerbation events needed emergency department attendance (2 myCOPD and 1 usual care) and 3 needed hospitalisations (1 myCOPD and 2 usual care).

Real world evidence

The NHS Grampian Evaluation reported the proportion of patients reporting exacerbations every other day reduced from 28% before using myCOPD to 22% six months after (McLaughlin and Skinner 2018).

Hospital admissions

RCT evidence

Data for hospital admissions for acute exacerbation of COPD symptoms was reported only in the RESCUE study. Hospital readmissions was lower in the myCOPD arm compared with the usual care arm (4 [20%] vs 7 [33%]). The adjusted odd ratio for readmission was reported to be 0.383 (95% CI 0.074 to 1.987), but it was not statistically significant. This was not an ITT analysis and included only participants who had competed the study (n=35).

Real world evidence

The NHS Grampian evaluation found that hospital admissions dropped from 6 to 0 at 5 months, compared with patient data prior to myCOPD.

Cooper et al. reported that overall there were no statistically significant differences in hospital admissions, inpatient bed days, or other health service utilisation before and after myCOPD activation at 12 months (Cooper et al. 2021b).

Inhaler error

RCT evidence

Results for inhaler error were reported in RESCUE, EARLY and North 2015 (Table 5.5).

Table 5.5: Inhaler Errors

Study identifier	Intervention	Number of patients analysed	Timepoint	Outcome definition	Baseline Mean (SD)	End of the study period Mean (SD)	Change from baseline	Adjusted comparison (OR, RR)
RCT								
RESCUE	myCOPD	17	3 months	Average inhaler errors	5.1 (3.1)	1.17 (1.7)	NR	RR, 0.377 (95% CI 0.179 to 1.04, p=NR)
	Usual care	18			5.0 (3.3)	4 (4.97)	NR	
EARLY	myCOPD	24	3 months	Average inhaler errors	1.1 (1.3)	NR	-0.3 (1.61)	RR, 0.97 (95% CI 0.52 to 1.8, p=0.93
	Usual care	30			1 (1.1)	NR	-0.1 (1.20)	
	myCOPD	24	3 months	⩾1 inhaler error	21 (72.4)	NR	-0.3 (0.70)	OR, 0.30 (95% CI 0.09 to 1.06, p=0.061)
	Usual care	30			18 (58.1)	NR	0.1 (0.71)	
Observational study								
North (2015)	myCOPD	22	3 months	NR	NR	NR	NR	NR
	Paper-based system	5		NR	NR	NR	NR	NR

Abbreviations: CI – confidence interval; COPD – chronic obstructive pulmonary disease; NR – not reported; OR – odds ratio; RCT – randomised clinical trial; RR – risk ratio; SD – standard deviation

In RESCUE each company's recommendations for use of their devices were used to assess whether the inhaler technique was correct. Each participant had their technique assessed by an unblinded and blinded assessor for each inhaler device they used. The mean (SD) number of inhaler errors at 90 days months in the people who completed the study (n=35) was greater in the usual care arm (4 [4.97]) than in the myCOPD arm (1.17 [1.70]). Participants in the myCOPD arm had 0.38 (95% CI 0.18 to 0.80) times the errors compared with usual care. This result was statistically significant.

In EARLY, inhaler technique was assessed using placebo devices and the seven steps developed by the UK Inhaler Group. The technique was assessed by an unblinded assessor at the baseline visit and the blinded assessor at end of study. The odds of at least 1 inhaler error was lower in myCOPD arm compared with usual care (0.30, 95% CI 0.09 to 1.06, p=0.061). However, this was not statistically significant. The rate of average inhaler errors for myCOPD was 0.97 times the rate of average inhaler errors for usual care, but it was also not statistically significant (95 % CI 0.52 to 1.81, p=0.93). The analysis for inhaler technique was adjusted for baseline values, COPD severity and centre and included only those participants who were present at the final study visit (n=54).

Observational evidence

The North study (North 2015) did not provide detailed numerical data for this outcome. The authors stated that 98% of participants (n=36) used their inhalers incorrectly at the start of the study, and most showed at least 2 critical errors in their technique. By the end of the study (n=27), 98% were using their inhalers correctly. The authors state that people using myCOPD showed a significant improvement in their inhaler technique, with fewer critical errors; in comparison people in the paper-based system group did not show an improvement in their inhaler technique and continued to have critical errors in using their devices.

Real world evidence

The myCOPD Leeds evaluation reports feedback from 1 client who claimed the inhaler videos helped correct her inhaler technique, which she shared with other group members who also improved their inhaler technique. No further details or data are reported. Time of follow up was not reported.

The NHS Grampian evaluation reported that "Good inhaler technique" practices increased from 48% to 91% (n=64) at 5 months, with a reduction in mean rescue inhaler use from 3.17 to 2.13.

Adherence and usage of myCOPD

RCT evidence

Data on adherence and usage of myCOPD were provided in 3 RCTs. In TROOPER, adherence to the PR programme in both study arms was incomplete. Overall, 72% of the 2 face-to-face exercise sessions were attended in the comparator arm, compared with 62% of the suggested 5 online exercise sessions a week on myCOPD, over the 6-week study period.

This study provided detailed adherence data for 0 to 7 sessions for the myCOPD arm and for 0 to 2 sessions for face-to-face PR, for each week of the 6-week assessment period. Mean participation in the myCOPD arm declined over the 6-week intervention period, from a mean of 3.9 to 2.5 sessions per participant. However, attendance at face-to-face sessions was relatively stable (mean 1.6 and 1.4 sessions per participant at weeks 1 and 6, respectively). In week 6, 22% of patients in the myCOPD group completed the recommended 5 or more sessions and 77% of patients in the comparator group attended their 2 face-to-face sessions. The full results on adherence are provided in appendix C.

In RESCUE, 85% (n=17) of the participants in the myCOPD group activated the app. All activations took place in the first week of the study. During the study period of 3 months, 8 people (40%) used myCOPD as recommended (once weekly) for the duration of the trial. The mean days myCOPD was used a week was 4.9. The authors noted that, although the mean days per user a week did not change, there was a continual decline in the number of users a week, with only 40% of people still using myCOPD by week 12. The study provided app usage data for each week for the 12-week study period which is provided in appendix D.

In EARLY, the participants could use the myCOPD app as they wished and received no encouragements from the researchers during the study. The myCOPD app was registered by 89.7% (n=26) and activated by 72.4% (n=21) of the participants in myCOPD group. The median (IQR) time for participants to activate the app was 1 (1 to 2) day. The numbers of app users seemed to fluctuate over the study period. The minimum number of app users in a given week was 13 (45%) and18 (62%) participants were still using it in the last month of the study.

20 out of 21 participants who activated the app accessed it on least 2 other days. The mean (SD) days myCOPD was used was 44 (31.6) over the 90 days study period but only 12 (41%) of participants used the app for more than 30 days. The mean (SD) total number of app activities recorded was

87.8 (118.7) and these were mainly related to recording of clinical scores (42.5%) and accessing educational videos (45.3%). Forty-eight percent (14) of the participants in myCOPD group had an activity in the app in at least 50% of the trial weeks.

EARLY also captured patient's experience of using the app in form of feedback questionnaire. Twenty four out of 29 (83%) participants responded to the survey, with 87.5% of respondents rating their experience of the app as very good or fairly good. Most of the respondents felt that the app had allowed them to understand (19 [79.2%]) and manage (17 [70.8%]) their COPD better. The domains of the app found most useful were exercise videos, education videos, inhaler videos and medication diaries. Other domains of the app like self-management plan, appointment dairy, chest clearance videos and weather and pollution forecast were less popular among the respondents.

Real world evidence

The Southend CCG evaluation reported that 52.5% using myCOPD at home (n=59) completed the full PR programme compared with 24.1% of the group not using the app (n=29). Time of follow up was not reported.

The NHS Highland evaluation 2021 preprint reported that a total of 78.8% activated myCOPD account, with 56% (50/89) doing so on the day of enrolment and 90% (80/89) within 1 month. Of activated patients, 88.7% used at least 1 module and enterted their symptoms score at least once. Data reported by module are:

- 57% of users engaged at least once with CAT scoring
- 54% of users initialted the PR course
- 10% of users engaged with inhaler use videos (started, not necessarily completed)
- 24% or users have begun or completed the education course.

Follow up data were collected up to 12 months.

The Ipswich and East Suffolk evaluation reported that the 127 activated patients logged in 2821 times, an average of 22.2 times per patient, with 48 (38%) becoming engaged users (at least 5 log-ins) and 15 patients (12%) became super users (logging in 50 or more times). The average duration of usage was 7 months. Further reported are the following engagement metrics:

- CAT scores were completed 1,041 times
- 489 PR exercise videos watched for a total of 6,901 minutes
- 328 Education videos watched, a total of 641 minutes.

- 91 inhaler videos watched
- Mean usage for activated patient = 1.2 hours of video content.

The data were collected at 18 months follow up.

The Coventry community project evaluation reported that [redacted]

The Southend CCG evaluation reported that completions rates for PR increased from 40% (usual care) to 72% in the hybrid arm (centre-based PR and home-based myCOPD PR) at 6 weeks.

The Kent CHFT evaluation reported that at 6 weeks, 49 (68%) had completed the PR course on myCOPD. This compared with the national average of 62% completing a conventional course. A total of 33 (67%) patients achieved an overall improvement in a single-stage exercise test, compared with the national average of 65%, and 60% for remote delivery. Finally, 102 (99%) of patients had accessed educational video content with a total of 2,788 views and 85 patients (83%) had accessed the PR course with 1,286 views (Stokes and Savage 2021).

Company data (my mhealth Ltd 2021b) reported [redacted]

The same document (my mhealth Ltd 2021b) also reported [redacted].

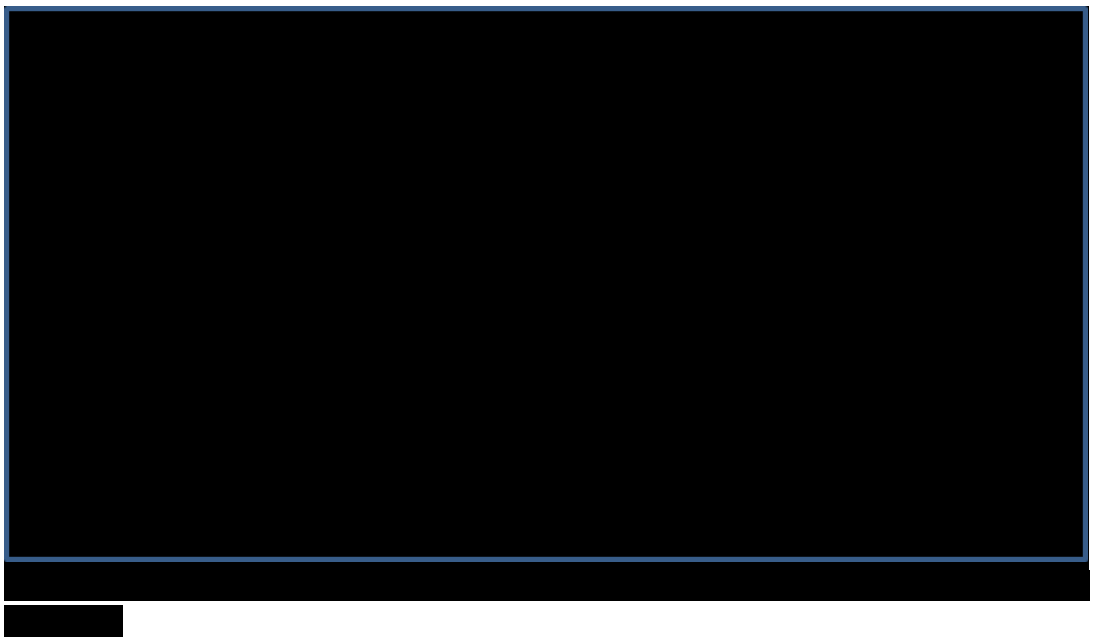
The company also [redacted].

Figure 5.1: [redacted]

[redacted]

[redacted]

Figure 5.2: [redacted]



[redacted]

Health-related quality of life (HRQoL)

RCT evidence

Results on the effect of the interventions on HRQoL were provided in TROOPER, RESCUE and EARLY.

HRQoL was assessed using a number of validated and standardised questionnaires. In TROOPER and RESCUE, the St George's Respiratory Questionnaire (SGRQ) and modified MRC dyspnoea scale (mMRC DS) were used to assess respiratory quality of life and the Hospital Anxiety and Depression Scale (HADS) was used to assess anxiety and depression. In addition to these, the RESCUE study used Veteran Specific Activity Questionnaire (VSAQ), and Work Productivity Activity Impairment (WPAI) Questionnaire. EARLY study used EuroQol 5 dimensions 5-level questionnaire (EQ5D-5L) to measure HRQOL. Table 5.6 provides mean scores for these questionnaires for the treatment arms at the start and end of the study period and the differences in mean scores between the groups. A decrease in score of these questionnaires indicates an improvement in symptoms except for EQ5D-5L questionnaire, where higher scores equates to better HRQoL.

In TROOPER, mean reductions in baseline scores at week 7 for all 3 questionnaires (SGRQ, mMRC DS and HADS) was observed in the myCOPD arm. However, in the face-to-face PR arm the mean baseline score decreased only for the mMRC dyspnoea scale and increased slightly for the other 2 measures. The differences in the mean reduction of the scores for all measures favoured myCOPD suggesting 'non-'inferiority. However, these differences were not statistically significant. Results were similar in the per-protocol analysis.

In RESCUE, both groups observed only slight changes from baseline scores for all 5 measures at 3 months. No statistically significant differences in mean scores were reported between the treatment arms. In EARLY, no statistically significant differences in mean scores for EQ5D-5L were reported between the treatment arms.

Table 5.6: Health-related quality of life (a reduction in score indicates an improvement in symptoms)

Study identifier	Intervention	Number of patients analysed	Timepoint	Mean (SD) baseline score	Mean (SD) final score	Mean difference (SD) Adjusted
Hospital anxiety and depression scale						
TROOPER	myCOPD	64	Week 7	10 (6.0 to 16.5)	7.0 (4.0 to 15.0)	-0.74 (95% CI -3.5 to 0.9, p=0.263)
	Face-to-face PR	26		10.0 (6.0 to 18.0)	10.5 (5.0 to 13.0)	
RESCUE	myCOPD	20	3 months	18.9 (10.6)	15.5 (8.8)	-3.078 (95% CI -7.6076 to 1.4506, p=NR)
	Usual care	21		18.1 (6.1)	18.1 (7.78)	
St Georges Respiratory Questionnaire						
TROOPER	myCOPD	64	Week 7	42.4 (18.6)	39.3 (18.5)	-3.72 (95% CI -10.7 to 3.3, p=0.291)
	Face-to-face PR	26		37.7 (17.2)	39.3 (18.5)	
RESCUE	myCOPD	20	3 months	66.4 (16.6)	61.9 (14.93)	-1.481 (95% CI -7.8165 to 4.8550, p=NR)
	Usual care	21		68.1 (13.7)	64.1 (15.94)	
Modified MRC Dyspnoea scale						
TROOPER	myCOPD	64	Week 7	2.0 (1.0 to 3.0)	1.0 (1.0 to 2.0)	0.03 (95% CI -0.56 to 0.63, p=0.909)
	Face-to-face PR	26		2.0 (1.0 to 2.0)	1.5 (1.0 to 2.0)	
RESCUE	myCOPD	20	3 months	2.9 (1.3)	2.8 (1.35)	0.018 (95% CI -0.7589 to 0.7956, p=NR)
	Usual care	21		3.1 (1.1)	2.8 (1.11)	
Work Productivity Activity Impairment Questionnaire						
RESCUE	myCOPD	20	3 months	7.3 (2.0)	6.2 (2.68)	-0.496 (95% CI -2.2139 to 1.2225, p=NR)
	Usual care	21		6.9 (2.3)	6.5 (2.98)	
Veteran Specific Activity Questionnaire						
RESCUE	myCOPD	20	3 months	3.2 (2.7)	2.94 (1.54)	-0.163 (95% CI -1.3992 to 1.073, p=NR)
	Usual care	21		2.6 (1.1)	2.95 (2.43)	
EuroQol 5 dimensions 5-level questionnaire Utility Score						
EARLY	myCOPD	24	3 months	0.6(0.3)	Change from baseline: 0.1 (0.23)	-0.04 (95% CI -0.12 to 0.05, p=NR)
	Usual care	30		0.7 (0.2)	Change from baseline: 0.0 (0.18)	
EuroQol 5 dimensions 5-level questionnaire VAS score						

Study identifier	Intervention	Number of patients analysed	Timepoint	Mean (SD) baseline score	Mean (SD) final score	Mean difference (SD) Adjusted
EARLY	myCOPD	24	3 months	61.9 (20.6)	Change from baseline: 62.0 (21.35)	0.86 (95% CI -9.46 to 11.18, p=NR)
	Usual care	30		61.9 (20.6)	Change from baseline: 60.9 (19.92)	

Abbreviations: COPD - Chronic obstructive pulmonary disease; MRC – Medical Research Council; NR – Not reported; PR – Pulmonary rehabilitation; SD – Standard deviation.

Real world evidence

No evaluation provided evidence on this outcome.

Patient activation measure

RCT evidence

The Patient Activation Measure (PAM) test which assesses patient knowledge, skill, and confidence for self-management was reported in RESCUE and EARLY. An increase in PAM test score indicates an improvement in self-management skill.

In RESCUE the mean increase in baseline PAM score at 3 months was greater for myCOPD arm compared with usual care (increase of 5 versus increase of 2.1). The difference in mean increase of scores was in favour of the myCOPD arm (5.02 (95% CI -8.28 to 18.32). However, this effect was not statistically significant.

In EARLY, the baseline PAM score was higher in the usual care group compared with the myCOPD group (mean [SD]: 69 [13.8] vs 59.9 [15.9]). At the end of study, PAM score decreased in both groups (myCOPD -0.7 [14.28]; usual care -3.5 [13.07]). The mean PAM score difference (adjusted for COPD severity, baseline values and centre) was -0.98 (95% CI −8.22 to 6.26) in favour of usual care, but the result was not statistically significant.

In EARLY, PAM was divided into 4 levels (1 to 4) and the proportion of participants moving to the highest PAM level (level 4) from baseline to the end of 90 days study period was analysed. There was a slight relative increase in the proportion of participants moving to the highest PAM level in the myCOPD group compared with usual care (1.4 vs 0.93). The adjusted odds ratio for being in a higher PAM level at 90 days was in favour of myCOPD 1.65 (95% CI 0.46 to 5.85) but it was not statistically significant.

Real world evidence

No evaluation provided evidence on this outcome.

Walking test - 6MWT

RCT evidence

TROOPER (Bourne et al. 2017) reported outcome data for the 6MWT. An increase in test score indicates an improvement in symptoms. The change from baseline in the mean score for the 6MWT at week 7 was greater for the myCOPD group compared with the face-to-face PR group (44.9m vs 28.6m respectively). The adjusted mean difference between groups was 23.8m (95%

CI −4.5 to 52.2, p=0.098) in favour of myCOPD. However, this difference was not statistically significant.

The study authors note that the lower 95% CI for the adjusted mean difference between groups was well above the 'non-'inferiority threshold of −40.5m and, therefore, the non-inferiority of the intervention was demonstrated.

Real-world evidence

The myCOPD Mid and South Essex evaluation reported an improvement in the 6MWT of 58m in the home-based PR group. Time of follow up was not reported. The Southend CCG evaluation reported patients in the myCOPD had a 105m improvement in the 6MWT at 6 weeks.

Number of consultations with healthcare professionals in primary and secondary care

RCT evidence

This outcome was not reported in any of the clinical studies.

Real-world evidence

This outcome was reported by the NHS Grampian evaluation where there were 20 (19%) fewer unscheduled GP appointments with myCOPD compared with before the study.

Self-efficacy for appropriate medication use

RCT evidence

Self-efficacy was reported only in the EARLY RCT. The study used the Self-Efficacy for Appropriate Medication Use Scale (SEAMS) questionnaire. With SEAMS, higher scores indicate higher levels of self-efficacy for medication adherence. SEAMS scores were similar between the groups at all timepoints and, the adjusted mean difference at 90 days was 1.48 (95% CI −1.47 to 4.42), in favour of myCOPD. However, this was not statistically significant and it was unclear if the improvement in score was clinically significant.

Real world evidence

No evaluation provided evidence on this outcome.

Clinician feedback

[redacted]

Subgroup data

Subgroup data by severity or time since COPD diagnosis were not reported in any of the included studies, although the EAC notes that, in all three RCTs, the population is a subgroup of the overall population with COPD.

In the EARLY study, activity monitoring (step count measured using Fitbit) was undertaken in a subgroup of study participants for a 7-day period at baseline and then for 7 days prior to the end of study visit. Fourteen (23.3%) participants volunteered to take part in the activity sub-study (5 [35.7%] from myCOPD and 9 [64.3%] from usual care). The mean (SD) number of steps a day at baseline was 4,949(1,668) for myCOPD and 9,060 (5,135) for usual care group. At the end of the study the mean number of steps a day increased for both groups (myCOPD: 5,458 [2,266]; usual care: 10,762 [7,199]). The adjusted mean daily step count was 2,252 steps lower (95% CI −10 434 to 5,928 in the myCOPD arm compared with usual care but this was not statistically significant.

Cooper et al. reported subgroup analysis that found those individuals with the greatest degree of myCOPD engagement showed a reduction in use of hospital bed days at 12 months (value not reported) (Cooper et al. 2021b).

Company data (my mhealth Ltd 2021b) reported that the mean CAT score for men was -0.60 (-1.14 to -0.06), which is significantly lower than females

(p=0.03) when adjusted for age. The mean CAT score decreased by 0.14 (0.16 to 0.11) for every 1-year increase in age (p<0.01) adjusting for gender. Data were collected at up to 12 months follow up. Furthermore, company data [redacted]

6 Adverse events

The company reported that no adverse events had occurred with myCOPD in section 5 and 7 of its submission.

Limited data in relation to complications and intervention-related adverse events were reported in the 3 included RCTs. TROOPER reported the following intervention related adverse events; back pain (1 person in each arm), muscular skeletal pain (1 person in myCOPD arm), inguinal pain (1 person in face-to-face arm) and cold (1 person in face-to-face arm). It was not clear how cold was associated with the intervention. Authors stated that the interventions were well tolerated with no safety issues identified.

In RESCUE adverse and severe adverse events were infrequent (adverse event: constipation: 1 person in myCOPD arm, serious adverse events: 1 constipation and 1 medication side effect in myCOPD arm, and 1 respiratory infection [other than acute acerbation of COPD] in usual care arm). The authors stated that no associated clinical link of adverse events to application use or usual care was apparent.

In EARLY adverse events were reported in 12 (20%) study participants including 5 (17%) from myCOPD and 7 (23%) from usual care. Type of adverse events that occurred was not reported. The authors stated that no serious adverse events were reported during the study.

A search of the FDA Manufacturer and User Facility Device Experience (MAUDE) website was done by the EAC on 10/2/2021. Date limits were applied to include records from the last 10 years with brand name ‘myCOPD’. No relevant records were returned. A search of Medicines & Healthcare products Regulatory Agency (MHRA) alerts and recalls for drugs and medical devices was also done on the 10/2/2021 for ‘myCOPD’ and no results were returned.

No RWE studies reported adverse events.

7 Evidence synthesis and meta-analysis

The company did not provide any synthesis of the data. The EAC concluded that, because of the differences across the 3 RCTs in terms of their population, comparators and follow up, meta-analysis was not appropriate.

In TROOPER (Bourne et al. 2017), participants were recruited from outpatient respiratory clinics. Most participants (67%) had moderate to severe COPD and data were reported after 6 weeks. In RESCUE (North et al. 2018), participants were recruited following a hospital admission for an acute exacerbation. All had moderately severe to very severe COPD and data were reported at 3 months. In EARLY (Crooks et al. 2020) participants with mild to moderate COPD or COPD of any severity diagnosed within last 12 months were recruited from 3 primary care centres. Data were reported at 3 months.

The comparators also varied across the RCTs. In TROOPER, the face-to-face PR programme included twice weekly supervised sessions delivered in a conventional community setting with additional home-based exercises. In RESCUE, the comparator was usual care with additional written support, which included education booklet plus self-management plan. In EARLY, the comparator was usual care in line with the current NHS management plan but no details of the components were provided.

The change in outcomes reported from the clinical studies and RWE have been reported in section 5.3. A short synthesis of the key outcomes is provided in Table 7.1.

Table 7.1: Synthesis of outcomes reported by clinical studies and RWE

CAT score	This was the best reported outcome. All clinical studies reported benefit from usual care and myCOPD but benefit was greater with the app. In the EARLY RCT the benefit was clinically significant (reduction of ≥ 2 scores). Evaluations done at Southend, Grampian and Essex also reported clinically significant reductions with the app
Rates of exacerbations	The RESCUE RCT reported a greater reduction with the app than with usual care but EARLY reported an increase in the rate in both arms (not statistically significant). The arms were unbalanced for baseline rates, making interpretation difficult. An evaluation done at NHS Grampian reported a a reduction in the proportion of patients reporting exacerbations every other day.
Hospital readmissions	RESCUE reported a lower rate of readmissions with myCOPD but numbers were small. Grampian also reported the rate reduced when patients used the app, with NHS Highland finding that the rate reduced but only for engaged users .
Inhaler errors	Two RCTs reported a reduction in risk of inhaler errors with myCOPD arm compared with usual care ($p<0.05$ for RESCUE). The observational

	study and RWE at Grampian also reported fewer inhaler errors with the app.
Adherence	Two RCTs reported adherence which declined over time. However the best evidence is from the company which reports activation rates have increased to 48%, with large variation across sites (from 22% to over 80%). The variation is being addressed by more robust clinical engagement when the person receives the app and easier activation (for example some sites now activate the app remotely). Usage of the various components is also reported for example 86% of users watched education videos, 28% watched videos on inhaler technique and 23% completed 12 sessions of PR (my mhealth Ltd 2021b). Kent and Southend reported higher completion of PR with the app than usual care.
HRQoL	The 3 RCTs found slight or no differences between treatment groups across a range of measures. No RWE.
6MWT	One RCT reported a greater increase from baseline with the app than usual care ($p>0.05$). Southend reported a mean increase of 105 m and Essex of 58m.

Abbreviations: 6MWT – 6-minute walking test; COPD – chronic obstructive pulmonary disease; HRQoL – health-related quality of life; PR – pulmonary rehabilitation; RCT – randomised controlled trial; RWE – real world evidence

There were no differences found in the RCTs for the other outcomes.

In summary, the clinical studies show evidence of benefit with the app in reducing CAT scores and improving inhaler techniques. These benefits did not translate into improved quality of life or reduced acute exacerbations. Limited RWE suggests that engaged users do see improved outcomes and are more confident in self-managing their COPD. The challenge is to increase the activation rate and the intensity of use.

No adverse events associated with the app were identified.

8 Interpretation of the clinical evidence

The published evidence of clinical effectiveness of myCOPD is based on 3 RCTs (TROOPER (Bourne et al. 2017), RESCUE (North et al. 2018) and EARLY (Crooks et al. 2020) and 1 ‘non-’randomised comparative observational study (North 2015). The populations in all 4 studies included adults with a confirmed diagnosis of COPD and matches the population in the scope. They were aged between 40 to 80 years and had mild to moderate (EARLY) or moderate to severe COPD (TROOPER and RESCUE). There was no information on the socioeconomic status of the participants. Participants were mainly recruited following hospitalisation, outpatient respiratory clinics, and in response to advert to local newspaper. It is likely that these recruitment methods would not recruit hard to reach COPD patients. However, in EARLY participants were recruited from primary care

and could be a more representative sample as most of the COPD patients in the UK are managed in primary care settings (see correspondence log).

Only 1 study, EARLY, was powered as a superiority study which was estimated to need 60 participants to show statistically significance. However, as the authors note this relatively low number, together with differences in the baseline characteristics of the 2 arms meant it only reported a statistically significant result for inhaler technique. The other 3 clinical studies were done in 3 single centres in the UK (EARLY was multi-centred and done in 3 centres in the UK). Hence, it is not clear if the population in each study is representative of the wider COPD population in the NHS, who are likely to vary in terms of age, disease severity and socioeconomic status. Nonetheless, together they are likely to provide a sample of patients with all stages of COPD from mild to severe and from recently diagnosed to more chronic cases.

The comparator in the scope is standard of care for COPD in NHS, which involves a combination of different components of care for COPD management and is likely to vary from one setting to another and also from one patient to another (see correspondence log). This was reflected in the studies which included face-to-face PR, usual care including additional written support and usual care (undefined) as comparators. However, as the studies were based in the UK, usual care is likely to be in line with current NHS practice (see correspondence log for a description of the variation across sites and delays in delivering key components).

The intervention was myCOPD, or myPR, in the studies, which was provided in addition to usual care. It is important to note that 2 RCTs (TROOPER and RESCUE) had ‘active comparators’ because the intervention arm did not receive the additional components of usual care (face-to face-PR, written support) in the comparison arm. Assuming that these interventions are not harmful, this is likely to dilute the effect of the intervention as any difference in outcomes between the 2 groups could not be attributed solely to ‘myCOPD’. This also does not align completely with scope, according to which the only difference between the 2 arms should be myCOPD. The intervention in TROOPER RCT was myPR (an earlier version of myCOPD focusing on PR). It is unclear what the differences between the 2 versions are and whether results from myPR can be generalised to myCOPD. The company has confirmed that in the EARLY RCT, the participants in the myCOPD group received the same usual care as the usual care group.

Apart from number of consultations, all relevant outcomes stated in the scope were assessed by the studies using standardised and validated outcome measures. The results of the studies showed that some of the symptoms of

COPD were better managed in myCOPD group compared with the comparator group (refer to section 5.3 for detail information on results). Participants in the myCOPD group showed greater improvements in CAT scores, reduced rates of hospital admission and improved 6MWT scores than the standard care groups.

Use of myCOPD was also associated with a greater reduction in inhaler error. The experts advised that technique of inhaler use is judged subjectively by observation and there is no standard way to measure the correct use of an inhaler. There was inconclusive evidence on rates of exacerbations: the rate reduced in both arms in the RESCUE study but increased in the EARLY study. The experts advised that exacerbations are a coarse measure and can be impacted by a number of factors (see correspondence log). Some context is provided from recent company data (my mhealth Ltd 2021b). [redacted]

The RWE also suggests that highly engaged users of myCOPD can improve clinical outcomes such as improvements in CAT scores (Southend myCOPD evaluation, Southend CCG evaluation, myCOPD Mid and South Essex), 6MWT (myCOPD Mid and South Essex), and good inhaler technique (myCOPD Leeds, NHS Grampian). Further, NHS Grampian evaluation reports a reduction in hospital admissions and unscheduled GP appointments compared with the period prior to myCOPD use.

The EARLY study reported that 17% of participants did not activate the app, a higher rate than the average national activation rate of [redacted] (see correspondence log). The national data (my mhealth Ltd 2021b) are the best evidence on variance in activation levels ([redacted]), user engagement and compliance as different sites adopted different practices. The individual evaluations reported a similar spectrum of outcomes. Concerns around low uptake of myCOPD and its long-term use were shared by other HCPs (Ipswich & East Suffolk CCG 2019, NHS Lothian 2018).

The company data provided on patient retention (my mhealth Ltd 2021b) aids in understanding patient use. [redacted]

The importance of engagement is illustrated by a subgroup analysis of NHS Highland data; individuals with the greatest degree of myCOPD engagement

showed a reduction in bed days (Cooper et al. 2021b). This suggests the most important aspect of improving the app's functionality going forward revolves around improving patient use and adherence.

All clinical studies had a short follow-up of 3 months, perhaps too short to capture any changes in clinical outcomes. Studies had relatively small sample sizes (<70) and hence limited power to detect statistical differences. This is unsurprising as 2 studies (TROOPER and RESCUE) were designed to assess feasibility and 'non-'inferiority of myCOPD compared with usual care and not to detect superiority of myCOPD. The small size also caused some imbalances between patients, particularly in the EARLY RCT. Small sample size is not unique to studies on myCOPD. A recent Cochrane systematic review on PR for COPD included 65 studies with a median sample size of 45 participants (McCarthy et al. 2015). The methodological quality of RCTs was acceptable but it was low for the observational study.

The real-world evidence data shows positive feedback from people who responded in terms of ease of use of the app and its facility in managing their symptoms. myCOPD was also said to [redacted]. Moreover, the real world data are snapshots at 1 point in time (and essentially a pre-COVID point in time). Sites and the company are learning from the evidence how to improve their processes and thus historic data are not always suitable to generalise to a later time point. The use of digital technologies has also increased across the NHS as sites reduced face-to-face contacts and directed patients to digital resources in line with NICE guideline on COVID-19 (National Institute for Health and Care Excellence 2020).

Potential benefits claimed by the company

Table 8.1 sets out the benefits to people with COPD and the healthcare system from using myCOPD as claimed by the company and whether these have been evidenced.

Table 8.1: Benefits claimed by the company and supporting evidence

Benefits	Evidence
Improvement in self-management of COPD symptoms	Yes and primarily in terms of use of inhaler techniques and improved CAT scores
Increased quality of life	The RCTs showed trends to improved quality of life
Enabling shared care between primary care and secondary care	Five settings used myCOPD across primary and secondary care but no evidence on shared use by HCPs.
Reduction in emergency admissions	One RCT (n=35) reported hospital readmissions were lower in the myCOPD arm compared with usual care but it was not statistically significant. NHS Grampian reported engaged users reduced hospital admissions.
Increased efficiency in patient management	Evidence from 3 evaluations that myCOPD does release clinical capacity.
Improvement in coordination of patient care or services	Not evidenced.

Abbreviations: CAT – COPD assessment test; COPD – chronic obstructive pulmonary disease; RCT – randomised controlled trial

Gaps with the RWE evidence relate to use of the app:

- By clinicians, although responses from 6 HCPs are discussed in section 5.3.
- The interaction between such use and patient engagement and outcomes.
- Impact of the app on service efficiency, system capacity and the co-ordination of care.

The evidence suggests that myCOPD is a useful addition to usual care as part of a blended approach to encourage self-management. Some users will engage more than others and where there is good engagement, the limited RWE suggests there better are clinical outcomes and possibly a reduction in NHS resource use.

In conclusion, some of the benefits claimed by the company in its submission have been supported by the clinical and RWE. Weaknesses identified in the clinical studies relate to alignment of the intervention to the scope in 2 RCTs, sample size of the studies and lack of long term follow up data. Gaps include whether usage improves clinical outcomes such as exacerbations (the main cause of hospitalisation) in NHS practice, clinician experiences and the potential impact on NHS capacity post-COVID.

8.1 *Integration into the NHS*

Clinical pathways

Information on the current clinical pathway and how myCOPD is expected to be integrated into this is described in section 3.

[redacted]. Staff at Southend CCG also report it is easy to use and well received by those receiving outpatient care for COPD. Further, it works in those undergoing PR to assist with exercising at home and reinforcing the existing face-to-face PR programme. Clinicians at Dorset also advised the app could easily be integrated into their clinical practice but not that it could be used to check on patients remotely (Matheson-Monet 2019). Where a CCG has attempted to use myCOPD with people receiving inpatient care, they have often been too unwell to engage with the app until they are discharged from hospital. For these people, community teams are needed to follow-up to ensure that they use myCOPD.

Clinical experts stated self-management, support for medication and symptom management, patient education and pulmonary rehabilitation should be used with patients across the disease spectrum to provide timely access to each component. The real-time patient information captured can then aid decision-making in managing the condition and does not rely on (potentially poor) recall. Also, patients have access to their own data which can encourage learning (see correspondence log).

One expert advised that the app is not used enough for follow-up – using myCOPD to deliver follow-up at 72 hours would increase compliance with that indicator in the British Thoracic COPD discharge care bundle (see correspondence log).

[redacted]. HCPs were able to offer patients PR at home when face-to-face sessions were not possible. However, all experts agreed that in the longer term face-to-face appointments should be the gold standard, with myCOPD offered in addition to standard care and in accordance with patient preference.

The SWOT analysis reported from West Lothian (NHS Lothian 2018) (detailed in section 6) and the Southend CCG 2019 unpublished report

(Southend CCG 2019b) [redacted]. Information from the Southend CCG evaluation suggests that a hybrid PR (both centre-based and home-based myCOPD PR) approach that integrates myCOPD PR home-based courses with centre-based check-ins may be an effective method of increasing patient long-term use.

Patient selection

Clinical experts noted that clinicians should determine eligibility for myCOPD through clinical assessment. The experts agreed that myCOPD has wide applicability for people affected by COPD. However, there was no consensus on if it should be targeted at specific patients, with 1 of the experts supporting targeting severe patients while a second suggested a good target group may be highly active, low risk COPD patients as they could use myCOPD as a top-up for lifestyle advice and self-management. A third stated that patients should be assessed before registering in order to improve adherence. The company noted it advised against sites seeking to identify patients to use this app as this generates bias (see correspondence log).

In addition, clinical experts also supported the idea of a" blended" approach, where patient groups who are able and willing to use myCOPD are offered myCOPD, but patients who need (or prefer) centre-based training/PR continue care as usual.

Training

The company describe the training requirements for myCOPD as a face-to-face training session for healthcare professionals that takes approximately 3 hours to complete and is provided by my mhealth. For patients, 'how to' videos are available alongside written explanations and phone and email support is available, but no formal face-to-face training is undertaken. Clinical experts noted that myCOPD is intuitive and easy to use, but initial time training patients on how to use the app effectively is usually provided (see correspondence log). The company noted good patient clinical engagement at the start is the key to engagement and adherence (see correspondence log).

Changes to infrastructure or systems

To support use of myCOPD and deliver the service to a larger population, the experts noted designated staff should be responsible for oversight of use of the app and HCPs should train patients on how to use the app effectively.

Clinical experts commented that improving inhaler technique using the app, by earlier and more regular training, or both, delivered by HCPs, initially in primary care, would be beneficial for patients, staff and improve the effectiveness of the medication. Hence more resource may be needed when initially training newly-diagnosed patients on correct inhaler technique, with myCOPD inhaler use videos also supporting patients practise and reinforce correct inhaler technique. Information from myCOPD Leeds evaluation shows the positive use patients can get form the inhaler education aspect of myCOPD.

Information from Southend CCG evaluation and Ipswich and East Suffolk evaluation (Ipswich & East Suffolk CCG 2019, Southend CCG 2019b) showed that clinic capacity increased by [redacted] by adopting either home-based PR or hybrid PR (home-based and centre-based). This suggests that once initial training has taken place with patients, the use of myCOPD has the potential to improve NHS capacity.

Clinical experts commented that they were not aware of any further significant capital costs but that there are on-going revenue costs to cover clinical time for allocating licences and monitoring take-up of myCOPD.

8.2 *Ongoing studies*

Ongoing studies

The company advises that it is undertaking ongoing work looking at the contribution myCOPD can make to big data, with a Horizon 2020 BigMedilytics grant. BigMEdilytics is a 3-year project which aims to enhance patient outcomes and increase productivity in the health care sector by applying big data technologies to complex datasets. The company has developed a real time database and user interface which enables prospective review of aggregated, anonymised data on app registration, app access and clinical outcomes.

The company provided full text of the study by Chmiel et al. (2020), which has not been peer reviewed (Chmiel et al. 2020). The study is a part of this ongoing project and was undertaken in partnership with the University of Southampton. The Chmiel at study used self-reported data from myCOPD to

predict exacerbation events using a machine learning model. The study analysed data from 2,374 patients with COPD, who entered 68,139 self-reported symptoms. Heuristic and machine-learnt models were applied to the entered symptom data. Results showed that both a baseline model and a machine learnt model showed moderate ability in predicting exacerbation events occurring within three days of a given self-report. Further studies are underway to improve the accuracy of such models.

Ongoing data based on use of myCOPD within the NHS

The company advised that several NHS sites are conducting on-going evaluations of myCOPD but none are sufficiently mature to inform this assessment.

9 Economic evidence

The EAC notes that the clinical submission was received and assessed in October 2019. A pause to the process was then implemented by NICE to allow the company to collect more evidence. The clinical assessment was updated in February 2021 to reflect this additional evidence. The economic evidence submission was received and assessed in July 2021 and therefore there was a delay between the development of the scope and original clinical submission and the economic submission. Within this time the company advised there were changes made to the way the app was costed and the likely clinical pathway based on real world evidence collected during this period.

9.1 *Published economic evidence*

Search strategy and selection

The company submission contained a description of the search methodology used to retrieve relevant economic evidence. There were some limitations to the methodology that could potentially impact on search sensitivity and the identification of relevant evidence. Details of the EAC critique of the company search strategy are provided in appendix A.

The company search methods as reported were used to re-run the searches. The re-run searches retrieved 458 records. After deduplication 328 records remained for assessment. Details of the re-run company searches are provided in appendix A.

As the company search methods had limitations that could potentially impact on search sensitivity and the identification of relevant evidence, the EAC also conducted a *de novo* literature search to identify economic evidence.

The EAC search was conducted in a range of resources containing research published in the journal literature and elsewhere. The EAC search retrieved 629 records. After deduplication (within-set and against the results retrieved by the re-run company searches) 404 records remained for assessment. Full details of the EAC's *de novo* search methods are provided in appendix A.

Critique of the company's study selection

The selection criteria applied by the company were specified as "economic analysis of myCOPD for self-management of COPD or delivery of pulmonary

rehabilitation" and "comparative clinical study including myCOPD". No list of excluded studies or PRISMA diagram were included hence is is unclear exactly how these were applied.

EAC's study selection

The selection criteria adopted by the EAC to select relevant economic studies used a PICO framework and are summarised in appendix A, Table A5. These criteria were applied to the searches reported in this section.

Included and excluded studies

The company did not include any economic evaluations in its economic submission. In an earlier clinical submission, reference was made to an economic study on myCOPD (myCOPD & YHEC). However, the company advised that this had not been included as part of the economic evidence review as it was a hypothetical analysis not based on any robust data (see correspondence log). This study was identified by the EAC searches and the EAC agrees with this judgement, noting that it is not a comparative cost analysis in thatno costs for the standard care arm are determined.

The EAC identified no economic studies suitable for inclusion from its own searches.

Within the company's economic submission an additional clinical study was identified (Cooper et al. 2021b). This is a pre-publication (i.e. additional paper) of a study included by the EAC in section 4 from NHS Highland. Relevent information from this paper is included in section 4.

Published economic evidence review

No studies were included.

Results from the economic evidence

No studies were included.

9.2 *Company de novo cost analysis*

Economic model structure

The NICE scope states that the population to be included in the evaluation should be all people with a diagnosis of COPD. However, the company submission states that the published evidence does not demonstrate clinical benefit in all people with a diagnosis of COPD and they have therefore

focussed their economic modelling on specific subgroups of the COPD population where they can demonstrate an economic benefit. For example, Crooks et al. explored the impact of myCOPD in people with mild to moderate, or recently diagnosed COPD of any severity and no statistically significant evidence of benefit was shown except for inhaler technique (Crooks et al. 2020). Sage et al. conducted a real-world study myCOPD with no inclusion or exclusion criteria beyond being able to connect to and use the app (Cooper et al. 2021b). Again, no significant evidence of clinical benefit was found. Due to no evidence of clinical benefit in this broad population, the company's decision to model only subgroups of people where benefit can be better demonstrated appears reasonable.

MyCOPD is priced for a CCG on a per member of the population basis. That is, the more people using myCOPD the lower the cost per user. Therefore, in the subgroups modelled benefits accrue only for those patients meeting the subgroup critera, but the cost of myCOPD is applied for all within the CCG. Therefore, if additional users outside of the subgroups modelled obtained benefit from myCOPD, this would be achieved without any additional licensing costs.

Two *de novo* models were developed by the company. Each model was relevant to a subgroup of patients with COPD and is described in turn below.

Model 1: Patients post-discharge for hospital admission for acute exacerbation of COPD (AECOPD)

Patients

The company states that the population entering the model are people post-discharge for hospital admission for AECOPD. The number of people in England registered with COPD in 2019/20 is 1,170,786, leading to a prevalence of COPD of 1.94% (NHS Digital 2020). There are 247 AECOPD hospital admissions per 100,000 people in England (England population of 56,550,138 in 2020) (OffIce for National Statistics 2020), leading to 139,678 admissions in England (Public Health England 2019). This is approximately 12% of the COPD population. This is likely slightly overestimated as the hospital admissions would include readmissions. This is based on the RESCUE study (North et al. 2020). This was an open, randomised controlled trial of myCOPD following hospital admission with an acute exacerbation (analysis based on myCOPD n =17, standard of care (SoC), n = 18).

Comparator

The comparator in the model is standard care. The company describes standard care as a written self-management plan at discharge. This aligns with the NICE scope. The company acknowledges that there are some discharge services available (for example, early supported discharge or community respiratory services) but these were not modelled as they are either not universal or poorly implemented. The 2020 COPD audit (NACAP) states that 77.9% of patients in England received a discharge plan when hospitalised with exacerbations (National Asthma and Chronic Obstructive Pulmonary Disease Audit Programme (NACAP) 2021). A British Thoracic Society discharge bundle includes a medication review, a written self-management plan, assessing and referral for smoking cessation support, assessing and referral for PR and arranging appropriate follow-up, with a follow-up arranged for 37.8% of patients (National Asthma and Chronic Obstructive Pulmonary Disease Audit Programme (NACAP) 2021). Expert opinion supported the use of a discharge bundle and leaflets. It can also involve an inhaler-use discussion (see correspondence log). One expert stated that in their service follow-up depends on whether or not the patient has had a previous hospital admission in the last three months, or if they are known to a community respiratory team. If the patient has had 1 previous hospital admission, they are asked to make a GP appointment for a review within 2 weeks of discharge (which often does not happen in practice). If a patient has had 2 or more hospital admissions within 3 months for AECOPD then they are considered for a secondary care appointment (which may not be appropriate if the patient is under the care of a community team). A futher expert stated that patients are discharged to community respiratory nurse teams (see correspondence log). Due to the clinical data available not including scheduled follow-up appointments and the number of admissions per patient within the previous 3 months being unknown, alongside the uncertainty of whether the follow-up appointments are implemented in practice, the EAC agreed with only including the written management plan as a comparator.

The NICE guidelines for managing COPD suggests that people who have had a recent hospitalisation for an acute exacerbation and view themselves as functionally disabled by COPD (MRC grade 3 and above) should be offered PR (National Institute for Health and Care Excellence 2021). The company have not modelled this in the AECOPD population but have modelled a PR population separately. The EAC deemed this to be appropriate as the outcomes data available for the two populations (AECOPD and PR) are covered in separate studies, with only a small overlap between the defined populations (for more detail see the patients described in Model 2).

Technology

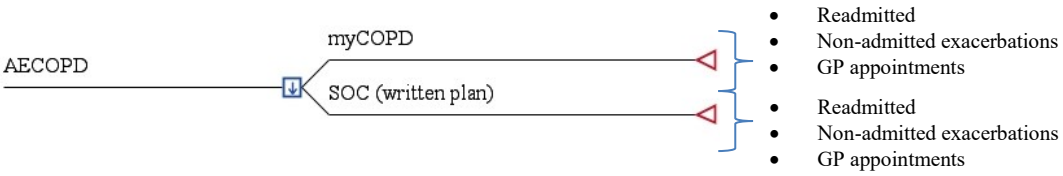
The intervention in the model is myCOPD. The NICE scope indicates the intervention should be myCOPD as an add-on intervention to standard care. The self-management plan given at discharge can be implemented using myCOPD but the outcomes were primarily based on the RESCUE study, where those in the intervention arm were not given a separate written plan as well as use of myCOPD. Expert opinion suggests that this may introduce bias, however, it can be argued that myCOPD should be able to replace a written management plan as it is aimed at providing a personalised plan. In the expert's practice, a written management plan is not issued if a patient is registered on myCOPD (see correspondence log). The EAC believed that using the RESCUE study for the outcomes, despite a separate written plan not being provided, was reasonable. Other elements of standard care (for example, inhaler use discussions) would be the same across both arms.

Model structure

The company's model comprises of a cost calculator and was developed in Treeage. Every person in the model has been admitted to hospital for an acute exacerbation of COPD (AECOPD). The company modelled a typical CCG purchasing the unlimited myCOPD license package (any number of COPD patients can receive the app for the same capital cost). The base case analysis is presented over a 1-year time horizon, with 3 months of outcomes captured for both myCOPD and standard of care. The licensing is part of a three-year contract (the Unlimited licence package). Once the 3 years is over, if the CCG wish to continue using myCOPD they would sign up for another 3-year licence. The company assume the same annual resource use savings and a constant number of referrals each year.

Resource use outcomes compared between the arms include hospital re-admissions for COPD, non-admitted exacerbations, and GP appointments. It is possible that there may be some overlap in outcomes regarding the cost of exacerbations and GP appointments. This is described in more detail under Table 9.5. The EAC judged the diagram presented by the company accurate but is of limited use to showing what the outcomes of the model are and so these have been added to Figure 9.1.

Figure 9.1: Company model diagram AECOPD



The company's model was replicated in Microsoft Excel to check for errors and the EAC confirm the model matched what was presented in the company submission. No errors or discrepancies were identified in the base case analysis. Discrepancies were found in the scenario analysis (best case scenario) which are described in the 'Sensitivity Analysis' section of section 9.2.

The assumptions included in the company submission are discussed further in Table 9.1.

Table 9.1: Company Assumptions AECOPD model

Assumptions – AECOPD model	Justification	Source	EAC comments
A typical CCG purchases the unlimited licence package for the patients in their population. This costs £0.25 pa for every patient registered with a GP in the CCG and the contract is for 3 years.	There are different modes of purchasing licences. However, purchasing a lifetime licence for a patient at £40 per licence is no longer an option.	Company	This was judged to be appropriate by the EAC as the licence package modelled is that which is available. However, the EAC have presented an approximate per patient cost in section 9.3.
All patients in the myCOPD arm are registered for a myCOPD licence. Patients choose whether to activate or use it.	In the RESCUE study, patients in the intervention group were provided with the app but chose whether and how much to use it. Outcomes were assessed based on provision, not use.	North et al (2020) - RESCUE	This was judged to be partially appropriate by the EAC. It is acknowledged that the data is based on a cohort of people provided with the app and not a proportion of those people who used it. However, not all patients eligible for myCOPD would agree to be registered for it. The RESCUE trial states that only 46% of people eligible for myCOPD agreed to use it.
Outcomes from the RESCUE study only apply to the 3-month period following the index admission.	There are no data to support extrapolating the benefits for a longer period. This is a conservative assumption as the patients have perpetual access to the app content and we could reasonably expect benefits to extend into the longer term.	North et al (2020) – RESCUE	This was judged to be appropriate by the EAC based on no available evidence to suggest the benefit continues. This is a conservative assumption which the EAC has explored in a scenario.
The maximum number of patients who have an index admission per year is estimated from PHE and QOF data (1,105).	The company were unable to find an estimate for the number of patients, rather than the number of admissions, per year. Patients may have more than 1 admission in a year, so this number includes those who	INHALE (PHE, 2021), QOF 2019/20	This was judged to be partially appropriate by the EAC due to the data available. The EAC agree that the number given by the company would include those readmitted within a year. This would mean that

Assumptions – AECOPD model	Justification	Source	EAC comments
	have a readmission within a year (90 days is specified by the company but the EAC has amended this due to the data spanning across 1 year).		the 1,105 value could include some patients being counted twice. The RESCUE data do not state that it only includes people who have not been admitted before and so the outcomes may reflect those with a mixture of first admissions and readmissions. Two of the 3 experts agreed that in principle someone may benefit from using myCOPD from its use a second time, but more evidence would benefit in this area. The third expert was unsure if any benefits would be seen in the first place for these benefits to be seen again (see correspondence log).
The model is replicated each year for the 3 years of the contract. For example, the same costs and benefits apply each year.	No rationale provided by the company	Assumption	The model is based on an average number of people in a CCG in a given year. It assumes the same number of admissions each year and the same outcomes. Due to the RESCUE study data not excluding those readmitted, and experts suggesting that benefits could potentially be expected to continue (see correspondence log), the EAC agree this is reasonable but will not present 3 years of results.
Patients discharged from an index admission do not attend a PR course during the following 3 months. Patients with myCOPD may access	Participants in the myCOPD arm of the RESCUE study had access to the PR module but were not told to use it. Participants in the SoC arm did not receive PR.	North et al (2020) – RESCUE	The authors of the RESCUE study were not able to track those using the PR section of myCOPD. In the evidence used to model GP

Assumptions – AECOPD model	Justification	Source	EAC comments
any of the PR content including the PR modules.			appointments, 28% of people completed the PR course. It is unknown if these people attended a PR course whilst not using myCOPD (North et al. 2020). Despite this, the EAC think this is appropriate due to rate of GP appointments not being a key driver of the results when tested in deterministic sensitivity analysis.
Only patients having an index admission for AECOPD are registered for a myCOPD licence.	All the costs of the licences are divided by those patients who are able to benefit from it. Benefits are not extrapolated to patients with stable COPD. This only affects the per patient values, as total budget spend and total costs saved are independent of whether additional patients receive myCOPD.		This was judged to be appropriate by the EAC. However, due to myCOPD being costed per CCG (independent of how many people have COPD), using a wider population would improve the results (providing myCOPD causes no harm or increased resource use).

Overall, the company's model structure was judged to be appropriate, however, the following potential issues were identified by the EAC:

- The outcomes have been applied to every person who has been discharged from hospital with AECOPD, assuming that all those offered myCOPD would agree to be registered for it.
- The company assumed that the benefits of myCOPD would only last the duration of the trial. This is a conservative assumption, and it is possible that the benefits may extend beyond that seen in the trial.
- The study used to demonstrate a reduction in GP appointments (McLaughlin and Skinner 2020) was from a broader COPD population than that modelled.
- The company have acknowledged that there is potential double counting in the number of GP appointments. This is because the evidence used to cost the non-admitted exacerbations includes a proportion of people having a GP appointment (Jordan et al. 2015). GP appointments are further counted from the McLaughlin and Skinner study (McLaughlin and Skinner 2020)

EAC changes to model structure

The EAC added an input for the uptake of myCOPD in the model to reflect that not everybody offered myCOPD would agree to be registered for it. The RWE presented by the company included usage data of the app but a lack of uptake data. There was also a lack of RWE specifically in the AECOPD population being modelled. Uptake may differ in a broad COPD population compared with a population discharged from hospital with an acute exacerbation (the EAC judged it reasonable that this population are more vulnerable and may be more willing to agree to use the app for extra help). The EAC judged that the RESCUE study was a reasonable source to use for uptake data due to lack of RWE. However, this source has its limitations which are listed below:

- Of the 124 patients identified as eligible for the trial (and use of myCOPD), 83 were excluded. 16 of these were for study-related issues, 1 person did not have access to the internet and 66 declined without reason. Of the 66 people who declined without reason it is unknown if this was due to the study or relating to the app. For the base-case 46% uptake was assumed (57 out of 124 – this includes the 16 people who declined for study-related reasons as they may use myCOPD otherwise). This is conservative as it assumes that the 66 people who declined without reason would have declined the use of

myCOPD outside of a clinical trial environment. However, it also assumes that those who declined it for study-related reasons would otherwise use myCOPD.

- The uptake may be different in the real world compared with when people are aware they will be involved in a clinical trial. An expert has suggested that a large proportion of patients did not have the technology to use the platform or were not competent in using it. Out of 4,630 patient contacts (not unique patients), only 167 licenses were issued in 1 year (see correspondence log). From this the exact percentage of uptake is unknown but is low compared with that seen in the RESCUE study. Another expert suggested that uptake is likely to be 80% (see correspondence log). This suggests there is a lot of variation around this figure dependent on location. Data suggests that 65% of people aged 65+ use a smartphone (Statista 2021). However, this is not in a COPD population and doesn't indicate the proportion who would be capable of using myCOPD.
- One expert suggested that there were likely to be confounding variables in the RESCUE study, such as socioeconomic factors. Patients who do not have access to a smart phone or internet may be from lower socioeconomic classes who are more likely to have poor health state and greater smoking exposure (see correspondence log).

Due to the uncertainty in uptake, this will be varied in a threshold analysis to see the point at which the conclusions of the model change (e.g., at which point myCOPD would be cost-neutral).

No other changes were made to the model structure for the base case. Some existing inputs were updated (see section on 'Economic model parameters').

For a scenario analysis, the functionality was added to the model to see the effect on the results when the benefits of myCOPD continued up to 1 year. The conservative assumption that the benefits of myCOPD will only be demonstrated for 3 months (the duration of follow-up in the RESCUE study) will remain in the base case analysis.

Model 2: Patients eligible for pulmonary rehabilitation (PR) within a CCG population; stable COPD with an MRC ≥3, and post-discharge for AECOPD

Patients

The population in Model 2 are those patients eligible for a PR programme and the model is populated based on the evidence generated by the TROOPER RCT (Bourne et al. 2017). Patients may be eligible for PR for a number of

reasons, including hospitalisation following acute exacerbation (as per the population in Model 1). The number of patients entering this model is based on QOF data for patients that are MRC ≥3 (NHS Digital 2020). Therefore, there may be some crossover between the population included in Model 1 and Model 2 (i.e. the population in Model 2 will also likely include some patients from Model 1 because patients can be offered PR when discharged from hospital after AE). The company acknowledge this in their submission. NACAP 2020 presents data on reasons for referral to PR and reports that 5.2% of patients participating in the audit were referred after admission to hospital for AECOPD (National Asthma and Chronic Obstructive Pulmonary Disease Audit Programme (NACAP) 2020). Therefore, it appears that the crossover between patients included in the models should be relatively low. Clinical efficacy data are based on the TROOPER study which recruited patients from a range of primary and secondary care clinical settings consistent with the route of referral for PR and therefore could have included some patients following hospital discharge for AECOPD (Bourne et al. 2017). Additionally, it is possible that some of the benefits of myCOPD are double counted if the results of both models are combined because, although patients in the RESCUE study were not told to use the PR elements of the myCOPD app there was no way of recording whether or not they did access them. Therefore, the EAC deemed the decision to keep the 2 models separate rather than combining the results of the models appropriate to avoid this double counting. Model 2 can be viewed as exploring the potential additional benefits of using myCOPD for delivery of PR when it has already been purchased by the CCG recognising that there is likely to be some double counting of benefits.

Comparator

The comparator in Model 2 is face-to-face PR which is the standard of care and therefore aligns with the scope. This consists of a 6-week programme plus education modules and is delivered via 2 supervised sessions per week with additional unsupervised exercises at home to be undertaken 3 times per week. This appears to be well aligned with the NICE scope where the comparator is standard care (National Institute for Health and Care Excellence 2019c). NACAP 2020 data indicate 88.9% of services offered 2 sessions per week to patients as part of their PR programme (National Asthma and Chronic Obstructive Pulmonary Disease Audit Programme (NACAP) 2020). However, it should be noted all data are pre COVID-19 pandemic and the delivery of face-to-face services may have changed recently. It is not clear whether the standard of care will return to the same delivery methods as before the pandemic. One expert suggested that the standard of care is likely to become more remote compared with before the pandemic.

Technology

The treatment arm in Model 2 comprises of 3 different treatment options. Patient choice has been explicitly modelled with patients able to choose from 3 options:

- face-to-face PR for 6 weeks as per the standard care arm
- a hybrid model which consists of 1 face-to-face session per week for 6 weeks plus use of the myCOPD app
- myCOPD only: 6-week exercise programme delivered via the app plus education modules.

This deviates from the NICE scope which specifies the intervention to be myCOPD as an add-on to standard care. However, the myPR element of the myCOPD app is intended to be used as an alternative to standard care and patient choice would be incorporated in clinical practice. The company also model a hybrid approach where myCOPD would be used alongside standard care, although the EAC notes no RCT evidence has been generated for this approach so far and therefore it is assumed in the model to be non-inferior to myCOPD alone.

Model structure

The structure of Model 2 is a decision tree also developed in Treeage (shown in Figure 9.2). People entering the model are those that are eligible for PR. The costs of myCOPD were not included in this model because it is assumed the CCG has already purchased the license, administered licenses to staff and trained staff in using and delivering services via myCOPD as per Model 1. Therefore, this model is intended as an add-on to demonstrate the potential *additional* benefits of using myCOPD as an alternative option for delivering PR. The only set-up costs related to myCOPD that are included in Model 2 are the costs of registering the additional PR patients on the myCOPD app. This assumes there will be no additional training requirements or additional administering of licenses in order to use myCOPD for delivery of PR services over and above that in Model 1. Therefore, the results of this model cannot be interpreted as stand alone. However, caution should be used if trying to combine the results of the 2 models due the overlap in populations described previously.

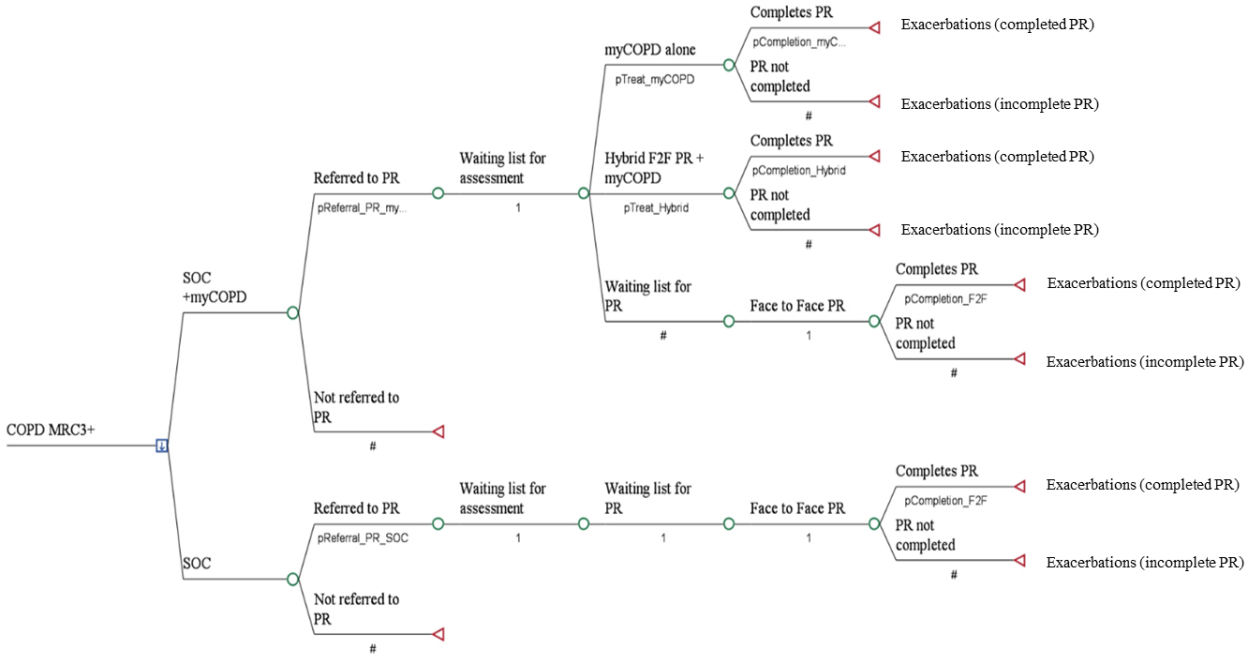
An alternative costing scenario was also included in this model whereby a PR service provider can purchase the myCOPD license specifically for use to help deliver PR services. In this case, a one-off annual fee is charged which

covers all patients registered with that GP or service provider. If this option is selected this one-off fee is included in the model along with set-up fees associated with administering licenses and training costs. Therefore, when this costing scenario is considered the results of the model can be considered as stand alone.

The analysis is presented over approximately a 1-year time horizon with all patients receiving an initial face-to-face assessment for PR. Here patient choice is explicitly modelled with patients in the SoC plus myCOPD arm being able to choose between face-to-face PR, hybrid or myCOPD alone. Following this they go on to receive the PR programme (either face-to-face, hybrid, or myCOPD alone) which they either complete or do not complete. The probability of completion is based on the TROOPER study which demonstrated non-inferiority of myCOPD compared with standard care. Therefore, the probability of completion is assumed to be the same regardless of the type of PR received. The number of exacerbations is then modelled with a different rate applied depending on whether the PR programme was completed or not (again the number of exacerbations for a complete or not complete PR course is assumed to be the same regardless of the type of PR programme based on non-inferiority of myCOPD delivered PR to face-to-face PR demonstrated by the TROOPER study). The company presented a diagram of the model structure which the EAC deemed to be accurate but not fully complete because it did not present the outcomes as part of the tree. The EAC amended this to incorporate the outcomes associated with each arm for clarity. The model submitted by the company for PR is essentially a cost comparison between offering PR with myCOPD and without. All outcomes are assumed to be the same between the different delivery mechanisms and therefore the only difference between the arms are the costs of delivering PR and the cost of waiting for PR for those in the comparator (face-to-face PR) arm. The EAC therefore notes that it was not necessary to model the full clinical pathway and a simple cost comparison could have been undertaken.

Again, the model was replicated in Microsoft Excel to check for errors and confirm consistency with the submission report and no errors or discrepancies were identified for the base case model. The results reported in the submission for the PR costing scenario did not appear to match the Treeage model submitted by the company (submission reported incremental cost per patient of -£17.65, and treeage model reports -£17.59). The EAC Excel replication of the PR costing scenario matched the Treeage model.

Figure 9.2: Model 2 diagram PR



The assumptions included in the company submission are discussed further in Table 9.2.

Table 9.2: Model 2 PR assumptions

Model 2 (PR) Assumptions	Justification	Source	EAC comments
Outcomes from the TROOPER study apply to the 3 month period following the index admission. The company assume that non-inferiority to SOC PR in outcomes extends to resource use and for 1-year post-PR.	The company is not aware of any data to support extrapolating the benefits (from 1 PR programme) for a longer period. This is a conservative assumption as the patients have perpetual access to the app content and we could reasonably expect benefits to extend into the longer term.	Bourne et al (2017)	This was judged to be reasonable however it is not necessarily conservative. It is reasonable to expect the benefits of PR could extend beyond 1 year (without PR being repeated annually), however, this would apply to all treatment arms if the assumption of equal benefit regardless of delivery method of PR is accepted and therefore would not impact on the incremental difference between treatment arms. No evidence has been generated to show non-inferiority extends beyond the study period and non-inferiority demonstrated in outcomes such as CAT score and 6-minute walk test are used as a surrogate measure and linked to a reduction in resource use and exacerbations. However, clinical experts queried by the EAC judged the assumption that these outcomes could be used as surrogate outcomes for reduction in exacerbations as reasonable (see correspondence log).
Completion rates for PR are the same for all modalities.	Completion rates are measured differently between face-to-face (F2F) and myCOPD PR. It is possible to tell if a patient has accessed material, but not whether they have participated in the exercises. Completion rates in Bourne et al were slightly lower in myCOPD, but the recommendation was for 5 sessions per week. The non-inferiority finding held despite the slight difference in completion.	Bourne et al (2017)	The EAC judged this to be reasonable based on the evidence demonstrated by TROOPER, however, it is noted that non-inferiority is not directly demonstrated in reduction in outcomes such as exacerbations and associated resource use which is also assumed non-inferior in the economic model. Additionally, completion rates could be different in a trial setting and clinical practice. However, limited real world evidence does show similar completion rates to those demonstrated in the trial (Southend CCG 2019b) (See section 5.3 Adherence and usage).

Model 2 (PR) Assumptions	Justification	Source	EAC comments
For the base case, all technology costs (unlimited contract, licence administration, training) are included in the AECOPD model (i.e. no costs for myCOPD are included in this model), except the additional per licence registration cost	CCGs would not purchase the Unlimited contract option solely for PR referrals. So this patient subgroup would be included in the Unlimited model only if this was purchased for a wider patient population.	Company	The EAC judged this to be reasonable because it is unlikely if the CCG purchased the unlimited contract they would restrict use solely to PR. The EAC confirmed with the company that even if PR services are run by separate organsitions/outsourced within a CCG they would not have to purchase separate licenses (see correspondence log).
There is no increase in PR capacity at the service due to the adoption of myCOPD.	There is no published data to support an increase in capacity. Increased referrals in the myCOPD arm is included in the sensitivity analysis, but has to be interpreted with care, as face-to-face PR is not an intrinsically cost saving intervention within this model.	Assumption due to data availability	The EAC judged this to be reasonable due to the purpose of the model being to assess the cost implications of myCOPD being used compared with face-to-face PR, and not PR compared with no PR. There is no need to include the consequences of any potential change in capacity (e.g., more capacity) from the adoption of myCOPD. This is discussed in more detail in the 'Clinical parameters' section.
All patients referred for PR attend a face-to-face assessment before commencing the programme.	Guidelines indicate that patients referred for PR be assessed for suitability and for baseline measures of exercise capacity.	BTS Quality Standards (2014) and Guidelines (2013)	The EAC judged this to be appropriate.
There is no distinction between patients referred for PR for stable COPD and those referred post-discharge.	Patients referred following an admission for AECOPD constitute about 5% of those attending PR. Also, many measures of PR activity do not distinguish between these subgroups.	NACAP PR Clinical Audit 2019	The EAC judged this to be reasonable and did not identify any data with which to separate them.
There are similar numbers of referrals for PR each year	NACAP reports from 2015 and 2018 report similar overall numbers of PR referrals for patients with COPD.	NACAP PR Organisational Audits (2015, 2018)	This was judged to be reasonable by the EAC.

Model 2 (PR) Assumptions	Justification	Source	EAC comments
Patients who are referred to PR but do not complete the course do not receive a benefit, or a cost other than initial assessment.	The company is not aware of any data to apply outcomes to partially completed PR.	Assumption due to data availability	The EAC judged this to be a conservative assumption because the cost of partial face-to-face PR would likely be a lot higher than with myCOPD, although there could also be some additional benefit to partially completing either programme which would not be captured by the exacerbation rate applied to those not completing PR.
Patients on the waiting list for PR and those not referred having the same rate of exacerbations as patients who do not complete PR.	There is no reason to expect differences in exacerbation rates between these subgroups.	Assumption due to data availability	The EAC judged this to be reasonable.
Patients receiving myCOPD alone do not subsequently go on to receive F2F PR (in the same year)	myCOPD alone is included as an alternative to F2F or hybrid PR modalities.	Company	The EAC judged this to be reasonable.
The published cost estimates for F2F PR include an element for the initial and final assessments	Most published cost estimates determine the cost of the whole service and then divide by the number of patients.	Source not provided by company	The EAC judged this to be reasonable.
The cost for the F2F part of hybrid PR is half the cost of F2F PR, plus the cost of initial and final assessments	Justification not provided by company.	Source not provided by company	The EAC judged this to be appropriate but notes that the cost of hybrid PR is just half the cost of F2F PR, assessment costs are not added to this.
Patients spend a total of 1 year in the model, so that the rate of exacerbations post-PR is proportional to the time left after allowing for the waiting time for PR. This is independent of whether they complete PR or not.	Justification not provided by company	Source not provided by company	This was judged to be reasonable. It is noted that the treatment time is not included in the model but this is expected to be equal between treatments and, therefore, this simplifying assumption was judged to be appropriate.

Model 2 (PR) Assumptions	Justification	Source	EAC comments
For the PR provider contract, referral is 100%, and uptake is governed by the patient accessing the myCOPD PR course and the patient completing it	This is a bespoke service that delivers PR only.	Company	This was judged to be reasonable to the EAC.
There are no additional training or set up requirements such as additional set up of staff licenses to implement myCOPD for PR alongside implementation for patients discharged from hospital for AE.	NA – assumption added by EAC		This was deemed to be reasonable, although it is noted there could be some additional costs associated with using myCOPD in a wider group of patients.

EAC changes to model structure

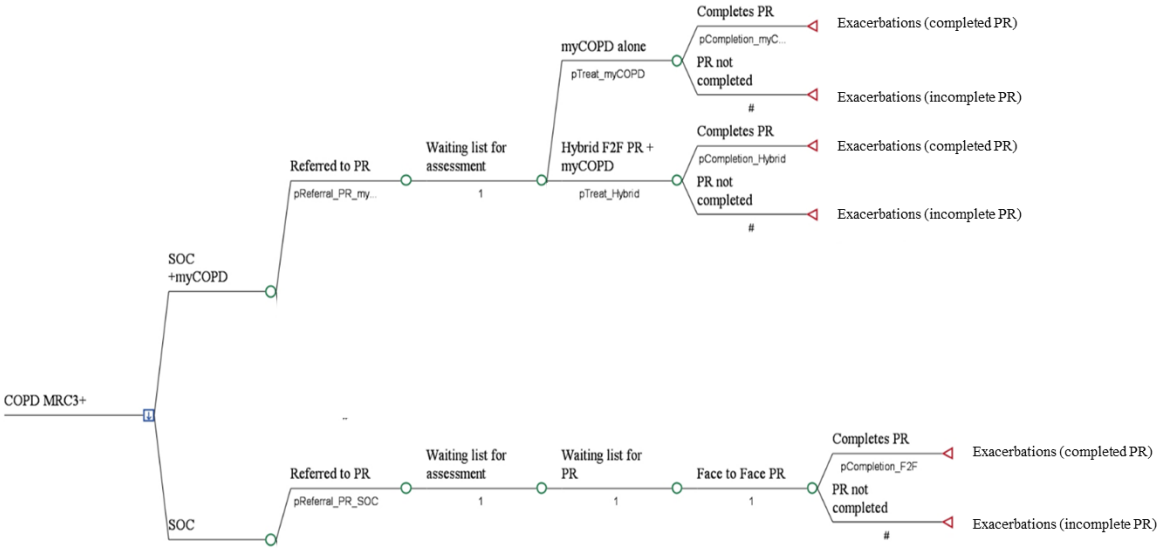
Overall, the company's model and structure were judged to be appropriate. However, the following changes were made by the EAC:

- There is likely to be a cost associated with non-completion of PR programmes. The company included the cost of a face-to-face assessment for all patients referred to PR regardless of whether they start a PR programme, however, no additional cost is included for those who start but do not finish a programme. The EAC included a cost for those starting but not completing their programme for all treatment arms in the model. This leads to additional estimated savings with myCOPD due to these costs being higher in the face-to-face treatment arm of the model. However, it should be noted that any benefits of partially completing a PR programme will not be captured in the number of exacerbations assigned to patients not completing a PR programme. Some other minor changes were made to input parameters which is discussed further in the 'Economic model parameters' section.
- The EAC also changed the decision point in the model from referral to PR, to the point at which patients have opted in for or shown they are willing to use myCOPD. The reasons for this were:
    - To align Model 1 and Model 2 in terms of the decision point (i.e., the point at which myCOPD has been chosen).
    - To align the treatment in the model with the scope (i.e., the treatment will change from a choice of myCOPD, hybrid or face-to-face to just a choice between the 2 myCOPD options (myCOPD alone or hybrid option)).
    - To better align the population in the model with those in the TROOPER study (i.e., these patients had opted to use myCOPD).
    - To allow for the calculation of a cost per patient using myCOPD.

  This will not change the direction of results, only the magnitude.

The updated model structure is shown in Figure 9.3.

Figure 9.3: EAC Model 2 structure



Other uncertainties identified with Model 2 include:

- Uptake is still a key uncertainty. This will not have any impact where myCOPD has already been purchased by the CCG and therefore this model just shows potential additional benefits, however, where the PR costing method is used this could influence whether myCOPD is cost saving.
- The uptake figures are based on a real-world evaluation of myCOPD in Southend hospital. Patients were offered remote PR; however, some patients did not have access to the internet or an appropriate device with which to use myCOPD and therefore were provided with alternatives including DVDs, written plans etc. The uptake figure used in the model is based on all patients opting for remote PR including those without suitable devices or internet access and therefore could be overstated. Only 3% of patients opted specifically for myCOPD. However, it is acknowledged that this was pre-pandemic and, therefore, this could have changed since then given the remote delivery of health care services has become more widespread, however, the EAC could not source an updated value. The EAC did update the uptake number for a calculation error which is discussed in more detail in the 'Clinical parameters' section.
- Where the PR costing method is used it is assumed there are approximately 500 referrals per year to a PR service. This is based on

a median reported by the NACAP audit (National Asthma and Chronic Obstructive Pulmonary Disease Audit Programme (NACAP) 2020). Some services will have fewer referrals than this which could influence whether purchasing the PR service contract would be cost saving for those with fewer referrals due to it being based on a fixed cost. This is explored in sensitivity analysis.

Overlap between Model 1 AECOPD and Model 2 PR

There is a small overlap in patients between the AECOPD model and the PR model. A small proportion of patients in the PR model may be referred after having an AECOPD. However, the company thought this to be limited to approximately 5% (see correspondence log). This is based on data in NACAP (2020), which presents data on reasons for referral to PR and reports that 5.2% of patients participating in the audit were referred after admission to hospital for AECOPD (National Asthma and Chronic Obstructive Pulmonary Disease Audit Programme (NACAP) 2020).

In the RESCUE study (North et al. 2020) (data used in the AECOPD model) it could not be traced whether people were using the PR section of the app. People in the SOC arm were not reported to have had PR. In McLaughlin and Skinner (McLaughlin and Skinner 2020), a proportion of people completed PR, and it is unknown if anybody had PR in the previous months where they were not using the app. In both studies, it is possible that some of the benefits demonstrated from using myCOPD could stem from PR, leading to an overestimate of benefits when compared with SoC. One clinical expert agreed that the use of the PR section of the app was likely to give additional benefits alongside those given from other sections of the app (see correspondence log). The EAC judged that, despite the overlap, the models will not be combined due to the small overlap and the potential to double-count benefits if combined.

Economic model parameters

Clinical parameters and variables

Table 9.3 shows the clinical parameters used in the company's models and any changes made by the EAC. Any parameters that warranted further explanation are discussed below the table.

Table 9.3: Clinical parameters used in the company's model and any changes made by the EAC

Variable	Company value	Source	EAC value	EAC comment
Model 1 AECOPD				
Mean number of patients registered in a CCG	447,464	QOF 2019/20, COPD tab, Average of list size (National Health Service 2020)	No change	Used to calculate the annual license fee
Average number of admissions for AECOPD per 100,000 in England	247	PHE Inhale - Interactive Health Atlas of Lung conditions in England. Period 2018/19. All of England (Public Health England 2019)	No change	Used to calculate the number of admissions for AECOPD in an average CCG
Uptake of myCOPD	Not in company model	RESCUE study – 124 people eligible and 67 people did not go on to use myCOPD	46%	66 of the 67 people gave no reason for starting the trial. It is unknown if this was for study reasons and these people would have otherwise used myCOPD. 46% is a conservative estimate. In 2018, 10% of the adult UK population were described as 'non-internet users' (Office for National Statistics 2019)
Number of exacerbations over 90 days post AECOPD (standard of care arm)	1.88	RESCUE study. Table 5	No change	Used to calculate the overall cost of non-admitted exacerbations
Number of exacerbations over 90 days post AECOPD (myCOPD)	1.06	RESCUE study. Table 5	1.09	Used to calculate the overall cost of non-admitted exacerbations. A 3-month adjusted rates ratio was presented in the RESCUE study of 0.581 (Table 5). This adjusted for baseline score and stratification variables. The EAC judged it more appropriate to apply this to the model (SOC

Variable	Company value	Source	EAC value	EAC comment
				exacerbation of 1.88*0.581 = 1.09) instead of using the raw risk
Number of GP appointments over 90 days post AECOPD (standard of care arm)	2.28	(McLaughlin and Skinner 2020)	No change	Used to calculate the overall cost of GP appointments
Number of GP appointments over 90 days post AECOPD (myCOPD)	1.85	(McLaughlin and Skinner 2020)	No change	Used to calculate the overall cost of GP appointments
Readmission rate over 90 days post AECOPD (standard of care arm)	0.39	RESCUE study. Table 5.	No change	Used to calculate the overall cost of readmissions
Readmission rate over 90 days post AECOPD (myCOPD)	0.24	RESCUE study. Table 5	0.20	Used to calculate the overall cost of readmissions. A 3-month adjusted odds ratio was presented in the RESCUE study = 0.383 (Table 5). This adjusted for baseline score and stratification variables. The EAC judged it more appropriate to apply this to the model. The odds ratio was converted to a relative risk (see calculations in the paragraph below the table) and the readmission rate seen in the SOC arm (0.39) was multiplied by the calculated relative risk (0.504)

Variable	Company value	Source	EAC value	EAC comment
Model 2 PR				
Probability of having a diagnosis of COPD in the general population	1.94%	(NHS Digital 2020) Sum of registered patients divided by sum of list size on COPD tab.	No change	Used to calculate number of patients with COPD which contributes to calculation of number of patients entering the model
Proportion of patients eligible for PR referral	29.7%	(NHS Digital 2020) Average of patients with COPD and MRC≥3 (denominator plus PCAs) divided by average of COPD patients per CCG	No change	Used to calculate number of patients eligible for a PR referral which contributes to the calculation of number of patients entering the model
Proportion of eligible patients referred for PR (SoC)	20.2%	Eligible patients calculated using 40% eligibility rate from COPD prime and applied to QOF data to calculate eligible patients. 15% of these patients assumed to be offered PR based on COPD Prime (Chartered Society of Physiotherapy 2017). The resulting number is then applied to the QOF data eligible patients to calculate the percentage.	No change	Used to calculate number of patients referred for PR which contributes to the calculation of number of patients entering the model. It is noted by the EAC that the original figures of 40% and 15% could have been applied for proportion of patients eligible for PR referral and proportion of eligible patients referred for PR to give the same resulting number of patients entering the model.
Proportion of eligible patients referred for PR (myCOPD)	20.2%	Assumed to be the same capacity when myCOPD is introduced and therefore same referral rate	No change	Used to calculate number of patients referred for PR which contributes to the calculation of number of patients entering the model
Median patients referred to PR service (PR service costing scenario only)	495	Median of 298 reported per CCG in NACAP 2019 (National Asthma and Chronic Obstructive Pulmonary Disease Audit Programme (NACAP) 2020) over 6 month period (multiplied by 2 to give yearly referral rate). 84% of referrals are reported to be for COPD in NACAP 2018 (National COPD Audit Programme 2018).	No change	Percentage related to COPD not reported in latest audit. Used to calculate number of patients entering the model for PR service costing scenario

Variable	Company value	Source	EAC value	EAC comment
Probability of being treated with hybrid	11%	Assumption that uptake will be similar to that of myCOPD alone (My mhealth Ltd 2021a)	12%	Recalculated by the EAC to account for both people who completed and did not complete the courses. It is also noted this proportion reflects those willing to take up remote PR - not myCOPD - only 3.2% of patients took up myCOPD, the rest did not have internet access or a suitable device, however this was prior to the pandemic. This assumes there will be a further 11% of people willing to use myCOPD as part of a hybrid approach alongside the 11% who have opted to use it alone. Note uptake is different between Model 1 and Model 2 because the patient populations in the models are different and therefore it is expected their willingness to use myCOPD may be different.
Probability of being treated with myCOPD only	11%	Based on proportion of patients who took up remote PR in Southend study	12%	Recalculated by the EAC to account for both people who completed and did not complete the courses. It is also noted this proportion reflects those willing to take up remote PR not myCOPD, only 3.2% of patients took up myCOPD, the rest did not have internet access or a suitable device, however this was prior to the pandemic. It is also noted that no hybrid approach was offered in the study and therefore this assumes that uptake of myCOPD alone would be unchanged if a hybrid approach was also offered.
Number of patients entering the model (both arms)	2,577	Calculated based on all patients eligible for PR referral	127	Decision point in model changed so that only those that are willing to use myCOPD enter the model because the introduction of myCOPD is only expected to influence costs and outcomes for these patients
Number of patients entering the model (PR service costing scenario)	495	Calculated based on all patients referred to PR services	121	Decision point in model changed so that only those that are willing to use myCOPD enter the model.
Probability of starting and completing a PR course (face-to-face PR)	41.9%	COPD Prime reports of those referred 59% start a PR course and 71% complete (Chartered Society of Physiotherapy 2017)	No change	Used in the model to determine the completion rate for face-to-face PR

Variable	Company value	Source	EAC value	EAC comment
Probability of starting and completing a PR course (hybrid PR)	41.9%	Assumed equal to face-to-face PR based on TROOPER study	No change	Used in the model to dermine the completion rate for hybrid PR
Probability of starting and completing a PR course (myCOPD only PR)	41.9%	Assumed equal to face-to-face PR based on TROOPER study	No change	Used in the model to dermine the completion rate for myCOPD PR. The EAC notes that completion for the myCOPD arm in the trial was only 62% (compared with 72% for face-to-face PR). However, non-inferiority was still demonstrated and patients were asked to do 5 sessions per week in the myCOPD arm as opposed to 2 in the face-to-face group.
Annual exacerbations after completing PR	2.11	(Chartered Society of Physiotherapy 2017)	No change	Used in the model to calculate exacerbations following completion of any PR programme
Annual exacerbations after not completing PR	3.31	(Chartered Society of Physiotherapy 2017)	No change	Used in the model to calculate exacerbations following non-completion of any PR programme
Waiting time for PR after assessment (days)	13	(National Asthma and Chronic Obstructive Pulmonary Disease Audit Programme (NACAP) 2020)	No change	Used to inform the cost of waiting for those having face-to-face PR

Model 1 AECOPD

The uptake in the model was included by the EAC to reflect that not everybody eligible for myCOPD would agree to use it. This is discussed in the 'Model Structure' section.

There is uncertainty around the number used to calculate the number of admissions for AECOPD in an average CCG. As this number is based on admissions and not per person, it will include the readmissions in the same year. The RESCUE study (that the main outcomes are based on) does not state that it includes only people who have been admitted to hospital with an acute exacerbation for the first time. Therefore, the EAC judged this to be reasonable. However, there is uncertainty on whether benefits would be the same after using myCOPD following discharge from a readmission. Expert opinion suggested that it is possible, but more research is necessary to show this (see correspondence log). The EAC conducted a pragmatic search for number of people admitted for acute exacerbations (rather than number of admissions) but could not find a number which was specific to emergency admissions or not separated by COPD severity. The resource impact tool from NICE guidelines for COPD uses Hospital Episode Statistics to estimate 5.84% of people with COPD are admitted to hospital with acute exacerbations of COPD (National Institute for Health and Care Excellence 2019a). However, this is also based on the number of admissions rather than per person.

The number of exacerbations and the readmission rate were updated by the EAC to reflect the values adjusted for baseline score and stratification variables (such as COPD severity and smoking status). The baseline characteristics in the RESCUE study showed that 48% of people in the SoC arm had moderate COPD, compared with 20% of people in the myCOPD arm. 29% of people in the SoC arm had severe COPD, compared with 55% of people in the myCOPD arm. Therefore, the EAC judged it more appropriate to use the adjusted values than the unadjusted values, which would not have taken the differences in severity into account.

In the RESCUE study, the adjusted difference in exacerbations between arms was presented as a rate ratio which was used directly in the EAC model. The adjusted difference in readmissions between arms was presented as an odds ratio. For use in the economic model, the odds ratio was converted to a relative risk using the below formula (Grant 2014):

*Relative risk = odds ratio/(1- baseline risk + (baseline risk*odds ratio))*
*Relative risk = 0.383/(1 - 0.39 + (0.39*0.383)*
Relative risk = 0.504

The baseline risk of a readmission is equal to the 90-day readmission rate in the SOC arm (0.39). By multiplying this by the relative risk (0.504) the EAC estimated the readmission rate for the myCOPD arm (0.20).

Model 2 PR

There is some uncertainty around the number of referrals to PR when using the CCG approach; however, when using this approach myCOPD has already been paid for by the CCG and therefore cannot become cost incurring. The number of referrals estimated using QOF and COPD Prime data also matches well with the median number of referrals reported by the NACAP audit and therefore the EAC judged this to be reasonable. Increasing the number of referrals is likely to make the case for myCOPD more favourable in both the CCG and the PR model because it is likely this will increase uptake of myCOPD and therefore lower the cost per patient (due to the cost of myCOPD being mostly fixed).

Uptake of myCOPD is also still a key uncertainty, particularly in the PR service costing scenario. The uptake in the model is based on real world evidence generated by Southend hospital. The source of the data is from a webinar and therefore is unpublished and has not been peer-reviewed. Further, the figure is based on patients accepting any kind of remote PR not just myCOPD. The webinar states that alternatives were provided to those who did not have internet access or a suitable device. If those patients are not included in the uptake figure this reduces to around 3%. However, this study was conducted prior to the COVID-19 pandemic and patient acceptance of digital technologies may have changed in the past year so the EAC deemed the 11% figure used in the company base case to be reasonable. However, this figure was amended to include all patients who accepted remote PR (including those who did not complete the course). Uptake was also tested in sensitivity analysis.

The number of patients entering the model was updated by the EAC to reflect the change to the decision point taken in the model as discussed in under the ‘Model Structure’ section.

Clinical experts were queried by the EAC about the non-inferiority being demonstrated in outcomes such as CAT score and 6-minute walk test extending to a reduction in exacerbation. One expert commented that there is some small-scale evidence to say that 6-minute walk distance, speed and desaturations can be used to predict mortality and hospitalisation and therefore these measures could be a surrogate indicator of these. Similarly, CAT score can assist prediction of exacerbations. Another expert also agreed

that they would expect it to be possible that these outcomes would result in reduction of admissions for simple exacerbations (see correspondence log).

The COPD Prime tool is used to populate much of the PR model. This tool was developed by the Chartered Society of Physiotherapy in 2017 and, therefore, was judged to be an unbiased source of data by the EAC. It aims to model the impact of PR on exacerbations of COPD. Data from the Clinical Practice Research Database on over 200,000 patients with diagnosed COPD were analysed by the Chartered Society of Physiotherapy to obtain national data about PR eligibility and referral. However, it is noted that it is not always clear and transparent where data in the tool have come from.

Resource identification, measurement, and valuation

Resource use and costs in the model were described in the company's economic submission. However, there was insufficient detail to enable the EAC to validate all the values used and hence further information was requested. This was provided in a separate report (see correspondence log).

Table 9.4 shows the costs used in the company's model and any changes made by the EAC for the AECOPD and PR models.

Table 9.4: Cost parameters used in the company's model and changes made by the EAC

Parameter	Company value	EAC value	Source
Model 1 AECOPD			
Technology costs	£0.25 pa per patient registered (3-year contract)	No change	Company submission.
Exacerbation self-managed or managed in primary care (i.e. no admission)	£53.59	£81.75	Adapted from (Jordan et al. 2015). EAC updated with 2019/20 reference costs (National Health Service 2021). See breakdown in table below
Emergency hospital admission for AECOPD	£1,583	£1,721	COPD PRIME (Chartered Society of Physiotherapy 2017) (updated with reference costs 2018/19 (National Health Service 2021)). EAC updated with 2019/20 reference costs (National Health Service 2021). See breakdown in table below
GP appointment (9.2 mins)	£39	No change	PSSRU 2020 (Curtis and Burns 2020). The EAC agree this is the best source for staff costs.
Practice nurse per hour (band 5) to register patients and train	£39	No change	Company: PSSRU 2020 (Curtis and Burns 2020), NHS Jobs
Practice manager to administer top-level licences	£48	No change	PSSRU 2020 (Curtis and Burns 2020)
Cost of setting up licences for a CCG	£360	No change	7.5 hours of a practice manager's time at £48 an hour (PSSRU 2020 (Curtis and Burns 2020) and company assumption)
Cost of training 1 clinician to use myCOPD at every practice in the CCG	£1,950	No change	QOF data gives an average of 50 GP practices per CCG. Company: PSSRU 2020 Training given by band 5 practice nurse , NHS Jobs indicates a band.
Cost of registering a patient for a myCOPD licence a year	£9.75	£19.50	Company submission – time of 15 minutes to register a patient by a band 5 practice nurse (PSSRU 2020 (Curtis and Burns 2020)). Clinical experts queried by the EAC gave a range of between 15 to 45 minutes and 1 expert also noted that it would be band 6 or 7 staff because they do not have band 5 staff in their service (see correspondence log). The EAC judged it appropriate to be conservative and assume 30 minutes for the base case value, with the range of 15 (band 5) to 45 minutes (band 6) used in sensitivity analysis.

Parameter	Company value	EAC value	Source
Model 2 PR			
Annual cost of myCOPD per patient (PR service costing scenario only)	£10,000	No change	Provided by company
Cost to administer licenses (PR service costing scenario only)	£360	No change	Practice manager assumed to administer top-level licenses at a cost of £48 per hour (PSSRU 2020 (Curtis and Burns 2020)). Assumed to take 1 day.
Cost of training for a PR service to use myCOPD (PR service costing scenario only)	£195	No change	Assumed to be 5 x Band 5 staff trained for 1 hour each to reflect PR service being delivered more centrally. Costed using PSSRU 2020 (Curtis and Burns 2020). One clinical expert commented that they would expect true learning time to be greater than 1 hour because clinicians would likely trial it themselves after the training session (see correspondence log).
F2F PR programme	£695	No change	COPD Prime (Chartered Society of Physiotherapy 2017) (updated using PSSRU 2020 staff costs (Curtis and Burns 2020)) Assumed to include the cost of initial and post discharge assessment
Face-to-face assessment for PR	£79	No change	PSSRU 2020 (Curtis and Burns 2020), Expert opinion - 1 hour of band 6 and 1 hour of band 4 Same cost applied for initial assessment and post discharge assessment
Cost per exacerbation	£283	£328	15% probability of exacerbation being treated in hospital (COPD prime (Chartered Society of Physiotherapy 2017)) multiplied by the cost of a hospital admission for exacerbation. 85% probability of exacerbation being treated in primary care multiplied by the cost of of a non-admitted exacerbation. Costs of admitted and non-admitted exacerbation as per AECOPD model.
Telephone support for remote PR (myCOPD only)	£18	No change	Expert opinion 3 x 10-minute phone calls Assumed to be Band 6 community therapist at a cost of £49 per hour (PSSUR 2020 (Curtis and Burns 2020))
Cost to register a patient for myCOPD license	£9.75	£19.50	Assumed 15 minutes of band 5 practice nurse time at a cost of £39 per hour (PSSRU 2020 (Curtis and Burns 2020)). Clinical experts queried by the EAC gave a range of between 15 to 45 minutes and 1 expert also noted that it would be band 6 or 7 staff because they do not have band 5 staff in their service (see correspondence log. The

Parameter	Company value	EAC value	Source
			EAC judged it appropriate to be conservative and assume 30 minutes for the base case value, with the range of 15 (band 5) to 45 minutes (band 6) used in sensitivity analysis.
Cost of time waiting for assessment	£33	£39	Company: Cost per exacerbation (as above) multiplied by a total waiting time of 13 days multiplied by the annual number of exacerbations in people who didn't complete PR (3.31)
Cost of starting and not finishing PR – face-to-face PR	Not included by company	£26	Assumed to be the cost of face-to-face PR minus assessment costs divided by 6 to reflect the cost of patients attending 1 session before dropping out. Applied to 29% of patients based on COPD prime tool which states 59% of those referred start PR and of starting those 71% complete their PR programme (Chartered Society of Physiotherapy 2017)
Cost of starting and not finishing PR – Hybrid	Not included by company	£13	Assumed to be the cost of starting and not finishing face-to-face PR halved
Cost of starting and not finishing PR – myCOPD	Not included by company	£2	Assumed to be the cost of 1 support phone call Proportion starting but not finishing PR assumed to be the same as face-to-face PR

Model 1 AECOPD

The breakdown for the cost of a non-admitted exacerbation is presented in Table 9.5.

Table 9.5: Cost of a non-admitted exacerbation (derived from (Jordan et al. 2015)

Item	Resource	Company unit cost	EAC updated unit cost	Source
A&E no admission	33%	£74.82	£159.31	2019/20 NHS cost collection (National Health Service 2021) (company used 2018/19). Weighted average for all non-admitted A&E (EAC excluded those dead on arrival or in for dental treatment)
GP visit	66%	£39	£39	PSSRU 2020 (Curtis and Burns 2020)
Oral Corticosteroids	2 x 28 tablets x 5mg	£1.54	£1.54	Prednisolone £0.77; BNF 2020 (National Institute of Health and Care Excellence 2021)
Antibiotics	15 x 500mg	£1.11	£1.11	Amoxicillin; BNF 2020 (National Institute of Health and Care Excellence 2021)
Total cost per exacerbation		**£53.59**	**£81.75**	

The company acknowledged that there may be overlap between the GP visits included in the non-admitted exacerbations and the unscheduled GP visits costed for the GP visits outcome. The McLauglin & Skinner study refers to unscheduled GP appointments attributable to COPD, and not to appointments specific to exacerbations (McLaughlin and Skinner 2020). This could include non-exacerbation-related appointments. The EAC judged it appropriate to leave the proportion from the non-admitted exacerbations in Jordan et al. unchanged due to being relevant to the specific population (Jordan et al. 2015).

The EAC could not initially match the company's unit cost of a non-admission to A&E (£74.82) with the 2018/19 NHS reference costs. However, details of this were subsequently provided by the company on request. The EAC subsequently updated this to those found in the 2019/20 NHS reference costs. This was the weighted average for all non-admitted A&E values excluding those related to dental conditions and those dead on arrival. Those dead on arrival were excluded as the economic models do not incorporate

mortality. The updated total cost per non-admitted exacerbation is presented in Table 9.5.

The cost of a readmission for a COPD-related event was based on the COPD Prime tool and the company updated the values with NHS cost collection 2018/19. The EAC has updated these values with 2019/20 costs. The breakdown is presented in Table 9.6.

Table 9.6: Unit cost of a readmission (derived from COPD Prime (Chartered Society of Physiotherapy 2017))

Item	Company cost	EAC Updated cost	EAC Source
Admission cost (non-elective short and long stay)	£1,179	£1,292	2019/20 NHS cost collection (National Health Service 2021) (company used 2018/19). Weighted average for DZ65A-K non-elective short and long stay
A&E department – emergency medicine	£166	£186	2019/20 NHS cost collection (National Health Service 2021) (company used 2018/19). Weighted average of all (EAC excluded those dead on arrival or in for dental treatment)
Ambulance (90% of people)	£265	£243	PSSRU 2020 (Curtis and Burns 2020) – calls plus see, treat and convey. Hertel et al. (Hertel et al. 2012) 90% of people (cited in COPD Prime (Chartered Society of Physiotherapy 2017))
Total cost per exacerbation	**£1,583**	**£1,721**	

Model 2 PR

Key uncertainties in the costs related to the PR service costing scenario include the costs associated with training and administration of licenses. For this the company assumed 5 Band 5 staff would be trained to deliver a PR service to those opting to use myCOPD. They also assumed 1 day of practice manager or equivalent time to administer licenses per year. Clinical experts did not have the relevant expertise to validate this.

The cost of face-to-face PR was based on the COPD Prime tool and updated by the company with staff costs from PSSRU. This was deemed reasonable by the EAC because these staff costs will reflect the true cost of these staff including overheads to the NHS. The EAC did a pragmatic literature search for the cost of face-to-face PR and did not identify anything published recently that was more suitable. A cost of illness study by Chakravorty *et al*. reported a cost of face-to-face PR ranging between £522 to £1044 (Chakravorty et al.

2011). This was based on using the NHS tariff for programmed pulmonary rehabilitation at a cost per session of £232 per person per assessment. This was combined with 2 assessments and assumed a group size of 8 to 16 having 14 sessions (i.e. 2 per week for 6 weeks plus 2 assessments). Although this paper is from 2011 the reference cost for programmed PR has now decreased to £225 and, therefore, the calculated cost using this approach can be expected to be similar. The midpoint of the range of costs reported is around £783 and so using this approach would produce a very similar estimate to that used by the company. Similarly, a study by Griffiths et al reports a cost per patient of around £712 assuming 17 patients per programme (Griffiths et al. 2001). This paper is from 2001 so there may have been substantial changes to the way PR programmes are delivered since then. Therefore, the EAC deemed the value estimated by the company reasonable and did not change this value in the base case.

Patients entering the company model are all assumed to have the cost of a face-to-face assessment regardless of whether or not they start PR. It is noted by the EAC that data are available from COPD Prime on the proportion of patients that are likely to undergo a face-to-face assessment, however, because this is applied to all treatment arms in the model it will have no impact on the incremental difference between treatment arms and therefore was not altered by the EAC (Chartered Society of Physiotherapy 2017). The company also did not include any other cost associated with starting but not completing a PR programme. The EAC included a cost for a proportion of patients (29%) based on COPD Prime that started but did not finish a PR cost for all treatment arms in the model (Chartered Society of Physiotherapy 2017). For face-to-face PR this cost was assumed to be the cost of face-to-face PR, minus the cost of both assessments (first assessment already captured as described above), divided by 6 to reflect the approximate cost of attending 1 session. For those having hybrid PR, the cost was assumed to be half the cost associated with face-to-face PR. For the myCOPD only PR the cost was assumed to be 1 telephone support call (cost of license registration already captured elsewhere).

Sensitivity analysis

Company scenario analysis

Model 1 AECOPD

The company provided a best- and worst-case scenario for the AECOPD model to explore the range of economic outcomes that might results from implementing myCOPD.

Best-case scenario AECOPD

The best-case scenario used the most beneficial input parameter values for myCOPD. The company did not reduce the exacerbation or admission rates for myCOPD as the ranges given in RESCUE (North et al. 2020) would have led to negative values. Instead, the best-case values were equal to the base values for myCOPD. The company used a conservative approach. The EAC did not believe that this reflects the uncertaintly in the parameter and, without an appropriate value for uncertainty, the rate should be reduced by an assumed value to explore the impact of uncertainty in this parameter. Further to this, the EAC noted that if the adjusted rates were used in the base case the relative risk could instead be varied using the uncertainty intervals provided in RESCUE (North et al. 2020).

In the company submission, the best-case scenario for the rate of exacerbations is incorrectly reported (the base case value is 1.06 (also incorrectly reported) and, if the rate remains unchanged for the best-case scenario this would stay as 1.06). However, the standard deviation reported in RESCUE (North et al. 2020) is 0.83 for myCOPD, which can be subtracted from the base case value of 1.06 to produce a lower estimate of 0.23.

The base case value for the rate of exacerbations is also incorrectly reported. This should read 1.88. This is correct in the company model.

The best-case scenario value for the rate of readmissions for SoC is reported incorrectly in both the company model and the company submission. The standard deviation reported in RESCUE (North et al. 2020) is 0.5, and the base case value is 0.39. This leads to a best-case scenario value of 0.89.

The upper and lower quartiles were used as upper and lower ranges for the mean number of patients registered with a GP in a CCG, and the average number of admissions for AECOPD per 10,000 population. Whilst the company acknowledges that this is appropriate due to the data not being normally distributed, the interquartile range would be ordinarily be around the median and not the mean value. For the scenarios the upper and lower quartiles have been used by the EAC, but for the PSA an alternative method was used (see the PSA paragraph in the EAC sensitivity analysis section in section 9.2).

Table 9.7: Company best-case scenario input parameters AECOPD

Input parameters for the AECOPD model	Base case	Best
CCG population	447,464	559,000
Number of index admissions for AECOPD per 100,000	247	310
Number of index admissions in the CCG pa	1,105	1,733
Probability of having diagnosis of COPD **	0.0194	0.0246
Rate of GP appointments for myCOPD	1.85	1.46
Rate of GP appointments for SOC	2.28	2.74
Rate of readmissions for myCOPD	0.24	0.24
Rate of readmissions for SOC	0.39	0.44*
Rate of exacerbations for myCOPD	0.83*	0.83*
Rate of exacerbations for SOC	1.84*	3.72
Cost of a non-admitted exacerbation	£54	£123
Cost of a readmission	£1,583	£3,726

*Incorrectly reported
**Redundant parameter

Worst-case scenario AECOPD

The worst-case scenario used the least beneficial input values, but the company removed exacerbations and admissions as resource use outcomes. The company stated that there is no reason to consider that myCOPD should increase exacerbation frequency in the population and therefore consider the worst case to be equivalent to SOC in these outcomes. The EAC agree with this approach. The company acknowledge that there is a potential for self-management interventions to increase patient contact with primary and community services if patients become more aware of temporary deteriorations in health status or the intervention increases attention to, and anxiety about, their condition. Therefore, the company has retained GP appointments as an outcome, with an increase in resource use for the myCOPD arm of 20% and a reduction in SOC of 20%. The EAC agree with this approach.

The upper and lower quartiles were used as upper and lower ranges for the mean number of patients registered with a GP in a CCG, and the average number of admissions for AECOPD per 10,000 population. Whilst the company acknowledges that this is appropriate due to the data not being normally distributed, the interquartile range would be ordinarily be around the median and not the mean value.

There is an error in the company submission for the rate of GP appointments for SOC. This should read 1.83 (reduction in SOC by 20%) and is correct in the company model. Further to this, the EAC believe that exacerbations and admissions should remain in the analysis and be stated as equivalent to SOC

rather than 0. Although the incremental difference will remain the same, the total cost to the CCG for each arm will be better reflected this way.

Table 9.8: Company worst-case scenario input parameters AECOPD

Input parameters for the AECOPD model	Base case	Worst
CCG population	447,464	226,600
Number of index admissions for AECOPD per 100,000	247	184
Number of index admissions in the CCG pa	1,105	417
Probability of having diagnosis of COPD	0.0194	0.0164
Rate of GP appointments for myCOPD	1.85	2.22
Rate of GP appointments for SOC	2.28	1.85
Rate of readmissions for myCOPD	0.24	0
Rate of readmissions for SOC	0.39	0
Rate of exacerbations for myCOPD	0.83*	0
Rate of exacerbations for SOC	1.84*	0
Cost of a non-admitted exacerbation	£54	NA
Cost of a readmission	£1583	NA

*Incorrectly reported but correct in company model

Model 2 PR

The company presented an additional scenario for the PR model where no impact on resource use was included due to the uncertainty around PR outcomes. In this scenario costs for exacerbations are removed from the PR model to model 'no difference' in resource use outcomes for patients completing PR.

The company also presented the results of the PR costing scenario (whereby a PR service purchases the myCOPD license for use just within their PR service) as a scenario analysis.

Tornado diagram

The company presented tornado diagrams to explore the impact of varying each input parameter separately. This was used to identify parameters that were key drivers for the model outcomes. The input parameters are presented below. The ranges were taken from published literature, updated from other economic sources, or use an arbitrary value.

Model 1 AECOPD

The company did not reduce the readmission rates, as the uncertainty presented in RESCUE (North et al. 2020) would result in negative rates.

Therefore, the lower range is kept at the base case values and the standard deviation is used to determine the upper limit. The EAC does not believe that this reflects the uncertaintly in the parameter. The EAC have used the adjusted readmission rates in the base case and have varied the the relative risk by the uncertainty limit provided in RESCUE to arrive at the lower value for the myCOPD arm. The odds ratio was converted to a relative risk as described previously (in the text below Table 9.3). The upper value was limited to a relative risk of 1 due to the assumption that myCOPD would likely not lead to an increased number of readmissions when compared with SoC. The same method was used to derive the upper and lower values for the exacerbation rate for the myCOPD arm.

The cost for a hospital admission for AECOPD was only increased by the company as the base case estimate was towards the lower end of published values reported in the submission. The EAC agreed that it is a low estimate but it remains slightly higher than the lowest published cost and believe the lowest published cost should be used (Punekar et al, 2015) (Punekar et al. 2015). The company increased the training costs by doubling the staff members per practice trained to use myCOPD (from 1 to 2 staff members). Licence administration costs were doubled to reflect 2 days of staff time per year. Although arbitrary values, the EAC thought this appropriate. Based on clinical expert opinion, the EAC judged the low and high values for the time to register a patient for a myCOPD licence to be too low. Clinical opinion suggested that this could take between 15 and 45 minutes. There is also the possibility that a practice does not have a band 5 nurse (see correspondence log). Values used in the sensitivity analysis are given in Table 9.9.

Table 9.9: Input parameters for company's tornado diagram - AECOPD

Input parameter	Low	Base	High
Readmission rate, SOC	0.39	0.39	0.89
Readmission rate, myCOPD	0.24	0.24	0.68
Cost of readmission	£1,583	£1,583	£3,726
Exacerbation rate, SOC	0.04	1.88	3.72
Exacerbation rate, myCOPD	0.23	1.06	1.89
Cost of a non-admitted exacerbation	£37.55	£53.59	£123
Average number of admissions for AECOPD per 100,000	184	247	310
Number of registered patients in CCG	226,600	447,464	559,000
Time to register a patient for a myCOPD licence (hours)	0.2	0.25	0.5
Cost of training clinicians to use myCOPD for each practice in the CCG (avg 50)	£1,950	£1,950	£3,950
Cost of administering the staff licences	£360	£360	£1,080
Probability of having COPD diagnosis*	0.0164	0.0194	0.0246

*Redundant parameter. Red values = judged by the EAC not to have been varied appropriately.

The company varied all necessary parameters. Some total costs were varied instead of individual parameters. The EAC judged this to be appropriate. The ranges used by the company were judged to be mostly appropriate although in certain instances they do not appear to have been varied in both directions. These instances are highlighted in red in the above table.

The company conducted threshold analysis on the 90-day rate of readmissions in the myCOPD arm to see where the base case model changes from cost saving to cost-neutral/cost-incurring.

Model 2 PR

Two tornado diagrams were presented for the PR model, 1 for each of the costing scenarios presented. The input parameters varied, and their ranges are shown in Table 9.10.

Table 9.10: Input parameters for company's tornado diagram – PR model

Input parameter	Low	Base	High
Probability of referral myCOPD:SoC	0.9	1	1.5
Probability of being treated with myCOPD only	5%	11%	50%
Probability of being treated with hybrid model	5%	11%	50%
Probability of referral to PR by GP (SoC)	13%	20%	43%
Cost per face-to-face PR treatment	£418	£695	£837
Probability of starting and completing PR – F2F	33.5%	42%	50.3%
Time taken for first and last assessment (minutes)	30	60	90
Time for a clinician to register a patient for a myCOPD license (hours)	CCG:0	0.25	0.5
	PR: 0	0.25	0.25
Cost of a band 6 community physiotherapist	£39	£49	£58
Cost of a band 4 community nursing staff	£24	£30	£36
Cost of treating each exacerbation in hospital	£1,583	£1,583	£3,726
Annual number of exacerbations for patients who have not received PR	2.64	3.31	3.97
Annual number of exacerbations for patients who have received PR	1.64	2.11	2.52
Cost of administering licenses for the CCG	CCG: £0	£0	£360
	PR: £0	£360	£360
Probability of each exacerbation being treated in hospital	12%	15%	18%
Cost of a non-admitted exacerbation	£38	£54	£123
Time waiting for first assessment	CCG:0	0	229
	PR: 51	0	229
Mean number of patients registered in QOF for CCGs (CCG model only)	226,600	447,464	559,000
Probability of MRC>3 given diagnosis of COPD (CCG model only)	20%	29.7%	40%
Probability of having diagnosis of COPD from general population (CCG model only)	1.6%	1.94%	2.5%
Median patients in PR service (PR costing scenario only)	270	495	718

Red values = judged by the EAC not to have been varied appropriately.

The company did not vary all of the parameters. For example, waiting time following first assessment, support required for myCOPD patients, and cost of training in the PR model do not appear in the tornado diagrams. The ranges used by the company were judged to be mostly appropriate although in certain instances they do not appear to have been varied in both directions. These instances are highlighted in red in the above table.

A threshold analysis around the number of patients in a PR service was also conducted by the company which was judged to be useful given myCOPD may not be cost saving for smaller services with fewer referrals.

EAC analysis

The EAC conducted deterministic and probabilistic sensitivity analysis as well as an updated best and worst scenario for the AECOPD model. The EAC also conducted deterministic sensitivity analysis in the form of a tornado diagram, and threshold analysis for the key drivers of the model results in both models.

Model 1 AECOPD

Best-case scenario

In the best-case scenario, the EAC included a scenario whereby the benefits of myCOPD continue for the 9 months following the 3 months of benefits seen in the clinical trial. The same relative decrease in GP appointments, exacerbations and readmissions were used for myCOPD that are seen in the trials. For SOC, the number of GP appointments stayed the same for the subsequent 9 months compared with the first three months. This was due to the study (McLaughlin and Skinner 2020) including a broad population of people with COPD, rather than just being discharged from hospital (McLaughlin and Skinner 2020).

In the RESCUE study, the number of exacerbations in the year before hospitalisation were recorded. This was 3.1. The EAC assumed a linear distribution and scaled this down to estimate the number of exacerbations in 9 months (2.33). This number was used in the SoC arm for the exacerbation rate. Readmissions before hospitalisation were not recorded and so the EAC assumed the same readmission rate for the subsequent 9 months (there were 7 readmissions in 3 months in the SOC arm). This was multiplied by 3 to estimate the number of readmissions in 9 months (21). Twenty-one divided by the number of patients in the SoC (18) gives a mean rate of 1.17 exacerbations per person in the subsequent 9 months. In the best-case scenario, these values were multiplied by the base case relative risk seen in the RESCUE trial, rather than the lowest CI, to be plausible.

The SoC values for readmission and exacerbation rate stayed the same as the base case due to the relative risk of readmissions and exacerbations being varied. This is to to avoid over-adjusting values and to present a plausible scenario.

The values used for the best scenario are presented in Table 9.11 for the AECOPD model.

Table 9.11: EAC best-case scenario input parameters Model 1 AECOPD

Input parameters	Base case	Best	Source
CCG population	447,464	559,000	QoF (National Health Service 2020)
Number of index admissions for AECOPD per 100,000	247	310	PHE INHALE (Public Health England 2019)
Uptake rate of myCOPD	46%	65%	Proportion of people aged 65+ who use a smartphone (Statista 2021)
Rate of GP appointments for myCOPD (first 90 days)	1.85	1.48	Assumption (-20%)
Rate of GP appointments for SOC (first 90 days)	2.28	2.74	Assumption (+20%)
Rate of readmissions for myCOPD (first 90 days)	0.20	0.05*	Based on the lower CI of the odds ratio from RESCUE* (North et al. 2020)
Rate of readmissions for SOC (first 90 days)	0.39	0.39	RESCUE (North et al. 2020)
Rate of exacerbations for myCOPD (first 90 days)	1.09	0.59**	Based on the lower CI of the rate ratio from RESCUE** (North et al. 2020)
Rate of exacerbations for SOC (first 90 days)	1.88	1.88	RESCUE (North et al. 2020)
Rate of GP appointments for myCOPD (subsequent 9 months)	N/A	5.56	Assumed same trend from McLaughlin and Skinner (McLaughlin and Skinner 2020)
Rate of GP appointments for SOC (subsequent 9 months)	N/A	6.85	Assumed same trend from McLaughlin and Skinner (McLaughlin and Skinner 2020)
Rate of readmissions for myCOPD (subsequent 9 months)	N/A	0.59	Assumed same trend from RESCUE (North et al. 2020)
Rate of readmissions for SOC (subsequent 9 months)	N/A	1.17	Assumed same trend from RESCUE (North et al. 2020)
Rate of exacerbations for myCOPD (subsequent 9 months)	N/A	1.35	Assumed same trend from RESCUE (North et al. 2020)
Rate of exacerbations for SOC (subsequent 9 months)	N/A	2.33	Derived from exacerbation rate 1 year before hospitalisation (North et al. 2020)
Cost of a non-admitted exacerbation	£82	£126	Value in Jordan et al. (Jordan et al. 2015) (£114.28) inflated from 2012 to 2019/20 prices using PSSRU inflation indices (Curtis and Burns 2020).
Cost of a readmission	£1,721	£3,726	Value based on the cost of a severe exacerbation reported in McLean et al. (McLean et al. 2016) (based on HRG code long stays only with proportions defined by expert opinion)

* The lower confidence interval of the odds ratio for readmission in RESCUE is 0.07. This was converted to a relative risk of 0.12 and applied to the base-case readmission rate in the SoC arm of 0.39.
**The lower confidence interval of the rate ratio in RESCUE for exacerbations is 0.315. This was applied to the base-case exacerbation rate in the SoC arm of 1.88.

The EAC updated the best-case cost of a non-admitted exacerbation from £123 to £126. The company had this value as £123. The same method was used and so it was unclear why there is a small discrepancy between the company and EAC value.

Worst-case scenario

The EAC replicated the company's worst case scenario but included the rate of admissions and exacerbations to be equal in both arms as the EAC agree with the company that it is unlikely that myCOPD would increase exacerbations or readmissions. The EAC also included uptake of myCOPD in the scenario. For the worst-case scenario value, the EAC have used a value of 12% (equal to the PR uptake value used in the PR model) due to no other data being available. One expert gave an uptake value based on patient contact rather than unique patients (approximately 4% - see correspondence log). However, each patient could have been contacted several times, which would lead to this figure being inaccurate for use in this model.

Table 9.12: EAC worst-case scenario input parameters Model 1 AECOPD

Input parameters for the AECOPD model	Base case	Worst	Source
CCG population	447,464	226,600	QoF (National Health Service 2020)
Number of index admissions for AECOPD per 100,000	247	184	PHE INHALE (Public Health England 2019)
Uptake rate of myCOPD	46%	12%	Assumption based on the uptake of PR. The EAC has used this value as no data exists.
Rate of GP appointments for myCOPD	1.85	2.22	Assumption (+20%)
Rate of GP appointments for SOC	2.28	1.85	Assumption (-20%)
Rate of readmissions for myCOPD	0.20	0.39	Assumption that myCOPD would not lead to worse admission rates than SOC (North et al. 2020)
Rate of readmissions for SOC	0.39	0.39	Assumption that myCOPD would not lead to worse admission rates than SOC (North et al. 2020)
Rate of exacerbations for myCOPD	1.09	1.88	Assumption that myCOPD would not lead to worse admission rates than SOC (North et al. 2020)
Rate of exacerbations for SOC	1.88	1.88	Assumption that myCOPD would not lead to worse admission rates than SOC (North et al. 2020)

Input parameters for the AECOPD model	Base case	Worst	Source
Cost of a non-admitted exacerbation	£82	£82	Derived from Jordan et al. (Jordan et al. 2015)
Cost of a readmission	£1,721	£1,721	Derived from COPD Prime (Chartered Society of Physiotherapy 2017)

Scenario with continued benefit of myCOPD

Whilst included within the best-case scenario, the EAC conducted a scenario which included all the base case values with the continued benefit of myCOPD (parameters as described in the relevant rows of Table 9.11).

Tornado and threshold analyses

The EAC conducted deterministic sensitivity analysis. The high and low parameters are shown in Table 9.13. Uptake of myCOPD was added to the analyses (base case value 46%, low value 12%, high value 65%).

The EAC then conducted threshold analysis on the uptake rate and readmission rates to see at what uptake rate myCOPD becomes cost-incurring.

PSA

The appropriate distribution was selected for each of the parameters in the PSA. This was a gamma distribution for any costs, and a beta distribution for any binomial probabilities. The PSA distributions and uncertainty are presented in Table 9.13. DSA totals were varied where possible to reflect the overall uncertainty across individual parameters when they are being combined, but for PSA individual parameters were varied so as to make use of measures of error reported where possible.

Table 9.13: EAC ranges used for deterministic and probabilistic sensitivity analysis inputs – Model 1 AECOPD

Parameter	Base case value	Low value (DSA)	High value (DSA)	EAC comments	PSA distribution	Standard Error (for PSA)
CCG population	447,464	226,600	559,000	Low and high values for DSA based on IQR for the parameter in QOF (National Health Service 2020)	Gamma	0.06 (SE of the natural log of 447,464 to create a normal distribution). The PSA was conducted on the log scale and back transformed to produce the PSA value.
Number of index admissions for AECOPD per 100,000	247	184	310	Low and high values for DSA based on IQR for the parameter in PHE INHALE (Public Health England 2019)	Gamma	0.03 (SE of the natural log of 247 to create a normal distribution). The PSA was conducted on the log scale and back transformed to produce the PSA value.
Uptake rate of myCOPD	46%	12%	65%	Low value is an assumption based on the PR uptake (no other data available). Upper value is based on the proportion of people aged 65+ who use a smartphone (Statista 2021)	Beta	No SE. Alpha = 57 (number of people using myCOPD). Beta = 67 (number of people declining myCOPD). RESCUE trial
Rate of exacerbations for myCOPD	1.09	0.59	1.88	Derived from lower CI for adjusted arm difference from RESCUE study (North et al. 2020). Upper limit assumed to not go higher than SoC	Gamma	SE = 0.20 (calculated from RESCUE trial. SD = 0.83, n = 17). Assumed same SD as unadjusted risk.
Rate of GP appointments for myCOPD	1.85	1.48	2.22	High and low values - assumption = 20% of the mean	Gamma	SE = 0.37 (assumption = 20% of the mean)
Rate of readmissions for myCOPD	0.20	0.05	0.39	Derived from lower CI for adjusted arm difference from RESCUE study (North et al. 2020). Upper limit assumed to not go higher than SoC	Gamma	SE = 0.11 (calculated from RESCUE trial. SD = 0.44, n = 17). Assumed same SD as unadjusted risk.

Parameter	Base case value	Low value (DSA)	High value (DSA)	EAC comments	PSA distribution	Standard Error (for PSA)
Rate of exacerbations for SOC	1.88	0.04	3.72	High and low value based on SD from RESCUE study (North et al. 2020)	Gamma	SE = 0.43 (calculated from RESCUE trial. SD = 1.84, n = 18)
Rate of GP appointments for SOC	2.28	1.82	2.74	Low and high values (assumption = 20% of the mean)	Gamma	SE = 0.46 (assumption = 20% of the mean)
Rate of readmissions for SOC	0.39	0.31	0.89	High value based on SD from RESCUE study. Low value = 20% of the mean (North et al. 2020)	Gamma	SE = 0.12 (calculated from RESCUE trial. SD = 0.50, n = 18)
Cost of a non-admitted exacerbation	£82	£41.65	£126	Low value based on 100% treated in primary care (0% non-admitted emergency care) – derived from Jordan et al. (Jordan et al. 2015) High value – value in Jordan et al. (£114.28) (Jordan et al. 2015) inflated from 2012 to 2019/20 prices using PSSRU inflation indices (Curtis and Burns 2020).	Gamma	SE = £16.35 (assumption = 20% of the mean)
Cost of a readmission	£1721	£1,626	£3,726	Low value is the lowest value found in published evidence (Punekar et al. 2015) inflated to 2019/20 costs using the PSSRU inflation index (Curtis and Burns 2020). High value based on the cost of a severe exacerbation reported in McLean et al. (McLean et al. 2016) (based on HRG code long stays only with proportions defined by expert opinion)	Gamma	SE = £344.18 (assumption = 20% of the mean)
Cost to register a patient	£19.50	£7.50	£36.75	Low and high values (assumption = 20% of the mean value): based on 15 minutes (band 4 nurse) to register a patient. High value: based on 45 minutes (band 6 nurse) to register a patient	Not in PSA (varied individual parameters for PSA – see below)	NA

Parameter	Base case value	Low value (DSA)	High value (DSA)	EAC comments	PSA distribution	Standard Error (for PSA)
Cost of training a clinician of each CCG (50 practices)	£1,950	£1,560	£3,950	Lower value reduced by 20% (assumption based on a reduction of practices in a CCG from 50 to 40) Upper value: Training costs were increased by requiring that 2 staff members per practice were trained to use myCOPD (based on 50 practices)	Not in PSA (varied individual parameters for PSA – see below)	NA
Cost of administering staff licences	£360	£180	£1,080	Lower value based on half a day a year. Upper value based on 2 days per year for a practice manager to administer licences	Not in PSA (varied individual parameters for PSA – see below)	NA
Cost of practice nurse	£39	Not in DSA (varied cost as a whole)	Not in DSA (varied cost as a whole)	DSA totals were varied where possible to reflect the overall uncertainty across individual parameters	Gamma	£3.90 (assumption = 10% of the mean)
Cost of GP appointment	£39	Not in DSA (varied cost as a whole)	Not in DSA (varied cost as a whole)	DSA totals were varied where possible to reflect the overall uncertainty across individual parameters	Gamma	£3.90 (assumption = 10% of the mean)
Cost of practice manager	£48	Not in DSA (varied cost as a whole)	Not in DSA (varied cost as a whole)	DSA totals were varied where possible to reflect the overall uncertainty across individual parameters	Gamma	£4.80 (assumption = 10% of the mean)
Hours a year to set up licences	7.5	Not in DSA (varied cost as a whole)	Not in DSA (varied cost as a whole)	DSA totals were varied where possible to reflect the overall uncertainty across individual parameters	Gamma	0.75 (assumption = 10% of the mean)

Parameter	Base case value	Low value (DSA)	High value (DSA)	EAC comments	PSA distribution	Standard Error (for PSA)
Number of practices per CCG	50	Not in DSA (varied cost as a whole)	Not in DSA (varied cost as a whole)	DSA totals were varied where possible to reflect the overall uncertainty across individual parameters	Gamma	5.00 (assumption = 10% of the mean)
Time for a clinician to register a patient	0.5	Not in DSA (varied cost as a whole)	Not in DSA (varied cost as a whole)	DSA totals were varied where possible to reflect the overall uncertainty across individual parameters	Gamma	0.38 (assumption = 50% of the mean)

Model 2 PR

Scenario analyses

The EAC presents the PR costing scenario as an alternative base case and therefore these results are presented in section 9.3.

Removing the benefit of exacerbations has very little impact on the incremental difference between the two treatment arms due to the assumption of non-inferiority used in the model. The key cost differences occur in the model because of the difference in costs of delivering the PR service.

Tornado and threshold analyses

The EAC conducted deterministic sensitivity analysis. High and low values remained the same as that seen in the company model in some cases but where the EAC deemed that they had not been varied with a sufficiently wide interval to reflect uncertainty in the parameter this was updated. Values used by the EAC are shown in Table 9.14.

The EAC conducted threshold analysis on key drivers in the PR costing scenario. It was not deemed necessary to conduct them where the CCG had already funded myCOPD because it is not possible for plausible changes in individual parameters to change the direction of the results (due to myCOPD not costing anything additional other than the cost of registering patients).

A two-way sensitivity analysis was also conducted around the probability of being treated with myCOPD or the hybrid approach (i.e. uptake of myCOPD) due to this being 1 of the key uncertainties.

PSA

The appropriate distribution was selected for each of the parameters in the PSA. A gamma distribution was used for any costs as well as waiting time for face-to-face PR, and a beta distribution for any binomial probabilities.

Table 9.14: EAC ranges used for deterministic and probabilistic sensitivity analysis – Model 2 PR

Input parameter	Low	Base	High	EAC comments	PSA distribution	Standard error
Probability of being treated with myCOPD only	3%	12%	50%	Low value updated based on including only those who used myCOPD in Southend study	Beta	Alpha 69, Beta 495 (Southend study)
Probability of being treated with hybrid model	3%	12%	50%		Beta	Alpha 69, Beta 495 (Southend study)
Probability of referral to PR by GP (SoC)	13%	20%	43%	As per company submission	Beta	Alpha 71,247, Beta 277,384 (National Health Service 2020)
Cost per face-to-face PR treatment	£418	£695	£1,050	High value updated based on range reported by (Chakravorty et al. 2011)	Gamma	SE £69.53 (assumed 10% of mean)
Cost of band 5 staff nurse	NA	£39	NA	Not varied by EAC – total costs varied	Gamma	SE £3.90 (assumed 10% of mean)
Number of staff trained in a PR service (PR service costing scenario only)	NA	5	NA	Not varied by EAC – total costs varied	Gamma	SE 2.5 (assumed 50% of mean)
Cost of training for PR service (PR service costing scenario only)	£117	£195	£980	Not varied by company. Plausible range based on between 3 and 10 staff needing to be trained. For high value staff assumed to need 2 hours training and all band 6 based on expert input (see correspondence log).	Not varied in PSA. Number of staff trained and cost of staff individually varied	NA
Probability of starting and completing PR – F2F	33.5%	42%	50.3%	As per company submission	Beta	Alpha 28560, Beta 68000 (COPD Prime) (Chartered Society of Physiotherapy 2017)
Probability of starting and completing PR – Hybrid	33.5%	42%	50.3%	Not varied by the company. EAC varied as per face-to-face PR.	Beta	Alpha 42, Beta 58 (assumed)
Probability of starting and completing PR – myCOPD	33.5%	42%	50.3%		Beta	Alpha 42, Beta 58 (assumed)

Cost of band 4 community nursing staff	NA	£30	NA	Not varied by EAC – total costs varied	Gamma	SE £3.00 (assumed 10% of mean)
Cost of band 6 community physiotherapist	NA	£49	NA	Not varied by EAC – total costs varied	Gamma	SE £4.90 (assumed 10% of mean)
Time taken per phone call for myCOPD support (minutes)	NA	10	NA	Not varied by EAC – total costs varied	Gamma	SE 1.0 (assumed 10% of mean)
Cost of myCOPD support for those on myCOPD only PR	£13	£15	£40	Not varied by the company. Plausible range based on 1 x 10-minute phone call and 4 x 15-minute phone calls	Not varied in PSA – individual parameters varied	NA
Time taken for first and last assessment (minutes)	NA	60	NA	Not varied by EAC - varied as part of cost of assessment to capture uncertainty in time and staff band	Gamma	SE 6 (assumed 10% of mean)
Cost of PR assessment	£30	£79	£147	Time varied between 30 and 90 minutes. Staff varied between conducted by band 4 and conducted by band 6	Not varied in PSA – individual parameters varied	NA
Time for a clinician to register a patient for a myCOPD license (hours)	NA	0.5	NA	Not varied by EAC. Varied as part of cost of registering a patient for myCOPD license to allow for variation in time and staff member	Gamma	SE 0.13 (assumed 50% of mean)
Cost of registering a patient for myCOPD license	£7.50	£9.75	£36.75	Varied between 0.25 and 0.75 time taken to register and band 4 and 6 staff based on expert opinion (see correspondence log)	Not varied in PSA – individual parameters varied	NA
Cost of treating each exacerbation in hospital	NA	£1,721	NA	Not varied by EAC. Varied as part of overall cost per exacerbation to allow to variation in cost of	Gamma	SE £172.09 (assumed 10% of mean)

Probability of each exacerbation being treated in hospital	NA	15%	NA	treatment of exacerbations and proportion of patients managed in hospital	Beta	Alpha 15, Beta 85 (assumed)
Cost of a non-admitted exacerbation	NA	£82	NA		Gamma	SE £8.18 (assumed 10% of mean)
Total cost per exacerbation	£100	£328	£500	Hypothetical range chosen. Not varied by company who varied each element seperately	Not varied in PSA – individual parameters varied	NA
Annual number of exacerbations for patients who have not received PR	1.30	3.31	7.82	Wider range updated by EAC based on ranges reported by (van Ranst et al. 2014) (note study conducted in Netherlands)	Gamma	SE 0.7 (assumed 20% of mean)
RR of annual exacerbation following completed PR course	0.6	0.64	0.8		Lognormal	SE 0.15 (assumed confidence interval of between 0.5 and 0.9)
Annual number of exacerbations for patients who have received PR	1.64	2.11	2.52	Varied by EAC using RR of annual exacerbations after completion of PR	Not varied in PSA – individual parameters varied	NA
Total cost of starting and not finishing PR – F2F	£0	£23	£52	Input not included by the company. Plausible range based on 2 sessions attended before drop out	Not varied in PSA – individual parameters varied	NA
Total cost of starting and not finishing PR – Hybrid	£0	£11	£26	Input not included by the company. Plausible range based on half the cost of face-to-face PR	Not varied in PSA – individual parameters varied	NA
Total cost of starting and not finishing PR – myCOPD alone	£0	£1	£4	Input not included by the company. Plausible range based on 2 phone calls before drop out	Not varied in PSA – individual parameters varied	NA
Proportion starting and not finishing PR (F2F, hybrid or myCOPD)	NA	29%	NA	Not varied by EAC. Total cost of starting and not finishing PR varied	Beta	Alpha 29, Beta 71 (assumed)
Cost of administering licenses for the CCG (PR service costing scenario only)	£156	£360	£720	Wider range adopted by EAC to reflect a plausible range of time taken to administer being varied between 0.5 and 2 days	Gamma	SE £36 (assumed 10% of mean)

Time waiting for first assessment	Not varied by EAC – not deemed key parameter as waiting time for first assessment assumed to be equal between all methods of PR treatment					
Cost of waiting for PR – face-to-face	£17	£39	£100	Not varied by company. Range based on plausible range between waiting time of 7 to 28 days	Not varied in PSA – individual parameters varied	NA
Waiting time for PR after assessment (days)	NA	13	NA	Not varied by EAC. Varied as part of total cost of waiting for PR	Gamma	SE 6.5 (assumed 50% of mean)
Mean number of patients registered in QOF for CCGs (CCG model only)	226,600	447,464	559,000	Varied as per company submission.	Gamma	SE 0.06 (SE of the natural log of 447,464 to create a normal distribution). The PSA was conducted on the log scale and back transformed to produce the PSA value.
Probability of having diagnosis of COPD from general population (CCG model only)	1.6%	1.94%	2.5%	Varied as per company submission.	Beta	Alpha 1171789, Beta 59236899 (National Health Service 2020)
Probability of MRC>3 given diagnosis of COPD (CCG model only)	20%	29.7%	40%	Varied as per company submission.	Beta	Alpha 347631, Beta 823155 (National Health Service 2020)
Median patients in PR service (PR costing scenario only)	270	495	718	Varied as per company submission.	Not varied in PSA by EAC. Judged to be subject to variability rather than uncertainty	

9.3 *Results from the economic modelling*

The following results are presented in this section:

- base case results for AECOPD model
- base care results for PR model (per CCG and per service provider)
- sensitvity analysis:
    - determinstic – tornado diagram and threshold analysis
    - probabilistic
    - scenario analyses – best case, worst case, extrapolation of clncial benefit (AECOPD model only)
- impact of individual changes on company results after EAC updates
- base case results presented per person (rather than per CCG/service provider).

Base case results

The company and EAC base case results (per CCG) are presented in Table 9.15 for Model 1 AECOPD and for Table 9.16 and 9.17 for Model 2 PR.

The EAC notes that the licence cost for myCOPD is based on everyone in a CCG, and it is possible that people other than those in the population modelled could benefit from myCOPD. Any potential additional benefits would be incurred with only the additional cost of registering a patient for myCOPD (at £19.50 per patient).

Changes made by the EAC to the AECOPD model have resulted in a reduced cost saving from £204,641 to £86,297 per CCG. The differences between the company results and the EAC results are the registration cost of myCOPD and the resource use costs (exacerbations, readmissions and GP appointments). This is mainly influenced by the EAC including myCOPD uptake to the model. This leads to reduced registration costs and total resource use costs as there are fewer people are running through the model. However, the difference between the arms decrease as the uptake decreases (for example, if the cohort halves, the total cost of each arm halves, with the absolute difference being bigger in the arm where the total costs were higher).

Table 9.15: Summary of base case results for Model 1 AECOPD – per CCG

	Company's results			EAC results		
	myCOPD	**SoC**	**Incremental cost per CCG**	**myCOPD**	**SoC**	**Incremental cost per CCG**
myCOPD contract costs	£111,866	£0	£111,866	£111,866	£0	£111,866
myCOPD registration costs	£10,774	£0	£10,774	£9,914	£0	£4,957
myCOPD training costs	£1,950	£0	£1,950	£1,950	£0	£1,950
myCOPD administration	£360	£0	£360	£360	£0	£360
GP appointments	£79,742	£98,278	-£18,535	£36,682	£45,208	-£8,526
Exacerbations	£62,783	£111,352	-£48,568	£45,399	£78,140	-£32,741
Readmissions	£419,984	£682,473	-£262,490	£172,100	£341,221	-£169,121
Total	**£687,462**	**£892,102**	**-£204,641**	**£378,271**	**£464,568**	**-£86,297**

Changes made by the EAC to the PR model have resulted in an increased cost saving from £20,269 to £22,779 per CCG, or £8,707 to £11,093 per PR service provider if considering the PR costing scenario. The differences between the company results and the EAC results are the decision point used which impacts on the number of patients entering the model as well as the treatments being modelled. This mainly impacts on the magnitude of costs in each arm rather than the incremental difference. Other changes include some minor changes to the inputs and changes to the costs/resources associated with referral to PR, and those who start but do not finish their PR programme

Table 9.16: Summary of base case results for Model 2 PR – per CCG (results are not standalone)

	Company's results			EAC results		
	myCOPD	**SoC**	**Incremental cost per CCG**	**myCOPD**	**SoC**	**Incremental cost per CCG**
Licence and registration of myCOPD	£1,117	£0	£1,117	£2,485	£0	£2,485
myCOPD support/face-to-face assessments	£4,228	£0	£4,228	£10,553	£5,851	£4,703
Face-to-face assessments	£126,672	£151,703	-£25,031	£9,280	£37,119	-£27,839
Starting and not completing PR	£23,912	£23,912	£0	£546	£1,923	-£1,377
Exacerbations	£2,343,048	£2,343,631	-£583	£117,176	£117,926	-£751
Total	**£2,498,978**	**£2,519,246**	**-£20,269**	**£140,040**	**£162,819**	**-£22,779**

Table 9.17: Summary of base case results for Model 2 PR service costing scenario - per PR service provider (standalone results)

	Company's results			EAC results		
	myCOPD	**SoC**	**Incremental cost per PR service provider**	**myCOPD**	**SoC**	**Incremental cost per PR service provider**
Licence and registration of myCOPD	£11,617	£0	£11,617	£12,917	£0	£12,917
myCOPD support/face-to-face assessments	£26,742	£22,724	£4,018	£10,029	£5,560	£4,469
Face-to-face assessments	£120,379	£144,166	-£23,787	£8,819	£35,275	-£26,456
Starting and not completing PR	£0	£0	£0	£519	£1,828	-£1,309
Exacerbations	£395,142	£395,696	-£554	£111,354	£112,068	-£713
Total	**£553,879**	**£562,586**	**-£8,707**	**£142,456**	**£154,730**	**-£11,093**

Sensitivity analysis results

Model 1 AECOPD

Company sensitivity analysis results

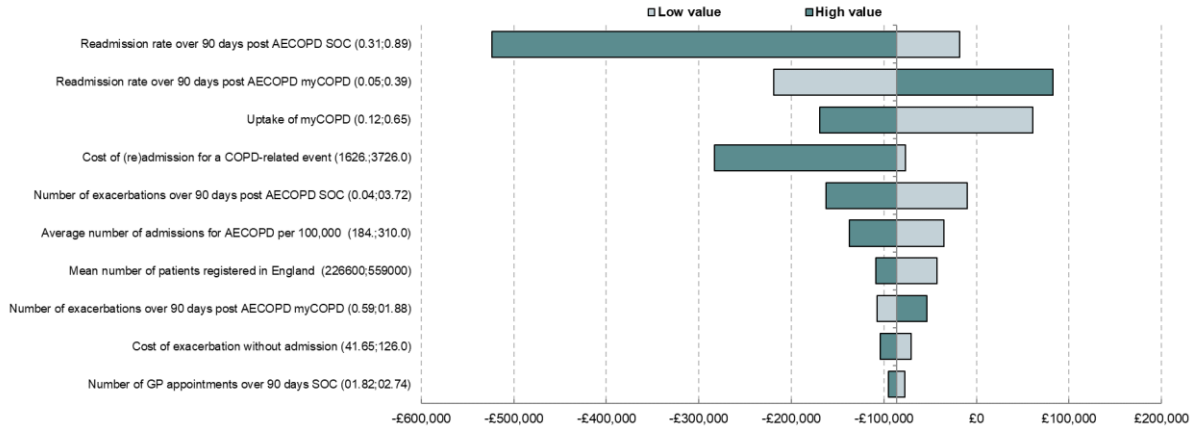
The company presented results for each of the scenarios described in section 9.2. The estimated results ranged from an £1,785,878 cost saving per CCG (best-case scenario) to £69,530 cost incurring per CCG (worst case scenario). The company identified the key driver from the sensitivity analysis as the readmission rate over 90 days post AECOPD, for both the intervention and comparator arm. The 90-day rate of readmissions in the myCOPD arm at which the base case model changed from cost saving to cost-neutral/cost-incurring was 0.357. The company did not conduct any probabilistic sensitivity analysis.

EAC sensitivity analysis results

In the EAC's updated model, the best-case scenario and worst-case scenario results ranged from £4,143,428 cost saving per CCG (best-case scenario) to £58,928 cost incurring per CCG (worst-case scenario). The scenario where only the myCOPD benefits were extended (and all other inputs remained the same) led to a cost saving of £658,312 per CCG.

The EAC also identified the key driver from the sensitivity analysis as the readmission rate. The uptake rate and number of non-hospitalised exacerbations both led to situations where myCOPD could be cost-incurring. The deterministic sensitivity analysis results for the AECOPD model are presented in a tornado diagram below. Parameters varied and ranges used are described fully in section 9.2. A tornado diagram is presented in Figure 9.4.

Figure 9.4: Tornado diagram Model 1 AECOPD



The rates at which the parameters in the myCOPD arm changed from cost saving to cost-neutral/incurring are presented in Table 9.18.

Table 9.18: Threshold analysis Model 1 AECOPD

Input parameter	Base case value	Threshold value*	EAC comments
90-day rate of readmissions in the myCOPD arm	0.20	0.30	The EAC judges that this is a plausible value. It is below the readmission rate of the SOC arm.
Uptake rate of myCOPD	46%	26.2%	The EAC is aware of the uncertainty of this value and so judges this a plausible value that could reflect real-world practice

*Value needed to make results cost neutral

The EAC conducted PSA as described in section 9.2 The model was run for 5,000 iterations and resulted in an average cost decrease per CCG of £86,059. The estimated probability that the intervention is cost saving is 73.5%.

Model 2 PR

Company sensitivity analysis results

The estimated results from the company ranged from an £8,707 cost saving per CCG (PR service contract scenario) to a £19,685 cost saving per CCG (scenario excluding costs for exacerbation).

The company presented a tornado diagram for the PR model which showed the key drivers for the CCG costing model to be:

- changes in the number of referrals with myCOPD
- proportion of patients who are treated with myCOPD
- proportion of patients referred to PR.

The only parameter identified by the company with the ability to change the direction of the results was the change in the number of referrals with myCOPD. The company justified keeping the number of referrals equal between treatment arms in the base case because the model was designed to assess myCOPD in comparison to face-to-face PR and not face-to-face PR vs no PR. The EAC deemed this to be a fair justification because face-to-face PR has already been established as standard practice in the UK for these patients. Further, increasing capacity of PR services may just lead to a reduction in waiting times for PR programmes rather than increased capacity which would increase cost savings with myCOPD. Increasing capacity should in theory be cost-effective because patients who undergo PR programmes demonstrate reduced exacerbations alongside other benefits which may not be fully captured by the either the company model or the EAC model. Face-to-face PR vs no PR has previously been shown to be cost-effective.

The key drivers identified by the company for the PR service costing scenario were the probability of being treated with myCOPD only and with a hybrid model, the cost per face-to-face PR treatment, and the number of patients referred to a PR service.

The company also presented a threshold analysis for the number of patients referred to PR and identified that myCOPD was likely to be cost saving as long as around 276 referrals were made per year.

EAC sensitivity analysis results

In the EAC's updated model the scenario result where no impact on resource use was included resulted in a cost saving of £22,029 per CCG and £10,379 per PR service when considering the PR service costing scenario.

The EAC identified the key drivers from the sensitivity analysis for the CCG base case model as:

- probability of being treated with myCOPD only and with the hybrid model
- probability of referral to PR
- cost of face-to-face PR.

In the PR service costing scenario, the key drivers were those listed above but with median patients referred to a PR service rather than probability of referral to PR.

In the CCG model it is not possible for the results to become cost incurring unless the cost of registering a patient on the myCOPD app becomes so expensive it outweighs all of the other cost benefits. This is because the CCG is assumed to have already purchased myCOPD in this model.

In the PR service costing scenario none of the parameters varied individually changed the direction of the results and therefore the results appear robust to changes in individual input parameters.

The deterministic sensitivity analysis results for the PR model is presented in Figures 9.5 and 9.6 with the top 10 drivers displayed. Parameters varied and ranges used are described fully in section 9.2, Sensitivity analysis.

Figure 9.5: Tornado diagram for Model 2 PR per CCG with no licence cost

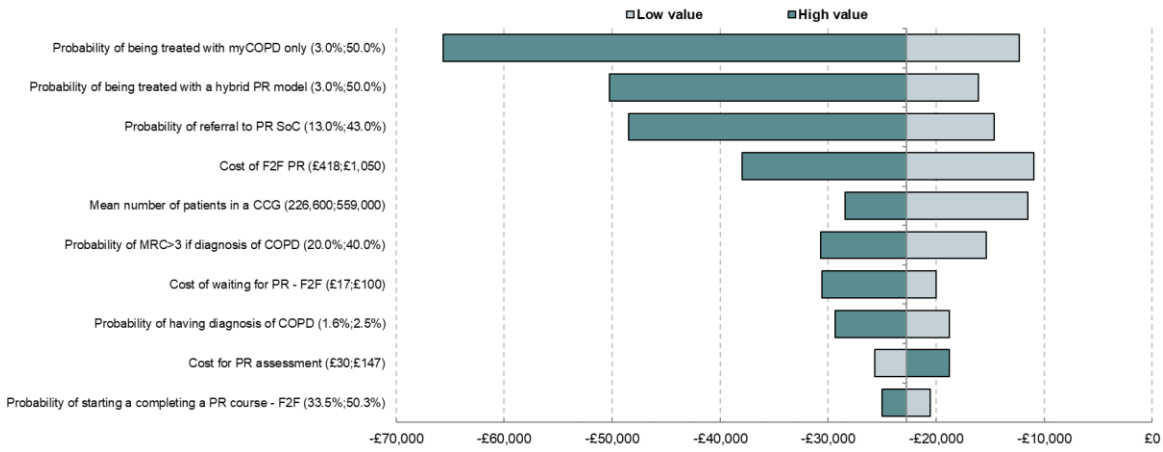
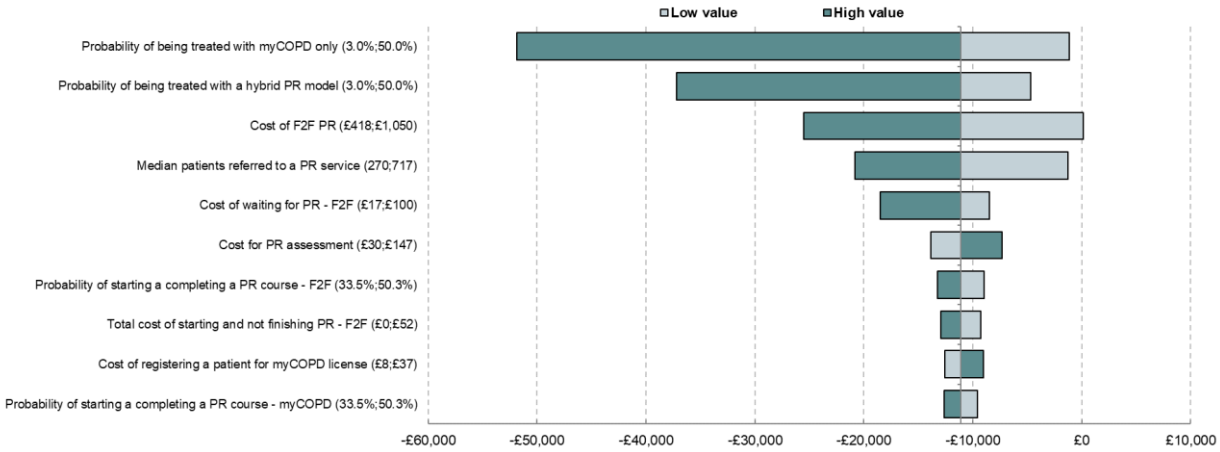


Figure 9.6: Tornado diagram for Model 2 PR per PR service provider – PR service costing scenario



The EAC also conducted threshold analysis around key parameters in the PR costing model, the results of which are shown in Table 9.19.

Table 9.19: Threshold analysis for Model 2 PR (per CCG)

Input parameter	Base case value	Threshold value*	EAC comments
Probability of being treated with myCOPD	12.2%	1.9% when hybrid model uptake is 12.2% Or 9.8% if hybrid model uptake is assumed 0%	If a hybrid model is not being used, uptake of myCOPD needs to be higher to demonstrate a cost saving. There is still a paucity of data around uptake in real world settings in the appropriate setting.
Probability of being treated with hybrid model	12.2%	NA, still cost saving at 0% when myCOPD alone uptake is 12.2% Or 15.2% if myCOPD alone uptake is assumed 0%	If use of myCOPD alone is not accepted, acceptance of the hybrid model needs to be higher in the model to demonstrate cost savings. A two-way sensitivity analysis on uptake is provided below.
Number of patients referred to PR service	495	240	myCOPD may not be cost saving in PR services with fewer than 240 referrals per year.

*Value needed to make results cost neutral or cost incurring

The results of the two-way sensitivity analysis around the uptake of myCOPD for PR is shown in Figure 9.7.

Figure 9.7: Two-way sensitivity analysis – uptake of myCOPD (Model 2 PR service costing scenario)

		Uptake Hybrid								
	-£11,092.54	0.0%	2.0%	4.0%	6.0%	8.0%	10.0%	12.0%	14.0%	16.0%
Uptake myCOPD only	0.0%		£9,173	£7,792	£6,410	£5,029	£3,647	£2,265	£884	-£498
	2.0%	£8,398	£7,016	£5,634	£4,253	£2,871	£1,490	£108	-£1,274	-£2,655
	4.0%	£6,240	£4,859	£3,477	£2,096	£714	-£668	-£2,049	-£3,431	-£4,813
	6.0%	£4,083	£2,702	£1,320	-£62	-£1,443	-£2,825	-£4,207	-£5,588	-£6,970
	8.0%	£1,926	£544	-£837	-£2,219	-£3,601	-£4,982	-£6,364	-£7,745	-£9,127
	10.0%	-£231	-£1,613	-£2,995	-£4,376	-£5,758	-£7,140	-£8,521	-£9,903	-£11,284
	12.0%	-£2,389	-£3,770	-£5,152	-£6,534	-£7,915	-£9,297	-£10,678	-£12,060	-£13,442
	14.0%	-£4,546	-£5,928	-£7,309	-£8,691	-£10,072	-£11,454	-£12,836	-£14,217	-£15,599
	16.0%	-£6,703	-£8,085	-£9,467	-£10,848	-£12,230	-£13,611	-£14,993	-£16,375	-£17,756

Provided that uptake of hybrid myCOPD remains over 16% it is expected that introducing myCOPD into PR delivery is likely to result in cost savings regardless of the uptake of myCOPD alone. Uptake of the hybrid approach can drop down to 0% if uptake of myCOPD alone remains above 10%.

A two-way analysis on the proportion of people starting and finishing PR with standard care and myCOPD was undertaken but is not presented. This did not appear to have a substantial impact on the incremental cost different between PR with myCOPD and with face-to-face delivery. This is because even where the proportion starting and finishing with myCOPD drops below that of face-to-face, the savings from delivering PR via myCOPD still outweigh the increase in exacerbations. However, it should be noted that in this case exacerbations in the model have increased in the myCOPD arm because people are not finishing their PR programmes and therefore costs would no longer be the only consideration i.e. myCOPD would be considered less effective.

The EAC conducted PSA as described in section 9.2, Sensitivity analysis. The model was run for 1,000 iterations and resulted in an average cost saving per CCG of £22,913, and £11,384 in the PR service costing scenario.

The estimated probability that the intervention is cost saving is 86% in the CCG model and 87% in the PR service costing scenario.

Additional results

Impact of each individual change on the results

The impact of each individual change by the EAC on the company results is shown in Table 9.20 and Table 9.21. This shows how the results change from individual changes the EAC has made to both models.

Table 9.20: Impact of each individual change in company results with EAC updates to Model 1 AECOPD

EAC change	EAC result: incremental cost per CCG*	Change from company's base case**	Impact of action (compared with company's base case incremental cost of -£204,641 per CCG)
Company's base case result	**-£204,641**		
Addition of myCOPD uptake to the model at 46%	-£32,480	£172,161	This reduces the cost saving of myCOPD by £172,161. This is because there is a cost to everyone in the CCG, but the benefits only apply to those who use myCOPD. The smaller the uptake, the less cost-saving myCOPD will be.
Update of costs of exacerbations and hospital readmissions with most recent NHS cost collection costs (change from £54 to £82 for exacerbations, and a change from £1,583 to £1,721 for readmissions)	-£252,976	-£48,335	This increases the cost saving of myCOPD by £48,335. This is due to larger costs being applied to a larger number of exacerbations and readmissions in the SoC arm compared with a larger cost being applied to a smaller number of exacerbations and readmissions in the myCOPD arm.
Updating the number of exacerbations (1.06 to 1.09) and readmission rate (0.24 to 0.20) in the myCOPD arm	-£278,496	-£73,856	This increases the cost saving of myCOPD by £73,856. Whilst the number of exacerbations increases, the rate of readmissions decreases. The cost saving of the readmissions outweighs the increase in costs due to exacerbations.
Updating the time for a clinician to register a patient from 15 minutes to 30 minutes	-£193,865	£10,776	This reduces the cost saving of myCOPD by £10,776. This is due to the total cost of registering a patient increasing.
All changes together	**-£86,297**	**£118,344**	The total change does not equal the total of the individual changes. This is due to an interaction between the above parameters.

* Negative results indicate cost savings.
** Negative results indicate an *increase* in cost savings from the company's base case.

Table 9.21: Impact of each individual change in company results with EAC updates to Model 2 PR

EAC change	EAC result: incremental cost per CCG*	Change from company's base case**	Impact of action (compared with company's base case)
CCG costing			
Company's base case result	**-£20,269**		
Change of decision point in the model so as to compare myCOPD interventions with standard care	-£20,269	£0	This has no impact on the incremental difference between arms, only the magnitude of the total costs reported for each arm.
Update of costs of exacerbations with most recent NHS cost collection costs (change from £54 to £82 for exacerbation treated in the community, and a change from £1,583 to £1,721 for exacerbation with admission)	-£20,360	-£91	This increases the cost saving of myCOPD by £91. This is due to larger costs being applied to a larger number of exacerbations in the SOC arm due to increased waiting time for face-to-face PR.
Addition of costs for starting but not finishing PR programmes	-£21,508	-£1,238	This increases the cost saving of myCOPD by £1,238 because the cost of starting but not finishing a PR programme is assumed to be higher for face-to-face PR.
Updating the time for a clinician to register a patient from 15 minutes to 30 minutes	-£19,152	£1,117	This reduces the cost saving of myCOPD by £1,117. This is due to the total cost of registering a patient increasing.
Correction to uptake figures (changed from 11% to 12.2%)	-£22,543	-£2,274	This increases the cost saving of myCOPD by £2,274 because improvement in uptake increases the cost benefits of myCOPD but does not increase the costs.
All changes together	**-£22,779**	**-£2,510**	The total change does not equal the total of the individual changes. This is due to an interaction between the above parameters.

EAC change	EAC result: incremental cost per PR service provider*	Change from company's base case**	Impact of action (compared with company's base case)
PR service costing scenario			
Company's base case result	**-£8,707**		
Change of decision point in the model so as to compare myCOPD interventions with standard care	-£8,707	£0	This has no impact on the incremental difference between arms, only the magnitude of the total costs reported for each arm.
Update of costs of exacerbations with most recent NHS cost collection costs (change from £54 to £82 for exacerbation treated in the community, and a change from £1,583 to £1,721 for exacerbation with admission)	-£8,794	-£87	This increases the cost saving of myCOPD by £87. This is due to larger costs being applied to a larger number of exacerbations in the SOC arm due to increased waiting time for face-to-face PR.
Addition of costs for starting but not finishing PR programmes	-£9,884	-£1,177	This increases the cost saving of myCOPD by £1,177 because the cost of starting but not finishing a PR programme is assumed to be higher for face-to-face PR.
Updating the time for a clinician to register a patient from 15 minutes to 30 minutes	-£7,645	£1,062	This reduces the cost saving of myCOPD by £1,062. This is due to the total cost of registering a patient increasing.
Correction to uptake figures (changed from 11% to 12.2%)	-£10,868	-£2,161	This increases the cost saving of myCOPD by £2,274 because improvement in uptake increases the cost benefits of myCOPD but does not increase the costs
All changes together	**-£11,093**	**-£2,386**	The total change does not equal the total of the individual changes. This is due to an interaction between the above parameters.

* Negative results indicate cost savings.
** Negative results indicate an *increase* in cost savings from the company's base case.

Results per patient

The EAC also calculated results per patient. These are presented in Table 9.22 for Model 1 AECOPD and Table 9.23 for Model 2 PR. Whilst myCOPD is costed per CCG, the EAC thought it useful to present the results per patient for ease of interpretation.

For Model 1, although an approximation for cost per patient is given, it would be more accurately described as cost per index hospital admission due to the number going into the model including any single person readmitted in a one-year period.

Table 9.22: Summary of EAC base case results for Model 1 AECOPD - per patient

	EAC results		
	myCOPD	**SoC**	**Incremental costs per patient**
myCOPD contract costs	£220	£0	£220
myCOPD registration costs	£20	£0	£20
myCOPD training costs	£4	£0	£4
myCOPD administration	£1	£0	£1
GP appointments	£72	£89	-£17
Exacerbations	£89	£154	-£64
Readmissions	£339	£671	-£333
Total	**£744**	**£914**	**-£170**

Table 9.23: Summary of base case results for Model 2 PR – per patient (results are not standalone)

	EAC results		
	myCOPD	**SoC**	**Incremental costs per patient**
Licence and registration of myCOPD	£20	£0	£20
myCOPD support/face-to-face assessments	£83	£46	£37
Face-to-face assessments	£73	£291	-£218
Starting and not completing PR	£4	£15	-£11
Exacerbations	£919	£925	-£6
Total	**£1,099**	**£1,278**	**-£179**

Table 9.24: Summary of base case results for Model 2 PR (PR service costing scenario) – per patient (standalone results)

	EAC results		
	myCOPD	**SOC**	**Incremental costs per patient**
Licence and registration of myCOPD	£107	£0	£107
myCOPD support/face-to-face assessments	£83	£46	£37
Face-to-face assessments	£73	£291	-£218
Starting and not completing PR	£4	£15	-£11
Exacerbations	£919	£925	-£6
Total	**£1,186**	**£1,278**	**-£92**

9.4 *The EAC's interpretation of the economic evidence*

The company focused its economic submission on two subpopulations of the overall population in the Scope (National Institute for Health and Care Excellence 2019c). The EAC judged this reasonable and deems the model structure for both the AECOPD and PR model reasonable.

Model 1 AECOPD

The AECOPD model demonstrates use of myCOPD in a population that have been discharged from hospital following acute exacerbation. The results of the EAC's updated model are less favourable than those presented by the company primarily due to the inclusion of uptake within the model. However, they remain cost saving.

The benefits of myCOPD in terms of hospitalisation and exacerbations are justified by use of the most robust trial data available. There is greater uncertainty when considering differences in GP appointments and it is difficult to separate the benefit due to myCOPD and SOC. One clinical expert stated that it is more likely that delivery of care bundle and support services are more likely to impact on unscheduled healthcare utilisation than myCOPD (see correspondence log). However, the number of GP appointments was not a key driver of the model results.

The base case results for the AECOPD model support the case for adoption in this population under base case parameters. However, the readmission rates for people using myCOPD could lead to myCOPD being cost incurring if the rates increase above 0.3 readmissions per 90 days. It is reasonable that the rates could increase above 0.3 as it lies within the uncertainty interval presented in RESCUE and is still below that of SOC.

The uptake of myCOPD is another key uncertainty. As a clinical trial, the use of the RESCUE study as a source of uptake has limitations. However, there is a lack of RWE regarding uptake and variation in clinical expert opinion (see correspondence log), leading to the RESCUE study being the most appropriate source. Despite variation in clinical opinion, 2 of the 3 experts defined values above the threshold value of 29%. The third expert could only give data based on patient contacts, rather than unique patients.

Model 2 PR

The PR model can be considered as an add-on to the AECOPD model. It explores the use of myCOPD for delivery of PR programmes. The results of the models should not be combined due to reasons discussed throughout the

report (i.e. risk of double-counting benefits through an overlap of populations); however, it gives an indication of the likely additional cost savings that might be realised if myCOPD were to be used for PR service delivery if a CCG has already purchased the myCOPD license. It should be noted, however, that the costs of the myCOPD license are not included when the CCG costing model is considered and hence the results cannot be considered as standalone.

An additional scenario is also presented whereby a PR service provider can purchase a PR license to use myCOPD specifically for delivery of PR services. In this model the costs of the myCOPD license are considered and therefore the results of the model can be considered as standalone. The changes made by the EAC to the PR model did not have a meaningful impact on its results.

The key uncertainties in the PR model relate to the assumption of non-inferiority of PR services delivered via the myCOPD app compared with face-to-face PR. This has been demonstrated via an RCT powered to detect non-inferiority of a range of outcomes including 6-minute walk test and distance and CAT scores. These outcomes have then been linked with a reduction in exacerbations in the economic model. However, clinical experts queried by the EAC believed that these outcomes could reasonably used as a surrogate for a reduction in exacerbations (see correspondence log).

Another key uncertainty in the model is the uptake of myCOPD. Provided the CCG has already purchased the myCOPD license, using myCOPD for delivery of PR services should only add additional benefits. However, if a license is to be purchased solely for use for PR services uptake and the number of referrals must be sufficient for the cost savings to outweigh the license fees. Provided that uptake of hybrid myCOPD remains over 16% it is expected that introducing myCOPD into PR delivery is likely to result in cost savings regardless of the uptake of myCOPD alone. Uptake of the hybrid approach can drop down to 0% if uptake of myCOPD alone remains above 10%.

10 Conclusions

10.1 *Conclusions from the clinical evidence*

The evidence comprised of 4 clinical studies (3 RCTs and a comparative observational study) and RWE from 22 documents, across 10 NHS settings, including over 800 patients. The 4 studies matched the population in the scope, including patients with all stages of COPD and recently diagnosed to chronic cases. The RWE is also reflective of NHS patients, albeit those with access to devices/the internet and motivated to respond to surveys.

MyCOPD was the key intervention and was typically provided as an add-on to standard care, consistent with NHS practice. Experts noted currently considerable variation exists, with frequent long delays in accessing education and key services such as PR, with many never getting access.

The RCTs provide robust evidence. The results from the RWE are potentially more generalisable to NHS patients but are prone to biases in the methods, primarily patient surveys and in the conduct of the intervention, with sites varying in the HCP support provided. Hence, there are considerable inconsistencies and uncertainties with these results.

Using myCOPD was associated with greater improvements in CAT scores 6MWT and inhaler techniques but evidence was inconclusive on rates of exacerbations. App usage fell over time in all 3 RCTs and in the RWE.

The RCTs had a 3 month follow-up period and smallish sample sizes (<70), thereby limiting the power to detect statistical significance differences and to match patient characteristics across the arms. Two RCTs were not designed to detect superiority of myCOPD over usual care for clinical endpoints.

Clinical experts reported concerns with attrition and adherence with myCOPD, highlighting the need for evidence that using the app changes behaviour and outcomes. These concerns are partially addressed by the company's data on usage over time and by component for over 11,000 users at January 2021.

The evidence suggests the myCOPD app can provide COPD patients with timely access to education and support to self-manage. More evidence is needed on its potential to improve system efficiencies and the coordination of care. The evidence supports a blended approach with face-to-face services, plus myCOPD depending on patient preference and assuming good clinical engagement when the app is introduced, and adequate monitoring is in place.

10.2 *Conclusions from the economic evidence*

There are no published economic evaluations of myCOPD. The company submitted two cost minimisation analyses, using decision trees, comparing myCOPD plus standard of care with standard of care alone. The AECOPD model demonstrated the use of myCOPD in a population that have been discharged from hospital following acute exacerbation. The base case PR model can be considered as an add-on to the AECOPD model and explores the use of myCOPD for delivery of PR programmes. The company also considered a PR service provider purchasing a PR license to use myCOPD specifically for delivery of PR services.

The EAC reviewed both models and agreed that they were broadly consistent with the decision problem. Whilst the NICE scope states that the population to be included in the evailuation should be all people with a diagnosis of COPD, due to no evidence of benefit in this broad population, the company's decision to model only subgroups of people where benefit can be better demonstrated.

For the AECOPD model, efficacy data were made up of values from published RCT (readmission rates and exacerbation data) and RWE (GP appointments). The EAC updated the efficacy data for readmission rate and exacerbations to reflect values adjusted for baseline data and included myCOPD uptake.

After applying the EAC's updated parameters, myCOPD remained cost-saving in the AECOPD population but reduced the cost savings to £86,297 per CCG.

The key uncertainties in the AECOPD model were the myCOPD uptake and the readmission rates. There was a lack of RWE of uptake in the AECOPD population and uptake may be different in the real-world compared with clinical trials (e.g., the RESCUE study). Clinical experts had differing opinions on what this value would be (see correspondence log).

The PR model can demonstrate additional savings to the CCG if myCOPD is used for delivery of PR services (cost saving of £11,093), but the results of both models should not be combined due to overlap between patient populations. The PR costing scenario also demonstrates purchasing a PR service license for use of myCOPD exclusively for PR delivery is also likely to be cost saving, provided uptake and referrals per year are sufficient.

Use of myCOPD outside of the modelled populations could generate additional cost savings should patient benefits outweigh the cost of registering additional patients.

11 Summary of the combined clinical and economic sections

There is a large evidence base for myCOPD (including 3 RCTs, a comparative observational study and RWE across 10 NHS settings, including over 800 patients). Across the 3 robust RCTs, benefits are only shown in two patient populations (people discharged from hospital with AECOPD and people referred for PR) but the sample sizes are small. There are considerable inconsistencies and uncertainties with the results of the RWE.

The EAC's cost analysis estimates that myCOPD generates cost savings for both patient populations. However, there is uncertaintly around this, particularly around the uptake rates of myCOPD. The analysis of the AECOPD model is based on uptake from a clinical trial, which may not be generalisable to the population. Clinical opinion on uptake rates varied widely (from ~4% (based on patient contacts, which likely underestimates the uptake) to 80%) (see correspondence log). Whilst the PR model can be considered as an add-on to the AECOPD model, if a license is to be purchased solely for use for PR services, uptake and the number of referrals must be sufficient for the cost savings to outweigh the license fees.

12 Implications for research

The EAC notes that further RWE is welcome to assess the uptake of myCOPD amongst those eligible for the app. This is important due to the cost-saving of myCOPD in the AECOPD model being dependent on this value. The higher the uptake, the more cost-saving myCOPD is due to the cost of myCOPD being applied to the whole CCG. The uptake should be assessed in populations specific to those where benefits are seen and modelled (e.g., the AECOPD population).

It would also be beneficial for RCTs to be conducted with longer follow-up to see if benefits of myCOPD continue past a 3-month period, as well as with a larger group of patients. RWE suggests some benefits may extend to 12 months.

The EAC further notes that standard of care may change post-pandemic, where it is possible that more people will use remote options of care rather than face-to-face (see correspondence log). This would affect those who are referred for PR and could potentially increase the uptake for myCOPD in this population. It would be beneficial to collect RWE in this regard.

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14 Appendices

Appendix A - Searches and study selection
Appendix B - Risk of bias assessment
Appendix C - Adherence to myCOPD (PR) from TROOPER
Appendix D - RESCUE, North 2020. App usage and mean days used for the myCOPD arm in participants who did not withdraw from the study

Appendix A: Searches and study selection

CLINICAL EVIDENCE: CRITIQUE OF THE SUBMISSION SEARCH METHODS

No literature search was reported in the clinical submission. It was therefore not possible to assess whether the search methodology was appropriate.

CLINICAL EVIDENCE: DETAILS OF RE-RUN COMPANY SEARCHES

No literature search was reported in the clinical submission. It was therefore not possible to replicate and re-run any searches conducted by the company.

CLINICAL EVIDENCE: DETAILS OF EAC *DE NOVO* SEARCHES

As the EAC was unable to assess or replicate any search conducted by the company for the clinical submission, the EAC conducted a *de novo* literature search to identify evidence. The search was originally conducted in October 2019, then repeated in January 2021.

Clinical evidence: EAC de novo *searches – search strategy*

A strategy was developed for MEDLINE (Ovid interface). The search was designed to identify evidence on the clinical effectiveness of myCOPD.

The strategy was devised using a combination of subject indexing terms and free text search terms in the Title, Abstract and Keyword Heading Word fields. The search terms were identified through discussion within the research team, scanning background literature, browsing database thesauri and use of the PubMed PubReminer tool (http://hgserver2.amc.nl/cgi-bin/miner/miner2.cgi). The approach taken to search strategy development aimed to balance sensitivity and precision, reflecting the project timelines. This balanced approach involved using a number of techniques to focus the search including, for example, restricting the range of variant search terms for both population and intervention concepts and using relatively close proximity

operators throughout the strategy. The final strategy for MEDLINE used for the 2021 update is shown in Figure A1 below.

The main structure of the strategy consisted of 2 concepts:

1) COPD (search lines 1 – 7)
2) myCOPD (search lines 8 – 45)

The search concepts were combined as follows: COPD AND myCOPD.

The terms for the myCOPD concept included a range of potentially relevant terms relating to, for example, mobile-based technologies, digital technologies, apps and online technologies. The strategy also included stand-alone lines which searched on terms related to the technology brand name and manufacturer name (search lines 47 to 50).

The strategy excluded animal studies using a standard algorithm (search line 52). The strategy also excluded records indexed as news, editorial and case report publication types, and records with the phrase 'case report' in the title (search line 53). The search was limited to studies published from 2015 to date (search line 55) as myCOPD was understood to be launched then. The company, in its response to the EAC's questions (see correspondence log), confirmed this. The search was limited to studies published in English (search line 56) as project timelines and resources precluded the translation of foreign-language papers. The search was not restricted by study design.

The final Ovid MEDLINE strategy was peer-reviewed by a second Information Specialist for errors in spelling, syntax and line combinations.

Figure A1: Clinical evidence: EAC search strategy for MEDLINE(R) ALL

1	exp Pulmonary Disease, Chronic Obstructive/ (57177)
2	(chronic adj (obstructive pulmonary or obstructive lung or obstructive airway or obstructive air-way or obstructive airflow or obstructive air-flow or obstructive bronchitis or obstructive bronchopulmonary or obstructive broncho-pulmonary or obstructive respiratory)).ti,ab,kf. (56452)
3	(chronic adj (pulmonary obstructi$ or lung obstructi$ or airway obstructi$ or air-way obstructi$ or airflow obstructi$ or air-flow obstructi$ or bronchitis obstructi$ or bronchopulmonary obstructi$ or broncho-pulmonary obstructi$ or respiratory obstructi$)).ti,ab,kf. (1147)
4	(chronic bronchitis or chronic bronchus or bronchitis chronica).ti,ab,kf. (10014)
5	emphysem$.ti,ab,kf. (28376)
6	(COPD or COAD or COBD or AECB).ti,ab,kf. (49656)
7	or/1-6 (112449)
8	Telemedicine/ or Telerehabilitation/ (26339)

9	(mhealth$ or m-health$ or ehealth$ or e-health$).ti,ab,kf. (12767)
10	mobile health$.ti,ab,kf. (5408)
11	Cell Phone/ (8787)
12	(mobile adj (phone$1 or telephone$1 or handset$1 or hand-set$1)).ti,ab,kf. (10144)
13	(cell$ adj (phone$1 or telephone$1 or handset$1 or hand-set$1)).ti,ab,kf. (3981)
14	mobiles.ti,ab,kf. (210)
15	exp Computers, Handheld/ (8757)
16	(smart adj (phone$1 or telephone$1 or handset$1 or hand-set$1)).ti,ab,kf. (1303)
17	smartphone$1.ti,ab,kf. (13577)
18	(iphone$ or i-phone$).ti,ab,kf. (975)
19	(i-pad$1 or ipad$1).ti,ab,kf. (1616)
20	(smart adj (television$ or tv$)).ti,ab,kf. (22)
21	(digital adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kf. (7228)
22	(mobile adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kf. (8943)
23	(electronic$ adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kf. (17872)
24	(smart adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kf. (2862)
25	((internet or online or on-line or web) adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kf. (14203)
26	(tablet$ adj3 (device or devices or technolog$)).ti,ab,kf. (772)
27	(smart adj3 (digital$ or mobile$ or electronic$ or internet or online or on-line or web)).ti,ab,kf. (826)
28	(device-based or mobile-based or smart-based).ti,ab,kf. (3853)
29	Mobile Applications/ (6831)
30	(app or apps).ti,ab,kf. (31414)
31	((digital$ or mobile or electronic$ or smart$ or internet or online or on-line or web or tablet$ or device or devices or software$) adj3 application$1).ti,ab,kf. (31502)
32	((health$ or medic$) adj application$1).ti,ab,kf. (12665)
33	(android or google play).ti,ab,kf. (3043)
34	(apple or ios).ti,ab,kf. (16523)
35	Online Systems/ (8394)
36	Internet/ (74532)
37	(online or on-line or internet$).ti,kf. (52705)
38	(online or on-line or internet$).ab. /freq=2 (47447)
39	(online based or on-line based or internet based).ti,ab,kf. (9274)
40	((online or on-line or internet$) adj6 (educat$ or self-manag$ or self-car$ or symptom$ or rehabilit$ or pr or tutorial$ or exercis$)).ab. (6555)
41	((online or on-line or internet$) adj3 (platform$1 or system$1 or program$ or access$)).ti,ab,kf. (17885)
42	web.ti,kf. (23427)
43	web.ab. /freq=2 (21194)
44	(web-based or webbased or web-site$1 or website$1 or web-page$ or webpage$1).ti,ab,kf. (68820)
45	or/8-44 (347302)
46	7 and 45 (1408)
47	(mycopd$2 or my copd$2).ti,ab,kf. (5)
48	(mypr$2 or my pr$2).ti,ab,kf. (23)
49	(mymhealth$2 or my mhealth$2 or my mobile health$2).ti,ab,kf,in. (6)
50	or/47-49 (29)
51	46 or 50 (1431)
52	exp animals/ not humans/ (4778499)
53	(news or editorial or case reports).pt. or case report.ti. (2956260)
54	51 not (52 or 53) (1380)

55 limit 54 to yr="2015 -Current" (870)
56 limit 55 to english language (846)
57 remove duplicates from 56 (817)

Key to Ovid symbols and commands

$	Unlimited right-hand truncation symbol
$N	Limited right-hand truncation - restricts the number of characters following the word to N
ti,ab,kf,in.	Searches are restricted to the Title, Abstract, Keyword Heading Word and Institution fields
pt.	Searches are restricted to the Publication Type field
adj	Retrieves records that contain terms next to each other, in the order shown
adjN	Retrieves records that contain terms (in any order) within a specified number (N) of words of each other
ab. /freq=N	Search is restricted to records where the terms occur at least N times in the abstract
/	Searches are restricted to the Subject Heading field
exp	The subject heading is exploded
or/1-6	Combines sets 1 to 6 using OR

Clinical evidence: EAC de novo *searches – resources searched*

The EAC conducted searches using each database or resource listed in Table A1. The information resources included a range of databases containing research published in the journal literature, conference abstracts and ongoing research. The EAC also conducted focused searches of a selection of websites informed by the list of external organisations identified on the NICE final scope document for the technology, and a focused search of the company website. The EAC also conducted a targeted search using Google for research evidence published on NHS websites or produced by NHS organisations.

For the 2019 search the HTA Database was searched via the University of York Centre for Reviews and Dissemination (CRD) interface. Although the HTA Database remains available via CRD, since 31 March 2018 the CRD have no longer added new records to it. INAHTA have now taken over production. For the 2021 update the previously run search strategy was therefore translated for use in the new INAHTA interface.

Table A1: Clinical evidence: EAC *de novo* searches – resources searched

Resource	Interface / URL
MEDLINE(R) ALL	OvidSP
Embase	OvidSP
Cochrane Central Register of Controlled Trials	Cochrane Library / Wiley
Cochrane Database of Systematic Reviews	Cochrane Library / Wiley
Database of Abstracts of Reviews of Effects	https://www.crd.york.ac.uk/CRDWeb/
HTA Database	https://database.inahta.org/

Resource	Interface / URL
PubMed	http://www.ncbi.nlm.nih.gov/pubmed
Science Citation Index Expanded (SCI-EXPANDED)	Web of Science
Conference Proceedings Citation Index- Science (CPCI-S)	Web of Science
Clinicaltrials.gov	https://clinicaltrials.gov/
WHO International Clinical Trials Registry Platform	http://apps.who.int/trialsearch/
Royal College of General Practitioners website	https://www.rcgp.org.uk/
Royal College of Nursing website	https://www.rcn.org.uk/
Royal College of Physicians website	https://www.rcplondon.ac.uk/
Primary Care Respiratory Society website	https://www.pcrs-uk.org/
British Thoracic Society website	https://www.brit-thoracic.org.uk/
British Lung Foundation website	https://www.blf.org.uk/
National Association of Primary Care website	https://napc.co.uk/
The Royal College of Emergency Medicine website	https://www.rcem.ac.uk/
British Society for Genetic Medicine website	https://www.bsgm.org.uk/
Association of Respiratory Nurse Specialists website	https://arns.co.uk/
Infection Prevention Society website	https://www.ips.uk.net/
Association for Respiratory Technology & Physiology website	http://www.artp.org.uk/
NARA – The Breathing Charity website	http://naratbc.org.uk/
my mhealth website	https://mymhealth.com/
Google	https://www.google.com/

The following additional search source was also sought, but was not found at date of search: Community Practitioners & Health Visitors Association website

In addition to the above searches, the company was contacted to supply details of any additional studies they were aware of. The studies provided by the company included one study that was made available as a pre-print (Cooper et al. 2021b) after the EAC search date.

Clinical evidence: EAC de novo *searches - running the search strategies and downloading results*

Searches were conducted using each database or resource listed above, translating the Ovid MEDLINE strategy appropriately. Translation included consideration of differences in database interfaces and functionality, in addition to variation in indexing languages and thesauri. The full strategies (including search dates) for all sources searched are shown below.

Where possible, results of searches were downloaded in a tagged format and loaded into bibliographic software (EndNote). The 2019 search results were deduplicated within-set using several algorithms and the duplicate references held in a separate EndNote database for checking if needed. The 2021 search results were imported into the EndNote library containing the 2019 results and deduplicated within-set and against the 2019 search results. Results from resources that did not allow export in a format compatible with EndNote were added to EndNote by hand.

Clinical evidence: EAC de novo searches - literature search results

The October 2019 EAC search retrieved 3,168 records, with 2,133 records remaining after deduplication. The January 2021 EAC search retrieved 4,593 records, with 1,147 records remaining after deduplication within-set and against the 2019 results (Table A2). From the 2019 and 2021 searches, 7,761 records in total were retrieved, with 3,280 remaining after deduplication for assessment.

Table A2: Clinical evidence: EAC *de novo* searches - literature search results

Resource	Number of records identified (October 2019)	Number of records identified (January 2021)
MEDLINE(R) ALL	569	817
Embase	1121	1645
Cochrane Central Register of Controlled Trials	267	376
Cochrane Database of Systematic Reviews	13	15
Database of Abstracts of Reviews of Effects	6	6
HTA Database	29	34
PubMed	254	385
Science Citation Index Expanded (SCI-EXPANDED)	443	628
Conference Proceedings Citation Index- Science (CPCI-S)	93	132
Clinicaltrials.gov	148	217
WHO International Clinical Trials Registry Platform	215	312
Royal College of General Practitioners website	0	0
Royal College of Nursing website	0	0
Royal College of Physicians website	0	0
Primary Care Respiratory Society website	0	0
British Thoracic Society website	0	0
British Lung Foundation website	0	0
National Association of Primary Care website	0	0
The Royal College of Emergency Medicine website	0	0
British Society for Genetic Medicine website	0	0
Association of Respiratory Nurse Specialists website	0	0
Infection Prevention Society website	0	0
Association for Respiratory Technology & Physiology website	0	0
NARA – The Breathing Charity website	0	0
my mhealth website	0	2
Google	8	8
Reference list checking	0	0
Contact with company	2	16
Total number of records retrieved	3,168	4,593
Total number of records after deduplication	**2,133**	**1,147**

Clinical evidence: EAC* de novo *searches - full search strategies (2021 update searches)

A.1: Source: MEDLINE(R) ALL

Interface / URL: OvidSP
Database coverage dates: 1946 to January 19, 2021
Search date: 20/01/21
Retrieved records: 817
Search strategy:

1 exp Pulmonary Disease, Chronic Obstructive/ (57177)
2 (chronic adj (obstructive pulmonary or obstructive lung or obstructive airway or obstructive air-way or obstructive airflow or obstructive air-flow or obstructive bronchitis or obstructive bronchopulmonary or obstructive broncho-pulmonary or obstructive respiratory)).ti,ab,kf. (56452)
3 (chronic adj (pulmonary obstructi$ or lung obstructi$ or airway obstructi$ or air-way obstructi$ or airflow obstructi$ or air-flow obstructi$ or bronchitis obstructi$ or bronchopulmonary obstructi$ or broncho-pulmonary obstructi$ or respiratory obstructi$)).ti,ab,kf. (1147)
4 (chronic bronchitis or chronic bronchus or bronchitis chronica).ti,ab,kf. (10014)
5 emphysem$.ti,ab,kf. (28376)
6 (COPD or COAD or COBD or AECB).ti,ab,kf. (49656)
7 or/1-6 (112449)
8 Telemedicine/ or Telerehabilitation/ (26339)
9 (mhealth$ or m-health$ or ehealth$ or e-health$).ti,ab,kf. (12767)
10 mobile health$.ti,ab,kf. (5408)
11 Cell Phone/ (8787)
12 (mobile adj (phone$1 or telephone$1 or handset$1 or hand-set$1)).ti,ab,kf. (10144)
13 (cell$ adj (phone$1 or telephone$1 or handset$1 or hand-set$1)).ti,ab,kf. (3981)
14 mobiles.ti,ab,kf. (210)
15 exp Computers, Handheld/ (8757)
16 (smart adj (phone$1 or telephone$1 or handset$1 or hand-set$1)).ti,ab,kf. (1303)
17 smartphone$1.ti,ab,kf. (13577)
18 (iphone$ or i-phone$).ti,ab,kf. (975)
19 (i-pad$1 or ipad$1).ti,ab,kf. (1616)
20 (smart adj (television$ or tv$)).ti,ab,kf. (22)
21 (digital adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kf. (7228)
22 (mobile adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kf. (8943)

23 (electronic$ adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kf. (17872)
24 (smart adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kf. (2862)
25 ((internet or online or on-line or web) adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kf. (14203)
26 (tablet$ adj3 (device or devices or technolog$)).ti,ab,kf. (772)
27 (smart adj3 (digital$ or mobile$ or electronic$ or internet or online or on-line or web)).ti,ab,kf. (826)
28 (device-based or mobile-based or smart-based).ti,ab,kf. (3853)
29 Mobile Applications/ (6831)
30 (app or apps).ti,ab,kf. (31414)
31 ((digital$ or mobile or electronic$ or smart$ or internet or online or on-line or web or tablet$ or device or devices or software$) adj3 application$1).ti,ab,kf. (31502)
32 ((health$ or medic$) adj application$1).ti,ab,kf. (12665)
33 (android or google play).ti,ab,kf. (3043)
34 (apple or ios).ti,ab,kf. (16523)
35 Online Systems/ (8394)
36 Internet/ (74532)
37 (online or on-line or internet$).ti,kf. (52705)
38 (online or on-line or internet$).ab. /freq=2 (47447)
39 (online based or on-line based or internet based).ti,ab,kf. (9274)
40 ((online or on-line or internet$) adj6 (educat$ or self-manag$ or self-car$ or symptom$ or rehabilit$ or pr or tutorial$ or exercis$)).ab. (6555)
41 ((online or on-line or internet$) adj3 (platform$1 or system$1 or program$ or access$)).ti,ab,kf. (17885)
42 web.ti,kf. (23427)
43 web.ab. /freq=2 (21194)
44 (web-based or webbased or web-site$1 or website$1 or web-page$ or webpage$1).ti,ab,kf. (68820)
45 or/8-44 (347302)
46 7 and 45 (1408)
47 (mycopd$2 or my copd$2).ti,ab,kf. (5)
48 (mypr$2 or my pr$2).ti,ab,kf. (23)
49 (mymhealth$2 or my mhealth$2 or my mobile health$2).ti,ab,kf,in. (6)
50 or/47-49 (29)
51 46 or 50 (1431)
52 exp animals/ not humans/ (4778499)
53 (news or editorial or case reports).pt. or case report.ti. (2956260)
54 51 not (52 or 53) (1380)
55 limit 54 to yr="2015 -Current" (870)
56 limit 55 to english language (846)
57 remove duplicates from 56 (817)

A.2: Source: Embase

Interface / URL: OvidSP
Database coverage dates: 1974 to 2021 January 20
Search date: 21/01/21
Retrieved records: 1645
Search strategy:

1 chronic obstructive lung disease/ or chronic bronchitis/ or lung emphysema/ (159183)
2 (chronic adj (obstructive pulmonary or obstructive lung or obstructive airway or obstructive air-way or obstructive airflow or obstructive air-flow or obstructive bronchitis or obstructive bronchopulmonary or obstructive broncho-pulmonary or obstructive respiratory)).ti,ab,kw,dq. (83165)
3 (chronic adj (pulmonary obstructi$ or lung obstructi$ or airway obstructi$ or air-way obstructi$ or airflow obstructi$ or air-flow obstructi$ or bronchitis obstructi$ or bronchopulmonary obstructi$ or broncho-pulmonary obstructi$ or respiratory obstructi$)).ti,ab,kw,dq. (1540)
4 (chronic bronchitis or chronic bronchus or bronchitis chronica).ti,ab,kw,dq. (12545)
5 emphysem$.ti,ab,kw,dq. (35986)
6 (COPD or COAD or COBD or AECB).ti,ab,kw,dq. (95494)
7 or/1-6 (207598)
8 telehealth/ or telerehabilitation/ (9392)
9 (mhealth$ or m-health$ or ehealth$ or e-health$).ti,ab,kw,dq. (13826)
10 mobile health$.ti,ab,kw,dq. (5479)
11 exp mobile phone/ (31856)
12 (mobile adj (phone$1 or telephone$1 or handset$1 or hand-set$1)).ti,ab,kw,dq. (12138)
13 (cell$ adj (phone$1 or telephone$1 or handset$1 or hand-set$1)).ti,ab,kw,dq. (5426)
14 mobiles.ti,ab,kw,dq. (326)
15 personal digital assistant/ or tablet computer/ (3048)
16 (smart adj (phone$1 or telephone$1 or handset$1 or hand-set$1)).ti,ab,kw,dq. (2703)
17 smartphone$1.ti,ab,kw,dq. (17643)
18 (iphone$ or i-phone$).ti,ab,kw,dq,dv,my. (2075)
19 (i-pad$1 or ipad$1).ti,ab,kw,dq,dv,my. (3428)
20 (smart adj (television$ or tv$)).ti,ab,kw,dq. (32)
21 (digital adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kw,dq. (9067)
22 (mobile adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kw,dq. (11294)
23 (electronic$ adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kw,dq. (20294)

24 (smart adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kw,dq. (3588)
25 ((internet or online or on-line or web) adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kw,dq. (19709)
26 (tablet$ adj3 (device or devices or technolog$)).ti,ab,kw,dq. (1434)
27 (smart adj3 (digital$ or mobile$ or electronic$ or internet or online or on-line or web)).ti,ab,kw,dq. (1076)
28 (device-based or mobile-based or smart-based).ti,ab,kw,dq. (4384)
29 exp mobile application/ (14128)
30 (app or apps).ti,ab,kw,dq. (43379)
31 ((digital$ or mobile or electronic$ or smart$ or internet or online or on-line or web or tablet$ or device or devices or software$) adj3 application$1).ti,ab,kw,dq. (35741)
32 ((health$ or medic$) adj application$1).ti,ab,kw,dq. (15386)
33 (android or google play).ti,ab,kw,dq,dv,my. (4811)
34 (apple or ios).ti,ab,kw,dq,dv,my. (33728)
35 online system/ (26545)
36 internet/ (112112)
37 (online or on-line or internet$).ti,kw. (68162)
38 (online or on-line or internet$).ab. /freq=2 (67526)
39 (online based or on-line based or internet based).ti,ab,kw,dq. (12609)
40 ((online or on-line or internet$) adj6 (educat$ or self-manag$ or self-car$ or symptom$ or rehabilit$ or pr or tutorial$ or exercis$)).ab. (10399)
41 ((online or on-line or internet$) adj3 (platform$1 or system$1 or program$ or access$)).ti,ab,kw,dq. (25272)
42 web.ti,kw. (27964)
43 web.ab. /freq=2 (25473)
44 (web-based or webbased or web-site$1 or website$1 or web-page$ or webpage$1).ti,ab,kw,dq. (98272)
45 or/8-44 (469119)
46 7 and 45 (2754)
47 (mycopd$2 or my copd$2).ti,ab,kw,dq,dv,my. (5)
48 (mypr$2 or my pr$2).ti,ab,kw,dq,dv,my. (51)
49 (mymhealth$2 or my mhealth$2 or my mobile health$2).ti,ab,kw,in,dq,dv,my,dm. (6)
50 or/47-49 (57)
51 46 or 50 (2805)
52 (animal/ or animal experiment/ or animal model/ or animal tissue/ or nonhuman/) not exp human/ (6173452)
53 editorial.pt. or case report.ti. (990109)
54 51 not (52 or 53) (2706)
55 limit 54 to yr="2015 -Current" (1693)
56 limit 55 to english language (1665)
57 remove duplicates from 56 (1645)

A.3: Source: Science Citation Index Expanded (SCI-EXPANDED)

Interface / URL: Web of Science
Database coverage dates: 1900-present
Search date: 22/01/21
Retrieved records: 628
Search strategy:

All lines: Indexes=SCI-EXPANDED

43 628 (#42) AND LANGUAGE: (English) Timespan=2015-2021
42 970 #41 OR #37
41 7 #40 OR #39 OR #38
40 2 ALL=(mymhealth* or "my mhealth*" or "my mobile health*")
39 3 TS=("mypr" or "myprr" or "myprtm" or "my pr" or "my prr" or "my prtm")
38 2 TS=(mycopd* or "my copd*")
37 966 #36 AND #6
36 555,906 #35 OR #34 OR #33 OR #32 OR #31 OR #30 OR #29 OR #28 OR #27 OR #26 OR #25 OR #24 OR #23 OR #22 OR #21 OR #20 OR #19 OR #18 OR #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8 OR #7
35 76,036 TS=("web-based" or "webbased" or "web-site*" or website* or "web-page*" or webpage*)
34 45,589 TI="web"
33 36,355 TS=(("online" or "on-line" or internet*) NEAR/3 (platform* or system* or program* or access*))
32 8,152 TS=(("online" or "on-line" or internet*) NEAR/6 (educat* or "self-manag*" or "self-car*" or symptom* or rehabilit* or "pr" or tutorial* or exercis*))
31 10,097 TS=("online based" or "on-line based" or "internet based")
30 98,482 TI=("online" or "on-line" or internet*)
29 51,010 TS=("apple" or "ios")
28 5,310 TS=("android" or "google play")
27 19,199 TS=((health* or medic*) NEAR/0 application*)
26 114,317 TS=((digital* or "mobile" or electronic* or smart* or "internet" or "online" or "on-line" or "web" or tablet* or "device" or "devices" or software*) NEAR/3 application*)
25 40,339 TS=("app" or "apps")
24 9,280 TS=("device-based" or "mobile-based" or "smart-based")
23 4,208 TS=("smart" NEAR/3 (digital* or mobile* or electronic* or "internet" or "online" or "on-line" or "web"))
22 1,310 TS=(tablet* NEAR/3 ("device" or "devices" or technolog*))
21 28,429 TS=(("internet" or "online" or "on-line" or "web") NEAR/3 ("device" or "devices" or technolog* or tool* or tablet*))

20 10,912 TS=("smart" NEAR/3 ("device" or "devices" or technolog* or tool* or tablet*))
19 49,176 TS=(electronic* NEAR/3 ("device" or "devices" or technolog* or tool* or tablet*))
18 23,220 TS=("mobile" NEAR/3 ("device" or "devices" or technolog* or tool* or tablet*))
17 14,883 TS=("digital" NEAR/3 ("device" or "devices" or technolog* or tool* or tablet*))
16 183 TS=("smart" NEAR/0 (television* or "tv" or "tvs"))
15 1,893 TS=("i-pad*" or ipad*)
14 1,291 TS=(iphone* or "i-phone*")
13 20,284 TS=smartphone*
12 3,075 TS=("smart" NEAR/0 (phone* or telephone* or handset* or "hand-set*"))
11 911 TS="mobiles"
10 7,030 TS=(cell* NEAR/0 (phone* or telephone* or handset* or "hand-set*"))
9 16,710 TS=("mobile" NEAR/0 (phone* or telephone* or handset* or "hand-set*"))
8 4,470 TS="mobile health*"
7 11,502 TS=(mhealth* or "m-health*" or ehealth* or "e-health*")
6 107,016 #5 OR #4 OR #3 OR #2 OR #1
5 62,408 TS=("COPD" or "COAD" or "COBD" or "AECB")
4 25,403 TS=emphysem*
3 8,865 TS=("chronic bronchitis" or "chronic bronchus" or "bronchitis chronica")
2 1,040 TS=("chronic" NEAR/0 ("pulmonary obstructi*" or "lung obstructi*" or "airway obstructi*" or "air-way obstructi*" or "airflow obstructi*" or "air-flow obstructi*" or "bronchitis obstructi*" or "bronchopulmonary obstructi*" or "broncho-pulmonary obstructi*" or "respiratory obstructi*"))
1 50,945 TS=("chronic" NEAR/0 ("obstructive pulmonary" or "obstructive lung" or "obstructive airway" or "obstructive air-way" or "obstructive airflow" or "obstructive air-flow" or "obstructive bronchitis" or "obstructive bronchopulmonary" or "obstructive broncho-pulmonary" or "obstructive respiratory"))

A.4: Source: Conference Proceedings Citation Index- Science (CPCI-S)
Interface / URL: Web of Science
Database coverage dates: 1990-present
Search date: 22/01/21
Retrieved records: 132
Search strategy:

All lines: Indexes=CPCI-S

43 132 (#42) AND LANGUAGE: (English) Timespan=2015-2021
42 202 #41 OR #37
41 2 #40 OR #39 OR #38
40 2 ALL=(mymhealth* or "my mhealth*" or "my mobile health*")
39 0 TS=("mypr" or "myprr" or "myprtm" or "my pr" or "my prr" or "my prtm")
38 0 TS=(mycopd* or "my copd*")
37 201 #36 AND #6
36 377,322 #35 OR #34 OR #33 OR #32 OR #31 OR #30 OR #29 OR #28 OR #27 OR #26 OR #25 OR #24 OR #23 OR #22 OR #21 OR #20 OR #19 OR #18 OR #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8 OR #7
35 50,107 TS=("web-based" or "webbased" or "web-site*" or website* or "web-page*" or webpage*)
34 44,208 TI="web"
33 33,267 TS=(("online" or "on-line" or internet*) NEAR/3 (platform* or system* or program* or access*))
32 5,141 TS=(("online" or "on-line" or internet*) NEAR/6 (educat* or "self-manag*" or "self-car*" or symptom* or rehabilit* or "pr" or tutorial* or exercis*))
31 4,980 TS=("online based" or "on-line based" or "internet based")
30 63,126 TI=("online" or "on-line" or internet*)
29 9,978 TS=("apple" or "ios")
28 12,534 TS=("android" or "google play")
27 8,897 TS=((health* or medic*) NEAR/0 application*)
26 98,385 TS=((digital* or "mobile" or electronic* or smart* or "internet" or "online" or "on-line" or "web" or tablet* or "device" or "devices" or software*) NEAR/3 application*)
25 13,642 TS=("app" or "apps")
24 4,363 TS=("device-based" or "mobile-based" or "smart-based")
23 5,667 TS=("smart" NEAR/3 (digital* or mobile* or electronic* or "internet" or "online" or "on-line" or "web"))
22 1,600 TS=(tablet* NEAR/3 ("device" or "devices" or technolog*))
21 31,179 TS=(("internet" or "online" or "on-line" or "web") NEAR/3 ("device" or "devices" or technolog* or tool* or tablet*))

20 13,709 TS=("smart" NEAR/3 ("device" or "devices" or technolog* or tool* or tablet*))
19 24,375 TS=(electronic* NEAR/3 ("device" or "devices" or technolog* or tool* or tablet*))
18 37,211 TS=("mobile" NEAR/3 ("device" or "devices" or technolog* or tool* or tablet*))
17 15,266 TS=("digital" NEAR/3 ("device" or "devices" or technolog* or tool* or tablet*))
16 326 TS=("smart" NEAR/0 (television* or "tv" or "tvs"))
15 796 TS=("i-pad*" or ipad*)
14 987 TS=(iphone* or "i-phone*")
13 18,139 TS=smartphone*
12 6,286 TS=("smart" NEAR/0 (phone* or telephone* or handset* or "hand-set*"))
11 1,519 TS="mobiles"
10 5,478 TS=(cell* NEAR/0 (phone* or telephone* or handset* or "hand-set*"))
9 15,077 TS=("mobile" NEAR/0 (phone* or telephone* or handset* or "hand-set*"))
8 1,616 TS="mobile health*"
7 5,521 TS=(mhealth* or "m-health*" or ehealth* or "e-health*")
6 13,823 #5 OR #4 OR #3 OR #2 OR #1
5 8,825 TS=("COPD" or "COAD" or "COBD" or "AECB")
4 2,060 TS=emphysem*
3 565 TS=("chronic bronchitis" or "chronic bronchus" or "bronchitis chronica")
2 58 TS=("chronic" NEAR/0 ("pulmonary obstructi*" or "lung obstructi*" or "airway obstructi*" or "air-way obstructi*" or "airflow obstructi*" or "air-flow obstructi*" or "bronchitis obstructi*" or "bronchopulmonary obstructi*" or "broncho-pulmonary obstructi*" or "respiratory obstructi*"))
1 4,694 TS=("chronic" NEAR/0 ("obstructive pulmonary" or "obstructive lung" or "obstructive airway" or "obstructive air-way" or "obstructive airflow" or "obstructive air-flow" or "obstructive bronchitis" or "obstructive bronchopulmonary" or "obstructive broncho-pulmonary" or "obstructive respiratory"))

A.5: Source: Cochrane Central Register of Controlled Trials

Interface / URL: Cochrane Library / Wiley
Database coverage dates: Information not found. Issue Issue 1 of 12, January 2021
Search date: 22/01/21
Retrieved records: 376
Search strategy:

#1 [mh "Pulmonary Disease, Chronic Obstructive"]5786
#2 (chronic next ("obstructive pulmonary" or "obstructive lung" or "obstructive airway" or "obstructive air-way" or "obstructive airflow" or "obstructive air-flow" or "obstructive bronchitis" or "obstructive bronchopulmonary" or "obstructive broncho-pulmonary" or "obstructive respiratory")) 15275
#3 (chronic next (pulmonary next obstructi* or lung next obstructi* or airway next obstructi* or air next way next obstructi* or airflow next obstructi* or air next flow next obstructi* or bronchitis next obstructi* or bronchopulmonary next obstructi* or broncho next pulmonary next obstructi* or respiratory next obstructi*)) 216
#4 ("chronic bronchitis" or "chronic bronchus" or "bronchitis chronica") 1812
#5 (emphysem*)1734
#6 (COPD or COAD or COBD or AECB) 17138
#7 #1 or #2 or #3 or #4 or #5 or #6 23843
#8 [mh ^Telemedicine] or [mh ^Telerehabilitation] 2279
#9 (mhealth* or m next health* or ehealth* or e next health*) 2986
#10 (mobile next health*) 1274
#11 [mh ^"Cell Phone"] 685
#12 (mobile next (phone* or telephone* or handset* or hand next set*)) 3107
#13 (cell* next (phone* or telephone* or handset* or hand next set*)) 1482
#14 mobiles 351
#15 [mh "Computers, Handheld"] 687
#16 (smart next (phone* or telephone* or handset* or hand next set*)) 759
#17 smartphone* 4084
#18 (iphone* or i next phone*) 280
#19 (i next pad* or ipad*) 769
#20 (smart next (television* or tv*)) 3
#21 (digital near/3 (device or devices or technolog* or tool* or tablet*)) 719
#22 (mobile near/3 (device or devices or technolog* or tool* or tablet*)) 1772

#23 (electronic* near/3 (device or devices or technolog* or tool* or tablet*)) 1671
#24 (smart near/3 (device or devices or technolog* or tool* or tablet*)) 371
#25 ((internet or online or web) near/3 (device or devices or technolog* or tool* or tablet*)) 1622
#26 (tablet* near/3 (device or devices or technolog*)) 319
#27 (smart near/3 (digital* or mobile* or electronic* or internet or online or web)) 225
#28 (device-based or mobile-based or smart-based) 469
#29 [mh ^"Mobile Applications"] 671
#30 (app or apps)6973
#31 ((digital* or mobile or electronic* or smart* or internet or online or web or tablet* or device or devices or software*) near/3 application*) 4902
#32 ((health* or medic*) next application*) 495
#33 (android or "google play") 761
#34 (apple or ios) 1798
#35 [mh ^"Online Systems"] 156
#36 [mh ^Internet] 3818
#37 (online or internet*):ti 6539
#38 ("online based" or "internet based") 3743
#39 ((online or internet*) near/6 (educat* or self next manag* or self next car* or symptom* or rehabilit* or pr or tutorial* or exercis*)) 3882
#40 ((online or internet*) near/3 (platform* or system* or program* or access*)) 6328
#41 (web):ti 2869
#42 (web-based or webbased or web next site* or website* or web next page* or webpage*) 14225
#43 #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #42 43169
#44 #7 and #43 959
#45 (mycopd* or my next copd*) 4
#46 (mypr or myprr or myprtm or "my pr" or "my prr" or "my prtm") 3
#47 (mymhealth* or "my mhealth*" or "my mobile health*") 4
#48 #45 or #46 or #47 7
#49 #44 or #48 959
#50 #49 with Publication Year from 2015 to 2021, in Trials 376

Search note: the term *on-line* was not explicitly included in the strategy. In the Cochrane Library, searching for *on-line* retrieves records containing 'SmithKline', 'Z-line', 'A-line' and so on. Alternative approaches such as searching for *"on-line"* or searching for *on next line* retrieve records including

'second-line', 'first-line' and so on. The included search term *online* retrieves records containing both 'online' and 'on-line.' Cochrane Library support were contacted to confirm this understanding. They confirmed that the term "on-line" is not a valid search term in the Cochrane Library, and recommended using the term "online".

A.6: Source: Cochrane Database of Systematic Reviews

Interface / URL: Cochrane Library / Wiley
Database coverage dates: Information not found. Issue 1 of 12, January 2021
Search date: 22/01/21
Retrieved records: 15
Search strategy:

#1 [mh "Pulmonary Disease, Chronic Obstructive"]5786
#2 (chronic next ("obstructive pulmonary" or "obstructive lung" or "obstructive airway" or "obstructive air-way" or "obstructive airflow" or "obstructive air-flow" or "obstructive bronchitis" or "obstructive bronchopulmonary" or "obstructive broncho-pulmonary" or "obstructive respiratory")):ti,ab,kw 14385
#3 (chronic next (pulmonary next obstructi* or lung next obstructi* or airway next obstructi* or air next way next obstructi* or airflow next obstructi* or air next flow next obstructi* or bronchitis next obstructi* or bronchopulmonary next obstructi* or broncho next pulmonary next obstructi* or respiratory next obstructi*)):ti,ab,kw 205
#4 ("chronic bronchitis" or "chronic bronchus" or "bronchitis chronica"):ti,ab,kw 1723
#5 (emphysem*):ti,ab,kw 1531
#6 (COPD or COAD or COBD or AECB):ti,ab,kw 16688
#7 #1 or #2 or #3 or #4 or #5 or #6 23224
#8 [mh ^Telemedicine] or [mh ^Telerehabilitation] 2279
#9 (mhealth* or m next health* or ehealth* or e next health*):ti,ab,kw 2305
#10 (mobile next health*):ti,ab,kw 1172
#11 [mh ^"Cell Phone"] 685
#12 (mobile next (phone* or telephone* or handset* or hand next set*)):ti,ab,kw 2905
#13 (cell* next (phone* or telephone* or handset* or hand next set*)):ti,ab,kw 1413
#14 (mobiles):ti,ab,kw 48
#15 [mh "Computers, Handheld"] 687
#16 (smart next (phone* or telephone* or handset* or hand next set*)):ti,ab,kw 681
#17 (smartphone*):ti,ab,kw 3942
#18 (iphone* or i next phone*):ti,ab,kw 237

#19 (i next pad* or ipad*):ti,ab,kw 695
#20 (smart next (television* or tv*)):ti,ab,kw 3
#21 (digital near/3 (device or devices or technolog* or tool* or tablet*)):ti,ab,kw 641
#22 (mobile near/3 (device or devices or technolog* or tool* or tablet*)):ti,ab,kw 1633
#23 (electronic* near/3 (device or devices or technolog* or tool* or tablet*)):ti,ab,kw 1467
#24 (smart near/3 (device or devices or technolog* or tool* or tablet*)):ti,ab,kw 338
#25 ((internet or online or web) near/3 (device or devices or technolog* or tool* or tablet*)):ti,ab,kw 1411
#26 (tablet* near/3 (device or devices or technolog*)):ti,ab,kw 275
#27 (smart near/3 (digital* or mobile* or electronic* or internet or online or web)):ti,ab,kw 175
#28 (device-based or mobile-based or smart-based):ti,ab,kw 437
#29 [mh ^"Mobile Applications"] 671
#30 (app or apps):ti,ab,kw 4753
#31 ((digital* or mobile or electronic* or smart* or internet or online or web or tablet* or device or devices or software*) near/3 application*):ti,ab,kw 4643
#32 ((health* or medic*) next application*):ti,ab,kw 450
#33 (android or "google play"):ti,ab,kw726
#34 (apple or ios):ti,ab,kw 1617
#35 [mh ^"Online Systems"] 156
#36 [mh ^Internet] 3818
#37 (online or internet*):ti 6539
#38 ("online based" or "internet based"):ti,ab,kw 3478
#39 ((online or internet*) near/6 (educat* or self next manag* or self next car* or symptom* or rehabilit* or pr or tutorial* or exercis*)):ti,ab,kw 2713
#40 ((online or internet*) near/3 (platform* or system* or program* or access*)):ti,ab,kw 5235
#41 (web):ti 2869
#42 (web-based or webbased or web next site* or website* or web next page* or webpage*):ti,ab,kw 11429
#43 #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38 or #39 or #40 or #41 or #4237578
#44 #7 and #43 592
#45 (mycopd* or my next copd*) 4
#46 (mypr or myprr or myprtm or "my pr" or "my prr" or "my prtm") 3
#47 (mymhealth* or "my mhealth*" or "my mobile health*") 4
#48 #45 or #46 or #47 7

#49 #44 or #48 593
#50 #49 with Cochrane Library publication date Between Jan 2015 and Jan 2021, in Cochrane Reviews, Cochrane Protocols 15

Search note: the term *on-line* was not explicitly included in the strategy. In the Cochrane Library, searching for *on-line* retrieves records containing 'SmithKline', 'Z-line', 'A-line' and so on. Alternative approaches such as searching for *"on-line"* or searching for *on next line* retrieve records including 'second-line', 'first-line' and so on. The included search term *online* retrieves records containing both 'online' and 'on-line.' Cochrane Library support were contacted to confirm this understanding. They confirmed that the term "on-line" is not a valid search term in the Cochrane Library, and recommended using the term "online".

A.7: Source: HTA database

Interface / URL: https://database.inahta.org/
Database coverage dates: Information not found. The former database was produced by the CRD until March 2018, at which time the addition of records was stopped as INAHTA was in the process of rebuilding the new database platform. In July 2019, the database records were exported from the CRD platform and imported into the new platform that was developed by INAHTA. The rebuild of the new platform was launched in June 2020.
Search date: 22/01/21
Retrieved records: 34
Search strategy:

11 #10 OR #6 185*
10 #9 OR #8 OR #7 1
9 mymhealth* 0
8 mypr* 1
7 mycopd* 0
6 #5 OR #4 OR #3 OR #2 OR #1 184
5 ((COPD OR COAD OR COBD OR AECB)) 102
4 (emphysem*)29
3 (("chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica")) 2
2 (chronic AND (pulmonary OR lung OR airway OR "air-way" OR airflow* OR "air-flow" OR bronchitis OR bronchopulmonary OR "broncho-pulmonary" OR respiratory) AND obstructi*) 126
1 "Pulmonary Disease, Chronic Obstructive"[mhe] 89

Search notes:

1. For the 2019 search, the HTA Database was searched on 17/10/19 via the University of York CRD interface. Although the HTA Database remains available via CRD, since 31 March 2018 the CRD have no longer added new records to it. INAHTA have now taken over production. For the 2021 update search the previously run search strategy was therefore translated for use in the new INAHTA interface.

2. Some aspects of search functionality in the new HTA Database interface are more limited than in the previous version. The translation was adapted appropriately in the context of these limitations.

3. It is not possible to search on the term *my* in the HTA database. Searching on this term returns zero results with the message: "Sorry please make your search terms a minimum of 3 characters". It was therefore not possible to search on the following previously included terms:

*my pr**
*my mhealth**
*my mobile health**

4. *Date restrictions were applied to the 185 results in line 11 using the available filter option (Filter: Year: 2015 to 2021). Search result numbers after applying the filter were shown as 34. On exporting all, 185 records were in exported file, including 151 pre-2015. The process was repeated with the same outcome. The 185 records were therefore downloaded into an EndNote library and the 151 records were removed by hand, leaving 34 retrieved records with publication dates from 2015 onwards.

A.8: Source: Database of Abstracts of Reviews of Effects (DARE)
Interface / URL: https://www.crd.york.ac.uk/CRDWeb/
Database coverage dates: Information not found. Bibliographic records were published on DARE until 31st March 2015. Searches of MEDLINE, Embase, CINAHL, PsycINFO and PubMed were continued until the end of the 2014.
Search date: 22/01/21
Retrieved records: 6
Search strategy:

1 (MeSH DESCRIPTOR Pulmonary Disease, Chronic Obstructive EXPLODE ALL TREES) 555
2 (((chronic adj1 (obstructive pulmonary or obstructive lung or obstructive airway or obstructive air-way or obstructive airflow or obstructive air-flow or obstructive bronchitis or obstructive bronchopulmonary or obstructive broncho-pulmonary or obstructive respiratory)))) 712

3 (((chronic adj1 (pulmonary obstructi* or lung obstructi* or airway obstructi* or air-way obstructi* or airflow obstructi* or air-flow obstructi* or bronchitis obstructi* or bronchopulmonary obstructi* or broncho-pulmonary obstructi* or respiratory obstructi*)))) 5
4 (((chronic bronchitis or chronic bronchus or bronchitis chronica))) 72
5 ((emphysem*)) 93
6 (((COPD or COAD or COBD or AECB))) 552
7 ((#1 or #2 or #3 or #4 or #5 or #6)) 993
8 ((mycopd* or my copd*)) 0
9 ((mypr* or my pr*)) 1
10 ((mymhealth* or my mhealth* or my mobile health*)) 0
11 ((#8 or #9 or #10)) 1
12 ((#7 or #11)) 994
13 ((#7 or #11)) FROM 2015 TO 2021 35
14 ((#7 or #11)) IN DARE FROM 2015 TO 2021 6

A.9: Source: PubMed

Interface / URL: https://pubmed.ncbi.nlm.nih.gov/
Database coverage dates: Information not found
Search date: 22/01/21
Retrieved records: 385
Search strategy:

1 "Pulmonary Disease, Chronic Obstructive"[mesh] 57,211
2 chronic obstructive pulmonary[tiab] OR chronic obstructive lung[tiab] OR chronic obstructive airway[tiab] OR (chronic obstructive[tiab] AND air-way[tiab]) OR chronic obstructive airflow[tiab] OR (chronic obstructive[tiab] AND air-flow[tiab]) OR chronic obstructive bronchitis[tiab] OR chronic obstructive bronchopulmonary[tiab] OR (chronic obstructive[tiab] AND broncho-pulmonary[tiab]) OR chronic obstructive respiratory[tiab] 56,089
3 (chronic pulmonary obstructi*[tiab] OR chronic lung obstructi*[tiab] OR chronic airway obstructi*[tiab] OR chronic airflow obstructi*[tiab] OR chronic air-flow obstructi*[tiab] OR chronic respiratory obstructi*[tiab]) OR (chronic[tiab] AND (air-way obstructi*[tiab] OR bronchitis obstructi*[tiab] OR bronchopulmonary obstructi*[tiab])) OR (chronic[tiab] AND broncho-pulmonary[tiab] AND obstructi*[tiab]) 1,172
4 (chronic bronchitis[tiab] OR (chronic[tiab] AND bronchus[tiab]) OR bronchitis chronica[tiab]) 10,726
5 emphysem*[tiab] 28,318
6 (COPD[tiab] OR COAD[tiab] OR COBD[tiab] OR AECB[tiab]) 49,417
7 (#1 OR #2 OR #3 OR #4 OR #5 OR #6) 112,602

8 "Telemedicine"[mesh:noexp] OR "Telerehabilitation"[mesh:noexp] 26,400
9 (mhealth*[tiab] OR m-health*[tiab] OR ehealth*[tiab] OR e-health*[tiab]) 12,139
10 mobile health*[tiab] 5,271
11 "Cell Phone"[mesh:noexp] 8,792
12 mobile phone*[tiab] OR mobile telephone*[tiab] OR mobile handset*[tiab] OR (mobile[tiab] AND hand-set*[tiab]) 10,008
13 cell phone*[tiab] OR cell telephone*[tiab] OR (cell[tiab] AND handset*[tiab]) OR (cellular[tiab] AND hand-set*[tiab]) OR cellular phone*[tiab] OR cellular telephone*[tiab] OR cellular handset*[tiab] OR (cellular[tiab] AND hand-set*[tiab]) 3,954
14 mobiles[tiab] 151
15 "Computers, Handheld"[mesh] 8,774
16 smart phone*[tiab] OR (smart[tiab] AND telephone*[tiab]) OR (smart[tiab] AND handset*[tiab]) OR (smart[tiab] AND hand-set*[tiab]) 1,362
17 smartphone*[tiab] 13,445
18 (iphone*[tiab] OR i-phone*[tiab]) 958
19 (i-pad*[tiab] OR ipad*[tiab]) 1,657
20 (smart[tiab] AND television*[tiab]) OR smart tv*[tiab] 63
21 (digital[tiab] AND (device[tiab] OR devices[tiab] OR technolog*[tiab] OR tool*[tiab] OR tablet*[tiab])) 32,465
22 (mobile[tiab] AND (device[tiab] OR devices[tiab] OR technolog*[tiab] OR tool*[tiab] OR tablet*[tiab])) 23,944
23 (electronic*[tiab] AND (device[tiab] OR devices[tiab] OR technolog*[tiab] OR tool*[tiab] OR tablet*[tiab])) 66,544
24 (smart[tiab] AND (device[tiab] OR devices[tiab] OR technolog*[tiab] OR tool*[tiab] OR tablet*[tiab])) 9,594
25 ((internet[tiab] or online[tiab] or on-line[tiab] or web[tiab]) AND (device[tiab] OR devices[tiab] OR technolog*[tiab] OR tool*[tiab] OR tablet*[tiab])) 71,058
26 (tablet*[tiab] AND (device[tiab] OR devices[tiab] OR technolog*[tiab])) 4,659
27 (smart[tiab] AND (digital*[tiab] OR mobile*[tiab] OR electronic*[tiab] OR internet[tiab] OR online[tiab] OR on-line[tiab] OR web[tiab])) 5,143
28 (device-based[tiab] OR mobile-based[tiab] OR smart-based[tiab]) 3,792
29 "Mobile Applications"[mesh:noexp] 6,849
30 (app[tiab] OR apps[tiab]) 31,961

31 ((digital*[tiab] OR mobile[tiab] OR electronic*[tiab] OR smart*[tiab] OR internet[tiab] OR online[tiab] OR on-line[tiab] OR web[tiab] OR tablet*[tiab] OR device[tiab] OR devices[tiab] OR software*[tiab]) AND application*[tiab]) 178,457

32 (health application*[tiab] OR healthcare application*[tiab] OR medical application*[tiab]) 10,321

33 (android[tiab] OR (google[tiab] AND play[tiab])) 3,784

34 (apple[tiab] OR ios[tiab]) 16,517

35 "Online Systems"[mesh:noexp] 8,399

36 "Internet"[mesh:noexp] 74,577

37 (online[ti] OR on-line[ti] OR internet*[ti]) 45,528

38 online based[tiab] OR (on-line[tiab] AND based[tiab]) OR internet based[tiab] 16,614

39 (online[tiab] OR on-line[tiab] OR internet*[tiab]) AND (educat*[tiab] OR self-manag*[tiab] OR self-care[tiab] OR self-caring[tiab] OR symptom*[tiab] OR rehabilit*[tiab] OR pr[tiab] OR tutorial*[tiab] OR exercis*[tiab]) 45,784

40 (online[tiab] OR on-line[tiab] OR internet*[tiab]) AND (platform*[tiab] OR system[tiab] OR systems[tiab] OR program*[tiab] OR access*[tiab]) 80,090

41 web[ti] 20,538

42 (web-based[tiab] OR webbased[tiab] OR web-site*[tiab] OR website*[tiab] OR web-page*[tiab] OR webpage*[tiab]) 67,963

43 (#8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42) 565,951

44 (#7 AND #43) 2,052

45 mycopd*[tiab] OR (my[tiab] AND copd*[tiab]) 48

46 mypr[tiab] OR myprr[tiab] OR myprtm[tiab] OR (my[tiab] AND pr[tiab]) OR (my[tiab] AND prr[tiab]) OR (my[tiab] AND prtm[tiab]) 20

47 mymhealth*[tiab] OR mymhealth*[ad] 2

48 (my[tiab] AND mhealth*[tiab]) OR (my[ad] AND mhealth*[ad]) 46

49 (my[tiab] AND mobile[tiab] AND health*[tiab]) OR (my[ad] AND mobile[ad] AND health*[ad]) 113

50 (#7 AND (#48 OR #49)) 4

51 (#44 OR #45 OR #46 OR #47 OR #50) 2,112

52 animals [mh] NOT humans [mh:noexp] 4,780,118

53	news[pt] OR editorial[pt] OR case reports[pt] OR case report[ti]	2,951,145	
54	(#51 NOT (#52 OR #53))	2,033	
55	(#51 NOT (#52 OR #53))	from 2015 - 2021	1,266
56	(#51 NOT (#52 OR #53))	English, from 2015 - 2021	1,232
57	medline[sb]	27,459,122	
58	(#56 NOT #57)	385	

Search notes:

1. The 2019 search used the previous PubMed interface at: https://www.ncbi.nlm.nih.gov/pubmed/. This version is no longer available and the legacy version (https://pmlegacy.ncbi.nlm.nih.gov/) has now been retired. The search was therefore done in the new PubMed interface at https://pubmed.ncbi.nlm.nih.gov/.

2. In relation to truncation, PubMed help pages on the new interface state that "at least four characters must be provided in the truncated term" (https://pubmed.ncbi.nlm.nih.gov/help/). For this update search the term in the original MEDLINE strategy *self-car*[tiab]* was therefore translated as *self-care[tiab] OR self-caring[tiab]* (search line 39).

A.10: Source: ClinicalTrials.gov

Interface / URL: https://clinicaltrials.gov/ct2/home
Database coverage dates: Information not found. ClinicalTrials.gov was created as a result of the Food and Drug Administration Modernization Act of 1997 (FDAMA). Site was made available to the public in February 2000.
Search date: 25/01/21 (searches 1 to 16), 27/01/21 (searches 17 to 26)
Retrieved records: 217
Search strategy:

The following 26 searches were done separately in the Expert search interface (https://www.clinicaltrials.gov/ct2/results/refine?show_xprt=Y).

Reflecting the search context, which aimed to balance sensitivity and precision, ClinicalTrials.gov field searching functionality was used.

The 26 sets of results (1032 records in total) were imported into an empty EndNote Library. Records were then deduplicated using Endnote default deduplication settings. 815 results were identified as duplicates and removed. The remaining 217 results were retrieved for assessment.

1. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] (online OR "on-line" OR internet OR internets OR web OR mobile OR mobiles OR app OR apps OR smart) AND AREA[StartDate] RANGE[01/01/2015, 01/25/2021] = 74

2. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] (online OR "on-line" OR internet OR internets OR web OR mobile OR mobiles OR app OR apps OR smart) AND AREA[PrimaryCompletionDate] RANGE[01/01/2015, 01/25/2021] = 63

3. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] (online OR "on-line" OR internet OR internets OR web OR mobile OR mobiles OR app OR apps OR smart) AND AREA[StudyFirstPostDate] RANGE[01/01/2015, 01/25/2021] = 78

4. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] (mhealth OR mhealthcare OR "m-health" OR "m-healthcare" OR ehealth OR ehealthcare OR "e-health" OR "e-healthcare" OR "cell phone" OR "cell telephone" OR "cell handset" OR "cell hand-set" OR "cell phones" OR "cell telephones" OR "cell handsets" OR "cell hand-sets" OR "cellular phone" OR "cellular telephone" OR "cellular handset" OR "cellular hand-set" OR "cellular phones" OR "cellular

telephones" OR "cellular handsets" OR "cellular hand-sets" OR smartphone OR smartphones OR iphone OR "i-phone" OR iphones OR "i-phones" OR ipad OR "i-pad" OR ipads OR "i-pads" OR "device-based" OR "health application" OR "health applications" OR "healthcare application" OR "healthcare applications" OR "medical application" OR "medical applications" OR android OR "google play" OR apple OR ios OR webbased OR website OR websites OR webpage OR webpages) AND AREA[StartDate] RANGE[01/01/2015, 01/25/2021] = 71

5. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] (mhealth OR mhealthcare OR "m-health" OR "m-healthcare" OR ehealth OR ehealthcare OR "e-health" OR "e-healthcare" OR "cell phone" OR "cell telephone" OR "cell handset" OR "cell hand-set" OR "cell phones" OR "cell telephones" OR "cell handsets" OR "cell hand-sets" OR "cellular phone" OR "cellular telephone" OR "cellular handset" OR "cellular hand-set" OR "cellular phones" OR "cellular telephones" OR "cellular handsets" OR "cellular hand-sets" OR smartphone OR smartphones OR iphone OR "i-phone" OR iphones OR "i-phones" OR ipad OR "i-pad" OR ipads OR "i-pads" OR "device-based" OR "health application" OR "health applications" OR "healthcare application" OR "healthcare applications" OR "medical application" OR "medical applications" OR android OR "google play" OR apple OR ios OR webbased OR website OR websites OR webpage OR webpages) AND AREA[PrimaryCompletionDate] RANGE[01/01/2015, 01/25/2021] = 61

6. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR

"chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] (mhealth OR mhealthcare OR "m-health" OR "m-healthcare" OR ehealth OR ehealthcare OR "e-health" OR "e-healthcare" OR "cell phone" OR "cell telephone" OR "cell handset" OR "cell hand-set" OR "cell phones" OR "cell telephones" OR "cell handsets" OR "cell hand-sets" OR "cellular phone" OR "cellular telephone" OR "cellular handset" OR "cellular hand-set" OR "cellular phones" OR "cellular telephones" OR "cellular handsets" OR "cellular hand-sets" OR smartphone OR smartphones OR iphone OR "i-phone" OR iphones OR "i-phones" OR ipad OR "i-pad" OR ipads OR "i-pads" OR "device-based" OR "health application" OR "health applications" OR "healthcare application" OR "healthcare applications" OR "medical application" OR "medical applications" OR android OR "google play" OR apple OR ios OR webbased OR website OR websites OR webpage OR webpages) AND AREA[StudyFirstPostDate] RANGE[01/01/2015, 01/25/2021] = 76

7. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive"

OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] ((digital OR digitally OR electronic) AND (device OR devices OR technology OR technologies OR tool OR tools OR tablet OR tablets)) AND AREA[StartDate] RANGE[01/01/2015, 01/25/2021] = 22

8. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] ((digital OR digitally OR electronic) AND (device OR devices OR technology OR technologies OR tool OR tools OR tablet OR tablets)) AND AREA[PrimaryCompletionDate] RANGE[01/01/2015, 01/25/2021] = 15

9. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive"

OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] ((digital OR digitally OR electronic) AND (device OR devices OR technology OR technologies OR tool OR tools OR tablet OR tablets)) AND AREA[StudyFirstPostDate] RANGE[01/01/2015, 01/25/2021] = 23

10. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] ((tablet OR tablets) AND (device OR devices OR technology OR technologies)) AND AREA[StartDate] RANGE[01/01/2015, 01/25/2021] = 11

11. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR

emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] ((tablet OR tablets) AND (device OR devices OR technology OR technologies)) AND AREA[PrimaryCompletionDate] RANGE[01/01/2015, 01/25/2021] = 10

12. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] ((tablet OR tablets) AND (device OR devices OR technology OR technologies)) AND AREA[StudyFirstPostDate] RANGE[01/01/2015, 01/25/2021] = 12

13. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] ((digital OR digitally OR

tablet OR tablets OR device OR devices OR software OR softwares) AND (application OR applications)) AND AREA[StartDate] RANGE[01/01/2015, 01/25/2021] = 59

14. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] ((digital OR digitally OR tablet OR tablets OR device OR devices OR software OR softwares) AND (application OR applications)) AND AREA[PrimaryCompletionDate] RANGE[01/01/2015, 01/25/2021] = 51

15. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] ((digital OR digitally OR

tablet OR tablets OR device OR devices OR software OR softwares) AND (application OR applications)) AND AREA[StudyFirstPostDate] RANGE[01/01/2015, 01/25/2021] = 59

16. (mycopd OR mycopdr OR mycopdtm OR "my copd" OR "my copdr" OR "my copdtm" OR mypr OR myprr OR myprtm OR "my pr" OR "my prr" OR "my prtm" OR mymhealth OR mymhealthr OR mymhealthtm OR "my mhealth" OR "my mhealthr" OR "my mhealthtm" OR "my mobile health" OR "my mobile healthr" OR "my mobile healthtm") = 6

17. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] (online OR "on-line" OR internet OR internets OR web OR mobile OR mobiles OR app OR apps OR smart) AND AREA[ResultsFirstPostDate] RANGE[01/01/2015, 01/27/2021] = 9

18. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-

flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] (online OR "on-line" OR internet OR internets OR web OR mobile OR mobiles OR app OR apps OR smart) AND AREA[LastUpdatePostDate] RANGE[01/01/2015, 01/27/2021] = 95

19. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] (mhealth OR mhealthcare OR "m-health" OR "m-healthcare" OR ehealth OR ehealthcare OR "e-health" OR "e-healthcare" OR "cell phone" OR "cell telephone" OR "cell handset" OR "cell hand-set" OR "cell phones" OR "cell telephones" OR "cell handsets" OR "cell hand-sets" OR "cellular phone" OR "cellular telephone" OR "cellular handset" OR "cellular hand-set" OR "cellular phones" OR "cellular telephones" OR "cellular handsets" OR "cellular hand-sets" OR smartphone OR smartphones OR iphone OR "i-phone" OR iphones OR "i-phones" OR ipad OR "i-pad" OR ipads OR "i-pads" OR "device-based" OR "health application" OR "health applications" OR "healthcare application" OR "healthcare applications" OR "medical application" OR "medical applications" OR android OR "google play" OR apple OR ios OR webbased OR website OR websites OR webpage OR webpages) AND AREA[ResultsFirstPostDate] RANGE[01/01/2015, 01/27/2021] = 6

20. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-

way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] (mhealth OR mhealthcare OR "m-health" OR "m-healthcare" OR ehealth OR ehealthcare OR "e-health" OR "e-healthcare" OR "cell phone" OR "cell telephone" OR "cell handset" OR "cell hand-set" OR "cell phones" OR "cell telephones" OR "cell handsets" OR "cell hand-sets" OR "cellular phone" OR "cellular telephone" OR "cellular handset" OR "cellular hand-set" OR "cellular phones" OR "cellular telephones" OR "cellular handsets" OR "cellular hand-sets" OR smartphone OR smartphones OR iphone OR "i-phone" OR iphones OR "i-phones" OR ipad OR "i-pad" OR ipads OR "i-pads" OR "device-based" OR "health application" OR "health applications" OR "healthcare application" OR "healthcare applications" OR "medical application" OR "medical applications" OR android OR "google play" OR apple OR ios OR webbased OR website OR websites OR webpage OR webpages) AND AREA[LastUpdatePostDate] RANGE[01/01/2015, 01/27/2021] = 100

21. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic

bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] ((digital OR digitally OR electronic) AND (device OR devices OR technology OR technologies OR tool OR tools OR tablet OR tablets)) AND AREA[ResultsFirstPostDate] RANGE[01/01/2015, 01/27/2021] = 2

22. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] ((digital OR digitally OR electronic) AND (device OR devices OR technology OR technologies OR tool OR tools OR tablet OR tablets)) AND AREA[LastUpdatePostDate] RANGE[01/01/2015, 01/27/2021] = 33

23. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic

bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] ((tablet OR tablets) AND (device OR devices OR technology OR technologies)) AND AREA[ResultsFirstPostDate] RANGE[01/01/2015, 01/27/2021] = 1

24. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] ((tablet OR tablets) AND (device OR devices OR technology OR technologies)) AND AREA[LastUpdatePostDate] RANGE[01/01/2015, 01/27/2021] = 13

25. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR

emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] ((digital OR digitally OR tablet OR tablets OR device OR devices OR software OR softwares) AND (application OR applications)) AND AREA[ResultsFirstPostDate] RANGE[01/01/2015, 01/27/2021] = 8

26. AREA[ConditionSearch] ("chronic obstructive pulmonary" OR "chronic obstructive lung" OR "chronic obstructive airway" OR "chronic obstructive air-way" OR "chronic obstructive airflow" OR "chronic obstructive air-flow" OR "chronic obstructive bronchitis" OR "chronic obstructive bronchopulmonary" OR "chronic obstructive broncho-pulmonary" OR "chronic obstructive respiratory" OR "chronic pulmonary obstruction" OR "chronic lung obstruction" OR "chronic airway obstruction" OR "chronic airflow obstruction" OR "chronic air-flow obstruction" OR "chronic respiratory obstruction" OR "chronic air-way obstruction" OR "chronic bronchitis obstruction" OR "chronic bronchopulmonary obstruction" OR "chronic broncho-pulmonary obstruction" OR "chronic pulmonary obstructive" OR "chronic lung obstructive" OR "chronic airway obstructive" OR "chronic airflow obstructive" OR "chronic air-flow obstructive" OR "chronic respiratory obstructive" OR "chronic air-way obstructive" OR "chronic bronchitis obstructive" OR "chronic bronchopulmonary obstructive" OR "chronic broncho-pulmonary obstructive" OR "chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica" OR emphysema OR emphysemas OR emphysemic OR COPD OR COAD OR COBD OR AECB) AND AREA[InterventionSearch] ((digital OR digitally OR tablet OR tablets OR device OR devices OR software OR softwares) AND (application OR applications)) AND AREA[LastUpdatePostDate] RANGE[01/01/2015, 01/27/2021] = 74

Search note: for the 2021 search two additional potentially useful date fields were identified in ClinicalTrials.gov - ResultsFirstPostDate and LastUpdatePostDate. Searches using these fields to limit the searches (searches 17 to 26) were therefore used for the 2021 update search, in addition to the date fields used for the 2019 search

A.11: Source: WHO International Clinical Trials Registry Portal (ICTRP)

Interface / URL: http://apps.who.int/trialsearch/Default.aspx
Database coverage dates: Information not found. Data sets from data providers are updated every Friday evening according to a schedule. On date of search, files had been imported from data providers between November 2020 and January 2021.
Search date: 25/01/21
Retrieved records: 312
Search strategy:

The following 14 searches were done separately using the advanced search interface at: http://apps.who.int/trialsearch/AdvSearch.aspx.

Reflecting the search context, which aimed to balance sensitivity and precision, ICTRP field searching functionality was used.

For all searches 'Without synonyms' was selected for both the condition terms and the intervention terms.

For all searches, 'ALL' was selected for recruitment status.

For all searches, 'Date of registration' was limited to between: 01/01/2015 and 25/01/2020

The results (410 in total) were imported into an empty EndNote Library. Records were then deduplicated using Endnote default settings. 98 results were identified as duplicates and removed. The remaining 312 results were retrieved for assessment.

Search 1:
The following terms were entered in the condition field search box: chronic obstructive pulmonary OR chronic obstructive lung OR chronic obstructive airway OR chronic obstructive air-way OR chronic obstructive airflow OR chronic obstructive air-flow

The following terms were entered in the intervention field search box: online OR on-line OR internet OR web OR mobile OR app OR smart OR mhealth OR m-health OR ehealth OR e-health OR digital OR electronic OR tablet

= 226 ("246 records for 226 trials found")

Search 2:
The following terms were entered in the condition field search box: chronic obstructive pulmonary OR chronic obstructive lung OR chronic obstructive airway OR chronic obstructive air-way OR chronic obstructive airflow OR chronic obstructive air-flow

The following terms were entered in the intervention field search box: cell phone OR cell telephone OR cell handset OR cell hand-set OR cellular phone OR cellular telephone OR cellular handset OR cellular hand-set OR iphone OR i-phone

= 1 ("1 record for 1 trial found")

Search 3.
The following terms were entered in the condition field search box: chronic obstructive pulmonary OR chronic obstructive lung OR chronic obstructive airway OR chronic obstructive air-way OR chronic obstructive airflow OR chronic obstructive air-flow

The following terms were entered in the intervention field search box: ipad OR i-pad OR device-based OR android OR google play OR ios

= 14 ("14 records for 14 trials found")

Search 4.
The following terms were entered in the condition field search box: chronic obstructive bronchitis OR chronic obstructive bronchopulmonary OR chronic obstructive broncho-pulmonary OR chronic obstructive respiratory

= 1 ("1 record for 1 trials found")

Search 5.
The following terms were entered in the condition field search box: chronic pulmonary obstruction OR chronic lung obstruction OR chronic airway obstruction OR chronic airflow obstruction OR chronic air-flow obstruction OR chronic respiratory obstruction

= 0 ("0 records for 0 trials found")

Search 6.
The following terms were entered in the condition field search box: chronic air-way obstruction OR chronic bronchopulmonary obstruction OR chronic broncho-pulmonary obstruction

= 0 ("0 records for 0 trials found")

Search 7.
The following terms were entered in the condition field search box: chronic pulmonary obstructive OR chronic lung obstructive OR chronic airway obstructive OR chronic airflow obstructive OR chronic air-flow obstructive OR chronic respiratory obstructive

= 2 ("2 records for 2 trials found")

Search 8.
The following terms were entered in the condition field search box: chronic air-way obstructive OR chronic bronchopulmonary obstructive OR chronic

broncho-pulmonary obstructive OR chronic bronchitis OR chronic bronchus OR bronchitis chronica OR emphysem

The following terms were entered in the intervention field search box: online OR on-line OR internet OR web OR mobile OR app OR smart OR mhealth OR m-health OR ehealth OR e-health OR digital OR electronic OR tablet

= 21 ("28 records for 21 trials found")

Search 9.
The following terms were entered in the condition field search box: chronic air-way obstructive OR chronic bronchopulmonary obstructive OR chronic broncho-pulmonary obstructive OR chronic bronchitis OR chronic bronchus OR bronchitis chronica OR emphysem

The following terms were entered in the intervention field search box: cell phone OR cell telephone OR cell handset OR cell hand-set OR cellular phone OR cellular telephone OR cellular handset OR cellular hand-set OR iphone OR i-phone

= 0 (0 records for 0 trials found)

Search 10.
The following terms were entered in the condition field search box: chronic air-way obstructive OR chronic bronchopulmonary obstructive OR chronic broncho-pulmonary obstructive OR chronic bronchitis OR chronic bronchus OR bronchitis chronica OR emphysem

The following terms were entered in the intervention field search box: ipad OR i-pad OR device-based OR android OR google play OR ios

= 2 ("2 record for 2 trials found")

Search 11.
The following terms were entered in the condition field search box: COPD OR COAD OR COBD OR AECB

The following terms were entered in the intervention field search box: online OR on-line OR internet OR web OR mobile OR app OR smart OR mhealth OR m-health OR ehealth OR e-health OR digital OR electronic OR tablet

= 128 ("157 records for 128 trials found")

Search 12.

The following terms were entered in the condition field search box: COPD OR COAD OR COBD OR AECB

The following terms were entered in the intervention field search box: cell phone OR cell telephone OR cell handset OR cell hand-set OR cellular phone OR cellular telephone OR cellular handset OR cellular hand-set OR iphone OR i-phone

= 0 ("0 records for 0 trials found")

Search 13.
The following terms were entered in the condition field search box: COPD OR COAD OR COBD OR AECB

The following terms were entered in the intervention field search box: ipad OR i-pad OR device-based OR android OR google play OR ios

= 4 ("4 records for 4 trials found")

Search 14:

The following search was done using the standard search interface at: http://apps.who.int/trialsearch/Default.aspx. 'Without Synonyms' was selected.

mycopd* OR my copd* OR mypr* OR mymhealth* = 11 ("11 records for 11 trials found").

Search notes:

1. WHO ICTRP has very limited search functionality. Translation of complex strategies, or strategies which combine multiple terms, is challenging.

2. The 'Search Tips' information was not available on date of search ("This page cannot be found")

3. In advanced search, the interface will search for records including part terms (for example the search term *ctio* will find records containing words such as *infection*, *reduction, action* and so on).

4. For search 14 it was not possible to download just those records with a registration date of 2015 to date.

5. It was not possible to search efficiently on the terms *my pr*, *my mhealth*, or *my mobile health* in ICTRP (the *my* is ignored by the interface) - these terms were therefore not included.

A.12: Source: Google

Interface / URL: https://www.google.com/
Database coverage dates: n/a
Search date: 27/01/21 (searches 1 to 3); 29/01/21 (searches 4 to 20)
Retrieved records: 8
Search strategy:

The following targeted searches for research evidence published on NHS sites or produced by NHS organisations were done using Google. The first 5 pages of returned results (or all results if less than 5 pages) for each search were rapidly screened by the Information Specialist for potential relevance. Order of returned results was determined by the Google ranking algorithm. The decision as to which results should be opened and explored further was based on the Information Specialist's judgement. Links within results were followed, as judged appropriate. Results which reported research evidence on myCOPD were retrieved.

1. allintitle: mycopd OR "my copd" site:.nhs.uk = "About 29 results" returned

Repeated the search "with the omitted results included" = "About 27 results" returned

2. allintitle: mypr OR "my pr" site:.nhs.uk = 0 results returned
3. allintitle: mycopd OR "my copd" filetype:pdf = "About 144 results" returned

Repeated the search "with the omitted results included" = "About 144 results" returned

4. allintitle: mypr OR "my pr" filetype:pdf = "About 33 results" returned
5. allintitle: mycopd OR "my copd" filetype:doc = 0 results returned
6. allintitle: mypr OR "my pr" filetype:doc = 1 results returned
7. allintitle: mycopd OR "my copd" filetype:ppt = 0 results returned
8. allintitle: mypr OR "my pr" filetype:ppt = 0 results returned
9. mycopd site:.nhs.uk filetype:pdf = "About 914 results" returned
10. mycopd site:.nhs.uk filetype:doc = 5 results returned
11. mycopd site:.nhs.uk filetype:ppt = 2 results returned
12. "my copd" site:.nhs.uk filetype:pdf = "About 364 results" returned
13. "my copd" site:.nhs.uk filetype:doc = 4 results returned
14. "my copd" site:.nhs.uk filetype:ppt = 2 results returned
15. mypr site:.nhs.uk filetype:pdf = 7 results returned

16. mypr site:.nhs.uk filetype:doc = 0 results returned
17. mypr site:.nhs.uk filetype:ppt = 0 results returned
18. "my pr" site:.nhs.uk filetype:pdf = 4 results returned
19. "my pr" site:.nhs.uk filetype:doc = 0 results returned
20. "my pr" site:.nhs.uk filetype:ppt = 0 results returned

A.13: Source: my mhealth website

Interface / URL: https://mymhealth.com/
Database coverage dates: n/a
Search date: 29/01/21
Retrieved records: 2
Search strategy:

Navigated to Studies page at: https://mymhealth.com/studies

The page content was browsed by the Information Specialist for studies on myCOPD. Studies judged to be relevant were checked against records already retrieved via searches of other sources. Duplicate studies were not retrieved.

Navigated to myCOPD page at https://mymhealth.com/mycopd

The page content was browsed by the Information Specialist for studies on myCOPD. Studies judged to be relevant were checked against records already retrieved via searches of other sources. Duplicate studies were not retrieved.

A.14: Source: Royal College of General Practitioners website

Interface / URL: https://www.rcgp.org.uk/
Database coverage dates: n/a
Search date: 29/01/21
Retrieved records: 0
Search strategy:

A site wide search was done using the search interface at https://www.rcgp.org.uk/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.15: Source: Royal College of Nursing website

Interface / URL: https://www.rcn.org.uk/
Database coverage dates: n/a
Search date: 29/01/21
Retrieved records: 0
Search strategy:

A site wide search was done using the search interface at https://www.rcn.org.uk/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.16: Source: Royal College of Physicians website

Interface / URL: https://www.rcplondon.ac.uk/
Database coverage dates: n/a
Search date: 29/01/21
Retrieved records: 0
Search strategy:

A site wide search was done using the search interface at https://www.rcplondon.ac.uk/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.17: Source: Primary Care Respiratory Society website

Interface / URL: https://www.pcrs-uk.org/
Database coverage dates: n/a
Search date: 29/01/21
Retrieved records: 0
Search strategy:

A site wide search was done using the search interface at https://www.pcrs-uk.org/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.18: Source: British Thoracic Society website

Interface / URL: https://www.brit-thoracic.org.uk/
Database coverage dates: n/a
Search date: 29/01/21
Retrieved records: 0
Search strategy:

A site wide search was done using the search interface at https://www.brit-thoracic.org.uk/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.19: Source: British Lung Foundation website

Interface / URL: https://www.blf.org.uk/
Database coverage dates: n/a
Search date: 29/01/21
Retrieved records: 0
Search strategy:

A site wide search was done using the search interface at https://www.blf.org.uk/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.20: Source: National Association of Primary Care website

Interface / URL: https://napc.co.uk/
Database coverage dates: n/a
Search date: 29/01/21
Retrieved records: 0
Search strategy:

A site wide search was done using the search interface at https://napc.co.uk/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.21: Source: The Royal College of Emergency Medicine website

Interface / URL: https://www.rcem.ac.uk/
Database coverage dates: n/a
Search date: 29/01/21
Retrieved records: 0
Search strategy:

A site wide search was done using the search interface at https://www.rcem.ac.uk/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.22: Source: British Society for Genetic Medicine website

Interface / URL: https://www.bsgm.org.uk/
Database coverage dates: n/a
Search date: 29/01/21
Retrieved records: 0
Search strategy:

A site wide search was done using the search interface at https://www.bsgm.org.uk/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.23: Source: Association of Respiratory Nurse Specialists website

Interface / URL: https://arns.co.uk/
Database coverage dates: n/a
Search date: 29/01/21

Retrieved records: 0
Search strategy:

A site wide search was done using the search interface at https://arns.co.uk/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.24: Source: Infection Prevention Society website
Interface / URL: https://www.ips.uk.net/
Database coverage dates: n/a
Search date: 29/01/21
Retrieved records: 0
Search strategy:

No site wide search found at http://naratbc.org.uk/. A search was done via Google (https://www.google.com/) using the following terms:

site:https://www.ips.uk.net/ myCOPD
site:https://www.ips.uk.net/ myCOPDR
site:https://www.ips.uk.net/ myCOPDTM
site:https://www.ips.uk.net/ myPR
site:https://www.ips.uk.net/ myPRR
site:https://www.ips.uk.net/ myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.25: Source: Association for Respiratory Technology & Physiology website
Interface / URL: http://www.artp.org.uk/
Database coverage dates: n/a
Search date: 29/01/21
Retrieved records: 0
Search strategy:

A site wide search was done using the search interface at http://www.artp.org.uk/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.26: Source: NARA – The Breathing Charity website
Interface / URL: http://naratbc.org.uk/
Database coverage dates: n/a
Search date: 29/01/21
Retrieved records: 0
Search strategy:

No site wide search found at http://naratbc.org.uk/. A search was done via Google (https://www.google.com/) using the following terms

site:http://naratbc.org.uk/ myCOPD
site:http://naratbc.org.uk/ myCOPDR
site:http://naratbc.org.uk/ myCOPDTM
site:http://naratbc.org.uk/ myPR
site:http://naratbc.org.uk/ myPRR
site:http://naratbc.org.uk/ myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

Details of the EAC's Study Selection

Full details of the eligibility criteria for the clinical review are presented in Table A3.

Table A3: EAC selection criteria (clinical)

	Inclusion criteria	Exclusion criteria
Population	People with a diagnosis of COPD	Patients with other health conditions Animal and in vitro studies
Intervention	MyCOPD (alone or in combination with 'standard of care')	Other self-management apps for COPD
Comparator	Anything (for example standard of care) or none (that is single arm study)	
Outcomes	The outcome measures should include: • COPD symptoms assessment (CAT score) • Rates of acute exacerbation • Rates of hospital admissions, readmissions or emergency admissions • Number of consultations with healthcare professionals in primary and secondary care • Rates of inhaler error • Compliance (adherence) to the use of myCOPD including pulmonary rehabilitation (rate of course completed), education, inhaler technique improvement and exercise. • Health-related quality of life • PAM • Self-efficacy for appropriate medication use • Walking test (a 6-minute walking test) • Device-related adverse events	
Study design	Prospective comparative head-to-head studies including RCTs and observational studies (published and unpublished). Non comparative and single arm study. Systematic reviews will be included for reference checking purposes only	Retrospective studies or studies making a retrospective comparison News articles, 'non-'systematic reviews, single case reports
Limits	English language	

A single researcher rapidly assessed the titles and removed the obviously irrelevant records such as those in diseases other than COPD. The titles and abstracts of remaining records were assessed for relevance against the selection criteria (Table A3) by double independent reviewer selection (AP and MC) with disagreements adjudicated by a third reviewer (RM). The EAC obtained the full text of potentially relevant studies (n=212) and these were assessed for relevance against the selection criteria by double independent reviewer selection with disagreements adjudicated by a third reviewer. A PRISMA diagram of record selection by the EAC is provided in Figure A2 and the reason for exclusion of full papers provided in Table A4. The included studies were also assessed for their generalisability to the decision problem.

Figure A2: PRISMA flow diagram of the EAC published study selection (clinical)

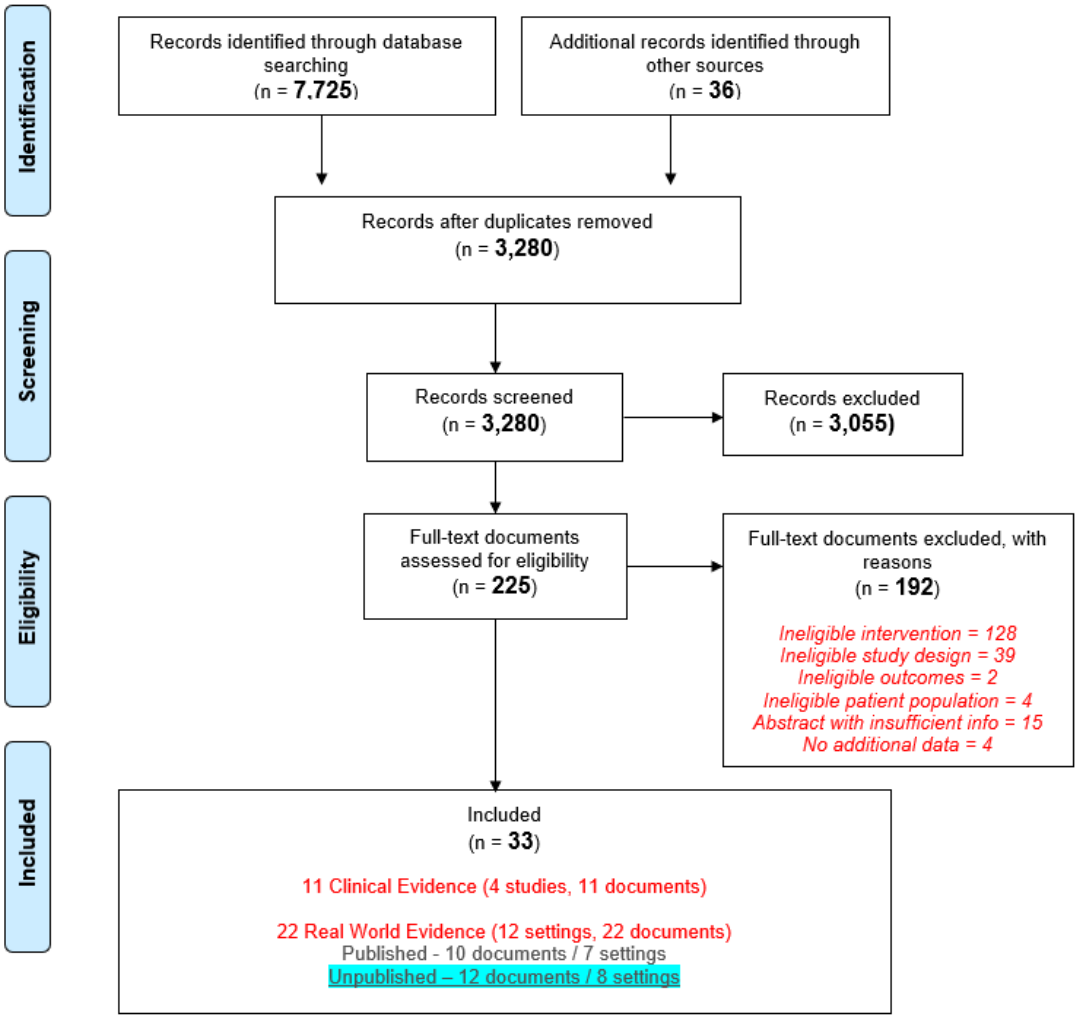

Table A4: Excluded studies at full text selection (n=192) (clinical)

Reference	Exclusion reason
Aalborg University. 2013. Telemedicine for Patients Suffering From COPD (Danish Telecare North Trial). Bethesda: US National Library of Medicine. Trial identifier: NCT01984840.	Ineligible intervention
ADIR Association. 2017. Telemonitoring in Pulmonary Rehabilitation: Feasibility and Acceptability of a Remote Pulse Oxymetry System. Bethesda: US National Library of Medicine. Trial identifier: NCT03295474.	Ineligible intervention
Air Liquide Santé International. 2016. Evaluation of the Performance of an e-Health System. Bethesda: US National Library of Medicine. Trial identifier: NCT02803489.	Ineligible study design
Alharbey R & Chatterjee S 2019. An mHealth Assistive System "MyLung" to Empower Patients with Chronic Obstructive Pulmonary Disease: Design Science Research. JMIR Formative Research, 3 (1), e12489. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6444216/	Ineligible intervention
Ancochea J, Garcia-Rio F, Vazquez-Espinosa E, Hernando-Sanz A, Lopez-Yepes L, Galera-Martinez R, Peces-Barba G, Perez-Warnisher MT, Segrelles-Calvo G, Zamarro C, Gonzalez-Ponce P, Ramos MI, Conforto JI, Jafri S & Soriano JB 2018. Efficacy and costs of telehealth for the management of COPD: the PROMETE II trial. European Respiratory Journal, 51 (5), 5. Available from: https://erj.ersjournals.com/content/51/5/1800354.long	Ineligible intervention
Andalo D 2015. Using apps in community pharmacy. Pharmaceutical Journal, 295 (7876-7877), 152-153.	Ineligible study design
Anonymous 2015. Abstracts from the 4th Chinese Congress on Gerontology and Health Industry. Journal of the American Geriatrics Society, 63 (Suppl 2), S323-S410. Available from: https://onlinelibrary.wiley.com/doi/10.1111/jgs.13704	Ineligible intervention
Anonymous 2018. 2018 Canadian Respiratory Conference Abstracts. Canadian Journal of Respiratory Critical Care and Sleep Medicine, 2 (2), 90-121. Available from: https://www.tandfonline.com/doi/full/10.1080/24745332.2018.1458516	Ineligible intervention
Anonymous 2018. Australia and New Zealand Society of Respiratory Science and the Thoracic Society of Australia and New Zealand Annual Scientific Meeting ANZSRS/TSANZ 2018. Respirology, 23 (Suppl 1), 4-103. Available from: https://onlinelibrary.wiley.com/toc/14401843/23/S1	Ineligible study design
Anonymous 2018. Correction to: Early Changes in eDiary COPD Symptoms Predict Clinically Relevant Treatment Response at 12 Weeks: Analysis from the CRYSTAL Study (COPD: Journal of Chronic Obstructive Pulmonary Disease, (2018), 15, 2, (185-191), 10.1080/15412555.2018.1445213). COPD: Journal of Chronic Obstructive Pulmonary Disease, 15 (3), 313. Available from: https://www.tandfonline.com/doi/abs/10.1080/15412555.2018.1445213?journalCode=icop20	Ineligible intervention
Anonymous 2018. Erratum: Filling the gaps in COPD: the TRIBUTE study (The Lancet (2018) 391(10125) (1004-1006) (S0140673618302526)(10.1016/S0140-6736(18)30252-6)). The Lancet, 391 (10125), 1022. Available from: https://www.sciencedirect.com/science/article/pii/S0140673618303180?via%3Dihub	Ineligible intervention
Anonymous 2019. 2019 Canadian Respiratory Conference Abstracts. Canadian Journal of Respiratory, Critical Care, and Sleep Medicine, 3 (Suppl 1), 1-52. Available from: https://www.tandfonline.com/doi/full/10.1080/24745332.2019.1623590	Ineligible intervention
Apps LD, Harrison SL, Mitchell KE, Williams JEA, Hudson N & Singh SJ 2017. A qualitative study of patients' experiences of participating in space for copd: a self-management programme of activity, coping and education.	Ineligible intervention

Reference	Exclusion reason
ERS monograph, 3 (4), 1-9. Available from: https://openres.ersjournals.com/content/3/4/00017-2017	
AstraZeneca. 2016. A Real-World Assessment of a COPD Disease Management Support Service (Me & My COPD). Bethesda: US National Library of Medicine. Trial identifier: NCT02300090.	Ineligible intervention
Bai, C. 2016. Management of Chronic Obstructive Airway Diseases with E-Health. Respirology, 21 (Suppl 1), 6.	Abstract with insufficent info
Barberan-Garcia A, Gimeno-Santos E, Blanco I, Cano I, Martinez-Palli G, Burgos F, Miralles F, Coca M, Murillo S, Sanz M, Steblin A, Ubre M, Benavent J, Vidal J, Sitges M & Roca J 2018. Protocol for regional implementation of collaborative self-management services to promote physical activity. BMC Health Services Research, 18, 560. Available from: https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-018-3363-8	Ineligible intervention
Barnes A, Newby C, Chaplin E, Houchen-Wolloff L & Singh S 2016. Purposeful physical activity in COPD patients comparing standard and web based pulmonary rehabilitation. European Respiratory Journal, 48 (Suppl 60), PA2056. Available from: https://erj.ersjournals.com/content/48/suppl_60/PA2056	Abstract with insufficent info
Barretto CM, Dekker MKJ, Priori R, Xanthopoulakis C, Wouters EFM, Klee, M., Spruit M & Saini P 2015. Engaging technology for encouraging physical activity in COPD patients: A first user test. European Respiratory Journal, 46 (Suppl 59), PA3564. Available from: https://erj.ersjournals.com/content/46/suppl_59/PA3564	Ineligible intervention
Benzo, R.P., Kramer, K.M., Hoult, J.P., Anderson, P.M., Begue, I.M. & Seifert, S.J. 2018. Development and feasibility of a home pulmonary rehabilitation program with health coaching. Respiratory Care, 63 (2), 131-140. Available from: http://rc.rcjournal.com/content/63/2/131	Ineligible intervention
Berkhof FF, van den Berg JWK, Uil SM & Kerstjens HAM 2015. Telemedicine, the effect of nurse-initiated telephone follow up, on health status and health-care utilization in COPD patients: a randomized trial. Respirology, 20 (2), 279-85. Available from: https://onlinelibrary.wiley.com/doi/full/10.1111/resp.12437	Ineligible intervention
Bernocchi P, Scalvini S, Galli T, Paneroni M, Baratti D, Turla O, La Rovere MT, Volterrani M & Vitacca M 2016. A multidisciplinary telehealth program in patients with combined chronic obstructive pulmonary disease and chronic heart failure: Study protocol for a randomized controlled trial. Trials [Electronic Resource], 17 (1), 462. Available from: https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-016-1584-x	Ineligible intervention
Bhatt SP, Patel SB, Anderson EM, Baugh D, Givens T, Schumann C, Gregory Sanders J, Windham ST, Cutter GR & Dransfield MT 2019. Video telehealth pulmonary rehabilitation intervention in chronic obstructive pulmonary disease reduces 30-day readmissions. American Journal of Respiratory and Critical Care Medicine, 200 (4), 511-513. Available from: https://www.atsjournals.org/doi/pdf/10.1164/rccm.201902-0314LE	Ineligible intervention
Bibeau KB, DiSantostefano RL & Hinds D 2015. Medication Guide Reading Behaviors and Attitudes Among Subjects With Migraine, Asthma, or COPD. Therapeutic Innovation and Regulatory Science, 49 (3), 377-386. Available from: https://journals.sagepub.com/doi/10.1177/2168479014561802	Ineligible study design
Blue Marble Rehab Inc. 2019. Inspiration Point-A Digital Pulmonary Rehabilitation Tool Management Interventions. Bethesda: US National Library of Medicine. Trial identifier: NCT03801330.	Ineligible intervention
Boer L, Bischoff E, van der Heijden M, Lucas P, Akkermans R, Vercoulen J, Heijdra Y, Assendelft W & Schermer T 2019. A Smart Mobile Health Tool Versus a Paper Action Plan to Support Self-Management of Chronic Obstructive Pulmonary Disease Exacerbations: Randomized Controlled	Ineligible intervention

Reference	Exclusion reason
Trial. Jmir Mhealth and Uhealth, 7 (10), e14408. Available from: https://mhealth.jmir.org/2019/10/e14408	
Bond CS & Worswick L 2015. Self Management and Telehealth: Lessons Learnt from the Evaluation of a Dorset Telehealth Program. The Patient: Patient-Centered Outcomes Research, 8 (4), 311-316. Available from: https://link.springer.com/article/10.1007%2Fs40271-014-0091-y	Ineligible intervention
Bourbeau J, Kessler R, Casan P, Koehler D, Tognella S, Viejo JL & Texereau J 2017. An international randomised study of a home-based self-management program for severe COPD: the COPD patient management European trial. Canadian journal of respiratory critical care and sleep medicine, 1 (2), 98. Available from: https://www.tandfonline.com/doi/full/10.1080/24745332.2017.1332400	Ineligible intervention
Bousquet J, Barbara C, Bateman E, Bel E, Bewick M, Chavannes NH, Cruz AA, Haahtela T, Hellings PW, Khaltaev N, Carlsen KL, Muraro A, Cordeiro CR, Rosado-Pinto J, Samolinski B, Strandberg T, Valiulis A, Yorgancioglu A & Zuberbier T 2016. AIRWAYS-ICPs (European Innovation Partnership on Active and Healthy Ageing) from concept to implementation. European Respiratory Journal, 47 (4), 1028-1033. Available from: https://erj.ersjournals.com/content/47/4/1028	Ineligible study design
Burkow TM, Vognild LK, Johnsen E, Risberg MJ, Bratvold A, Breivik E, Krogstad T & Hjalmarsen A 2015. Comprehensive pulmonary rehabilitation in home-based online groups: a mixed method pilot study in COPD. BMC Research Notes, 8, 766. Available from: https://bmcresnotes.biomedcentral.com/articles/10.1186/s13104-015-1713-8	Ineligible intervention
Cerdan J, Catalan-Matamoros D & Berg SW 2017. Online communication in a rehabilitation setting: Experiences of patients with chronic conditions using a web portal in Denmark. Patient Education and Counseling, 100 (12), 2283-2289. Available from: https://www.sciencedirect.com/science/article/pii/S0738399117303713?via%3Dihub	Ineligible intervention
Chamberlain D, Kodgule R, Thorat Y, Das V & Fletcher R 2016. Smart phone-based platform for diagnosing asthma and COPD. European Respiratory Journal, 48 (Suppl 60), PA1033. Available from: https://erj.ersjournals.com/content/48/suppl_60/PA1033	Ineligible intervention
Chaplin E, Hewitt S, Apps L, Edwards K, Brough C, Glab A, Bankart J, Jacob R, Schreder S, Williams J & Singh S 2016. An interactive web-based pulmonary rehabilitation programme: A randomised controlled feasibility trial. European Respiratory Journal, 48 (Suppl 60), PA2064. Available from: https://erj.ersjournals.com/content/48/suppl_60/PA2064	Abstract with insufficent info
Chaplin E, Hewitt S & Singh S 2017. Do patients gain as much knowledge around their condition from a web-based pulmonary rehabilitation programme? Thorax, 72 (Suppl 3), A52-A53. Available from: https://thorax.bmj.com/content/72/Suppl_3/A52.2	Abstract with insufficent info
Chen KY, Hung MH, Chang MC, Kuo C, Lin CM, Chuang LP & Kao KC 2018. Four-weeks remote pulmonary rehabilitation protocol with mobile apps of real-time heart rate monitoring for gold category B/C/D-A study design. Respirology, 23 (Suppl 2), 82. Available from: https://onlinelibrary.wiley.com/doi/10.1111/resp.13419_201	Ineligible intervention
Choi ME, Electricwala B, Hur P & Xiang P 2017. Analysis of Mobile Health Applications for Chronic Obstructive Pulmonary Disease Management Using the Mobile Application Rating Scale and Gold Guideline Recommendations. Value In Health, 20 (5), A3-A3. Available from: https://www.sciencedirect.com/science/article/pii/S1098301517302516	Abstract with insufficent info
Clinical Trials and Research Governance – University of Oxford. 2019. Optimising the feasibility and acceptability of a multi-component, digital health intervention to improve outcomes for people with chronic obstructive	Ineligible intervention

Reference	Exclusion reason
pulmonary disease. London: BioMed Central Limited. Trial identifier: ISRCTN82570166.	
COPD Foundation. 2018. Monitoring and Peer Support to Improve Treatment Adherence and Outcomes. Bethesda: US National Library of Medicine. Trial identifier: NCT03446768.	Ineligible intervention
Cox NS, McDonald CF, Hill CJ, O'Halloran P, Alison JA, Zanaboni P, Macdonald H & Holland AE 2018. Telerehabilitation for chronic respiratory disease. Cochrane Database of Systematic Reviews, 2018 (6), CD013040. Available from: https://www.cochrane.org/CD013040/AIRWAYS_telerehabilitation-chronic-respiratory-disease	Ineligible study design
Cravo J & Matos P 2017. Development of an internet portal on COPD in Portuguese. Chest, 151 (5), 95A-95A. Available from: https://journal.chestnet.org/article/S0012-3692(17)30643-8/abstract	Ineligible study design
de Boer G, Mennema B, van Noort E, Birnie E & In 't Veen J 2016. Self-efficacy in patients with COPD using an online selfmanagement program. European Respiratory Journal, 48 (Suppl 60), OA4973. Available from: https://erj.ersjournals.com/content/48/suppl_60/OA4973	Ineligible intervention
De Boer G, Mennema B, van Noort E, Birnie E & Veen HI 2017. Use of an online selfmanagement program improves self-efficacy abilities in COPD patients. European Respiratory Journal, 50 (Suppl 61), PA1092. Available from: https://erj.ersjournals.com/content/50/suppl_61/PA1092	Ineligible intervention
Dekker-van Weering MGH, Vollenbroek-Hutten MMR & Hermens HJ 2016. Adherence to an online exercise program for COPD patients in the home environment- a pilot study. Health and Technology, 6 (4), 259-268. Available from: https://link.springer.com/article/10.1007%2Fs12553-016-0137-3	Ineligible intervention
Deshpande PD, Vempada R & Sinharay A 2016. A Smart Mobile-Phone Based System to Assist in the Diagnosis of Copd Patients. Respirology, 21 (Suppl 3), 42-42. Available from: https://onlinelibrary.wiley.com/doi/10.1111/resp.12939_14	Ineligible intervention
Ding H, Karunanithi M, Ireland D, McCarthy L, Hakim R, Phillips K, Pradhan R, Seah EH, Bowman RV, Fong K, Masel P & Yang IA 2019. Evaluation of an innovative mobile health programme for the self-management of chronic obstructive pulmonary disease (MH-COPD): protocol of a randomised controlled trial. BMJ Open, 9 (4), e025381. Available from: https://bmjopen.bmj.com/content/9/4/e025381	Ineligible intervention
Disler R, Inglis S, Newton P, Currow D, Macdonald P, Glanville A, Donesky D, Carrieri-Kohlman V & Davidson P 2015. Attitudes to Online Delivery of Health Information and Chronic Disease Management in Chronic Obstructive Pulmonary Disease: Focus Group Study. Respirology, 20 (Suppl 2), 105. Available from: https://onlinelibrary.wiley.com/doi/10.1111/resp.12495_9	Ineligible study design
Donaldson GC, Finney L, Wiseman D, Pandis I, Rowe A, Loza M, Branigan P, Avey S, Stevenson CS, Baribaud F & Wedzicha JA 2019. Comparison of Paper and Tablet Based App Diary Cards in COPD Patients. American Journal of Respiratory and Critical Care Medicine, 199, A3278. Available from: https://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2019.199.1_MeetingAbstracts.A3278	Ineligible intervention
Dyrvig AK, Gerke O, Kidholm K & Vondeling H 2015. A cohort study following up on a randomised controlled trial of a telemedicine application in COPD patients. Journal of Telemedicine & Telecare, 21 (7), 377-84. Available from: https://journals.sagepub.com/doi/abs/10.1177/1357633X15572202?rfr_dat=cr_pub%3Dpubmed&url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org&journalCode=jtta	Ineligible intervention

Reference	Exclusion reason
Emory University. 2016. Smartphone Delivered In-home Cardiopulmonary Rehabilitation. Bethesda: US National Library of Medicine. Trial identifier: NCT02791685.	Ineligible intervention
Esteban C. 2010. Evaluation the Effectiveness of a Telemonitoring Program in a Cohort of COPD Patient With Frequent Readmissions. Bethesda: US National Library of Medicine. Trial identifier: NCT02528370.	Ineligible intervention
Evans CN, Volpp KG, Polsky D, Small DS, Kennedy EH, Karpink K, Djaraher R, Mansi N, Rareshide CAL & Patel MS 2019. Prediction using a randomized evaluation of data collection integrated through connected technologies (PREDICT): Design and rationale of a randomized trial of patients discharged from the hospital to home. Contemporary Clinical Trials, 83 (2019), 53-56. Available from: https://www.sciencedirect.com/science/article/pii/S1551714419301272?via%3Dihub	Ineligible intervention
Farias R, Sedeno M, Beaucage D, Drouin I, Ouellet I, Joubert A, Abimaroun R, Patel M, Rjeili MA & Bourbeau J 2019. Innovating the treatment of COPD exacerbations: A phone interactive telesystem to increase COPD Action Plan adherence. BMJ Open Respiratory Research, 6 (1), e000379. Available from: https://bmjopenrespres.bmj.com/content/6/1/e000379.abstract	Ineligible intervention
Farmer A, Williams V, Velardo C, Shah SA, Yu LM & Rutter H 2016. Self-management support using an Internet-linked tablet computer based intervention in chronic obstructive pulmonary disease (EDGE): randomised controlled trial. Npj Primary Care Respiratory Medicine, 26 (16022), 10-CR024. Available from: https://bmjopen.bmj.com/content/4/1/e004437	Ineligible intervention
Farmer A, Williams V, Velardo C, Shah SA, Yu LM, Rutter H, Jones L, Williams N, Heneghan C, Price J, Hardinge M & Tarassenko L 2017. Self-Management Support Using a Digital Health System Compared With Usual Care for Chronic Obstructive Pulmonary Disease: Randomized Controlled Trial. Journal of Medical Internet Research, 19 (5), e144. Available from: https://www.jmir.org/2017/5/e144/	Ineligible intervention
Figge HL 2018. Apps breathe life into COPD patients. U.S. Pharmacist, 43 (1), 25-29. Available from: https://www.uspharmacist.com/article/apps-breathe-life-into-copd	Ineligible study design
First Affiliated Hospital of Guangzhou Medical University. 2017. Platform construction of comprehensive prevention and control of Chronic Obstructive Pulmonary Disease in community based on the Internet. Chengdu: Chinese University of Hong Kong. Trial identifier: ChiCTR-OOC-17011794.	Ineligible intervention
First Affiliated Hospital of Guangzhou Medical University. 2018. Effect of the Integrated Tele-monitoring Management of NIV Treatment. Bethesda: US National Library of Medicine. Trial identifier: NCT03471091.	Ineligible intervention
Fitzsimmons DA, Thompson J, Bentley CL & Mountain GA 2016. Comparison of patient perceptions of Telehealth-supported and specialist nursing interventions for early stage COPD: a qualitative study. BMC Health Services Research, 16 (1), 420. Available from: https://bmchealthservres.biomedcentral.com/articles/10.1186/s12913-016-1623-z	Ineligible intervention
Fondazione Salvatore Maugeri. 2013. Telehealth Program in Chronic Patients. Bethesda: US National Library of Medicine. Trial identifier: NCT02269618.	Ineligible intervention
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Soerensen D & Svenningsen H 2016. Feasibility of web-based protocol in a 12 weeks home-based IMT program for individuals with COPD. European Respiratory Journal, 48 (suppl 60), PA1618. Available from: https://erj.ersjournals.com/content/48/suppl_60/PA1618	Ineligible intervention
Sollie A 2017. Smart technology in COPD: Effective for up to six months. Huisarts En Wetenschap, 60 (9), 431. Available from: https://link.springer.com/article/10.1007%2Fs12445-017-0270-x	Ineligible study design
Soriano JB, Garcia-Rio F, Vazquez-Espinosa E, Conforto JI, Hernando-Sanz A, Lopez-Yepes L, Galera-Martinez R, Peces-Barba G, Gotera-Rivera CM, Perez-Warnisher MT, Segrelles-Calvo G, Zamarro C, Gonzalez-Ponce P, Ramos MI, Jafri S & Ancochea J 2018. A multicentre, randomized controlled trial of telehealth for the management of COPD. Respiratory Medicine, 144 (Nov), 74-81. Available from: https://www.sciencedirect.com/science/article/pii/S0954611118303147?via%3Dihub	Ineligible intervention
Steimle F, Wieland M, Mitschang B, Wagner S & Leymann F 2017. Extended provisioning, security and analysis techniques for the ECHO health data management system. Computing, 99 (2), 183-201. Available from: https://link.springer.com/article/10.1007/s00607-016-0523-8	Ineligible study design
Swaminathan S, Gerber AN, Qirko K, Smith T, Corcoran E & Wysham N 2018. Revon Smart Symptom Tracker: A Mobile Diagnostic and Triage Application for Reducing COPD Exacerbations. American Journal of Respiratory and Critical Care Medicine, 197, A4982. Available from: https://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2018.197.1_MeetingAbstracts.A4982	Ineligible study design
Talboom-Kamp, E., Kasteleyn, M., Verdijk, N., Chavannes, N., Harmans, L., Talboom, I. & Numans, M. 2017. Stimulation of usage of self-management platforms through integration in disease management. European Respiratory Journal, 50. Available from: https://www.cochranelibrary.com/central/doi/10.1002/central/CN-01791859/full	Ineligible intervention
Talboom-Kamp EP, Verdijk NA, Kasteleyn MJ, Harmans LM, Talboom IJ, Looijmans-van den Akker I, van Geloven N, Numans ME & Chavannes NH 2017. The Effect of Integration of Self-Management Web Platforms on Health Status in Chronic Obstructive Pulmonary Disease Management in Primary Care (e-Vita Study): Interrupted Time Series Design. Journal of Medical Internet Research, 19 (8), e291. Available from: https://www.jmir.org/2017/8/e291/	Ineligible intervention
Talboom-Kamp EPWA, Holstege Marije S, Chavannes Niels H & Kasteleyn Marise J 2019. Effects of use of an eHealth platform e-Vita for COPD patients on disease specific quality of life domains. Respiratory Research, 20 (1), 146. Available from: https://respiratory-research.biomedcentral.com/articles/10.1186/s12931-019-1110-2	Ineligible intervention
Tamamoto K, Ueki J, Sano E, Ikeda M, Hino K, Sano Y, Wada H & Kurosawa H 2017. The Development of New-Generation Application Software of Tablet Pc That Interactively Carry out Personalized Self-Management Education to Patients with Copd Receiving Ltot. Respirology, 22 (suppl 3), 105-106. Available from: https://onlinelibrary.wiley.com/doi/full/10.1111/resp.13207_54	Ineligible study design
Tamamoto K, Ueki J, Sano E, Nomura N, Ikeda M, Hino K, Sano Y, Nagashima S, Suzuki Y & Sasaki S 2019. Developing a Novel Application Software for iPad that Interactively Carries Out Personalized Self-Management Education to COPD Patients Receiving Long-Term Oxygen Therapy: A Pilot Study. American Journal of Respiratory and Critical Care Medicine, 199, A2987. Available from:	Ineligible intervention

Reference	Exclusion reason
https://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2019.199.1_MeetingAbstracts.A2987	
Teylan M, Kantorowski A, Homsy D, Kadri R, Richardson C & Moy M 2018. Physical activity in COPD: Minimal clinically important difference for medical events. Chronic Respiratory Disease, 16, 1-9. Available from: https://journals.sagepub.com/doi/10.1177/1479973118816424#	Ineligible intervention
Thorax Research Foundation. 2015. Home Rehabilitation Via Telemonitoring in Patients With COPD. Bethesda: US National Library of Medicine. Trial identifier: NCT02618746.	Ineligible intervention
Tistad M, Lundell S, Nyberg A, Wiklund M & Wadell K 2017. The COPD-web - participatory development of an internet based tool to support health and an active lifestyle for people with COPD. European Respiratory Journal, 50 (suppl 61), OA3200. Available from: https://erj.ersjournals.com/content/50/suppl_61/OA3200	Ineligible study design
Toronto East General Hospital. 2012. Program of Integrated Care for Patients With Chronic Obstructive Pulmonary Disease and Multiple Comorbidities. Bethesda: US National Library of Medicine. Trial identifier: NCT01648621.	Ineligible intervention
Tsai L, McNamara R, Moddel C, McKenzie D, Alison J & McKeough Z 2016. Telerehabilitation improves exercise capacity and quality of life in people with chronic obstructive pulmonary disease (COPD): a randomised controlled trial. Respirology, 21 (suppl 2), 136. Available from: https://onlinelibrary.wiley.com/doi/full/10.1111/resp.12755	Ineligible intervention
Udsen FW, Lilholt PH, Hejlesen OK & LH, E. 2017. Subgroup analysis of telehealthcare for patients with chronic obstructive pulmonary disease: The cluster-randomized danish telecare north trial. Clinicoeconomics and Outcomes Research, 9, 391-401. Available from: https://www.dovepress.com/subgroup-analysis-of-telehealthcare-for-patients-with-chronic-obstruct-peer-reviewed-article-CEOR	Ineligible intervention
Ueki J, Takizawa M, Sano E, Kurosawa H, Wada H, Atsuta R, Ikeda M & Sano Y 2015. Development Of The Novel Interactive Application Software Of Ipad For COPD Self-Management Education. American Journal of Respiratory and Critical Care Medicine, 191, A1112. Available from: https://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2015.191.1_MeetingAbstracts.A1112	Ineligible intervention
Ullman TA & Atreja A 2017. Building evidence for care beyond the medical centre. The Lancet, 390 (10098), 919-920. Available from: https://www.sciencedirect.com/science/article/pii/S0140673617318573?via%3Dihub	Ineligible study design
Umeå University. 2016. Feasibility and Effects of KOL-webben in Patients With COPD. Bethesda: US National Library of Medicine. Trial identifier: NCT02696187.	Ineligible intervention
Umeå University. 2018. Increase Level of Physical Activity and Decrease Use of Health Care for People With COPD. Bethesda: US National Library of Medicine. Trial identifier: NCT03746873.	Ineligible intervention
University Health Network. 2016. Effects of remote patient monitoring on chronic disease management. BioMed Central Limited. Trial identifier: ISRCTN41238563.	Ineligible intervention
University Health Network Toronto. 2016. Effects of Remote Patient Monitoring on Chronic Disease Management. Bethesda: US National Library of Medicine. Trial identifier: NCT03127852.	Ineligible intervention
University Health Network Toronto. 2019. A Wearable and a Self-management Application for Chronic Obstructive Pulmonary Disease (COPD) Patients at Home. Bethesda: US National Library of Medicine. Trial identifier: NCT03857061.	Ineligible intervention

Reference	Exclusion reason
University Hospital Bispebjerg and Frederiksberg. 2016. COPD Online Rehabilitation (CORe). Bethesda: US National Library of Medicine. Trial identifier: NCT02667171.	Ineligible intervention
University Hospitals of Leicester NHS Trust. 2015. InterSPACE: feasibility of an integrated telehealth and self-management programme for individuals hospitalised with an exacerbation of COPD. London: BioMed Central Limited. Trial identifier: ISRCTN13081008.	Ineligible intervention
University of Alabama at Birmingham. 2017. Smart Telehealth Exercise Intervention to Reduce COPD Readmissions. Bethesda: US National Library of Medicine. Trial identifier: NCT03089853.	Ineligible intervention
University of Glasgow. 2014. An Evaluation of Web Based Pulmonary Rehabilitation. Bethesda: US National Library of Medicine. Trial identifier: NCT02404831.	Ineligible intervention
University of Kansas Medical Center. 2018. Innovative Pulmonary Rehabilitation Telehealth Program for Improving COPD Patient Outcomes. Bethesda: US National Library of Medicine. Trial identifier: NCT03489642.	Ineligible intervention
University of Lincoln. 2019. Use of MonitorMe in COPD. Bethesda: US National Library of Medicine. Trial identifier: NCT04108143.	Ineligible intervention
University of Southampton. 2015. Digital interventions for chronic obstructive pulmonary disease (COPD). London: BioMed Central Limited. Trial identifier: ISRCTN75958874.	Ineligible intervention
University of Sydney. 2019. Evaluation of the mobile pulmonary rehabilitation (m-PR) platform on exercise capacity and health status in people with chronic lung disease, 18 Years. Sydney: National Health and Medical Research Council (NHMRC) Clinical Trials Centre - University of Sydney. Trial identifier: ACTRN12619001253190.	Ineligible intervention
University of Wisconsin Madison. 2018. Multiple Chronic Conditions for Older Adults. Bethesda: US National Library of Medicine. Trial identifier: NCT03387735.	Ineligible intervention
VA Office of Research and Development. 2019. COPD Access to Pulmonary Rehabilitation Intervention. Bethesda: US National Library of Medicine. Trial identifier: NCT03794921.	Ineligible intervention
VA Office of Research and Development. 2020. The Impact of a Home-based Pulmonary Telerehabilitation Program in Acute Exacerbations of COPD. Bethesda: US National Library of Medicine. Trial identifier: NCT03997513.	Ineligible intervention
Van Alstyne S 2018. Smarter technology. Pharmaceutical Manufacturing and Packing Sourcer, 2018 (Aug), 44-47. Available from: http://www.samedanltd.com/magazine/15/peyperview/pdf/issue/292/article/4864	Ineligible study design
Van Berkel C, Almond P, Hughes C, Smith M, Horsfield D & Duckworth H 2019. Retrospective observational study of the impact on emergency admission of telehealth at scale delivered in community care in Liverpool, UK. BMJ Open, 9 (7), e028981. Available from: https://bmjopen.bmj.com/content/9/7/e028981	Ineligible intervention
van der Weegen S, Verwey R, Spreeuwenberg M, Tange H, van der Weijden T & de Witte L 2015. It's LiFe! Mobile and Web-Based Monitoring and Feedback Tool Embedded in Primary Care Increases Physical Activity: A Cluster Randomized Controlled Trial. Journal of Medical Internet Research, 17 (7), e184. Available from: https://www.jmir.org/2015/7/e184/	Ineligible intervention
Van Noort E, Kasteleyn M, Veen HIT, Mennema B & Chavannes N 2017. Selfmanagement by eHealth in asthma and COPD patients: with or without the professional. European Respiratory Journal, 50 (suppl 61), PA1606. Available from: https://erj.ersjournals.com/content/50/suppl_61/PA1606	Ineligible intervention
Vasilopoulou M, Papaioannou AI, Chynkiamis N, Vasilogiannakopoulou T, Spetsioti S, Louvaris Z, Kortianou E, Kocsis O, Tsopanoglou A & Feridou C 2015. Effectiveness of home telerehabilitation on functional capacity and	Abstract with

Reference	Exclusion reason
daily physical activity in COPD patients. European Respiratory Journal, 46 (suppl 59), OA273. Available from: https://erj.ersjournals.com/content/46/suppl_59/OA273	insufficent info
Vasilopoulou M, Papaioannou AI, Kaltsakas G, Louvaris Z, Chynkiamis N, Spetsioti S, Kortianou E, Genimata SA, Palamidas A, Kostikas K, Koulouris NG & Vogiatzis I 2017. Home-based maintenance tele-rehabilitation reduces the risk for acute exacerbations of COPD, hospitalisations and emergency department visits. European Respiratory Journal, 49 (5), 1602129. Available from: https://erj.ersjournals.com/content/49/5/1602129	Ineligible intervention
Vastra Gotaland Region. 2018. Remote Monitoring of Patients With COPD. Bethesda: US National Library of Medicine. Trial identifier: NCT03558763.	Ineligible intervention
Veen JI, Mennema B, Beekhof AL, Van Noort E & Chavannes N 2015. Adherence to online selfmanagement in patients with COPD or asthma: The role of disease burden. European Respiratory Journal, 46 (Suppl 59), PA2788. Available from: https://erj.ersjournals.com/content/46/suppl_59/PA2788	Ineligible intervention
Velardo C, Shah SA, Gibson O, Clifford G, Heneghan C, Rutter H, Farmer A & Tarassenko L 2017. Digital health system for personalised COPD long-term management. BMC Medical Informatics & Decision Making, 17 (1), 19. Available from: https://bmcmedinformdecismak.biomedcentral.com/articles/10.1186/s12911-017-0414-8	Ineligible intervention
Vitacca M, Fumagalli LP, Borghi G, Colombo F, Castelli A, Scalvini S & Masella C 2016. Home-Based Telemanagement in Advanced COPD: Who Uses it Most? Real-Life Study in Lombardy. Copd: Journal of Chronic Obstructive Pulmonary Disease, 13 (4), 491-498. Available from: https://www.tandfonline.com/doi/full/10.3109/15412555.2015.1113243	Ineligible intervention
Vitacca M, Paneroni M, Grossetti F & Ambrosino N 2016. Is There Any Additional Effect of Tele-Assistance on Long-Term Care Programmes in Hypercapnic COPD Patients? A Retrospective Study. Copd: Journal of Chronic Obstructive Pulmonary Disease, 13 (5), 576-82. Available from: https://www.tandfonline.com/doi/full/10.3109/15412555.2016.1147542	Ineligible intervention
Wan ES, Kantorowski A, Kadri R, Richardson CR, Gagnon D, Garshick E & Moy M 2019. Internet-Mediated, Pedometer-Based Physical Activity Intervention Reduces Risk of Future Acute Exacerbations in COPD: A Randomized Trial. American Journal of Respiratory and Critical Care Medicine, 199, A4274. Available from: https://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2019.199.1_MeetingAbstracts.A4274	Ineligible intervention
Wan ES, Kantorowski A, Teylan M, Kadri R, Richardson CR, Garshick E, Gagnon DR, Coull B & Moy ML 2017. Patterns of change in daily step count among COPD patients enrolled in A 3-month physical activity intervention. American Journal of Respiratory and Critical Care Medicine, 195 (9), A4939. Available from: https://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2017.195.1_MeetingAbstracts.A4939	Ineligible intervention
Wise J 2016. New app for COPD patients is among innovation tariff's six new technologies. British Medical Journal, 355, i5922. Available from: https://www.bmj.com/content/355/bmj.i5922	Ineligible study design
Wu R, De Lara E, Liaqat D, Thukral I & Gershon AS 2016. Feasibility Of Using Smartwatches And Smartphones To Monitor Patients With COPD. American Journal of Respiratory and Critical Care Medicine, 193, A1695. Available from: https://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2016.193.1_MeetingAbstracts.A1695	Ineligible intervention
Wysham NG, Mathews A, Nicolla J, Cox CE & Kamal A 2016. Derivation and User-Testing of Myq-COPD: A Question Prompt List App for Patients with Chronic Obstructive Pulmonary Disease. American Journal of Respiratory and Critical Care Medicine, 193, A1088. Available from:	Ineligible study design

Reference	Exclusion reason
https://www.atsjournals.org/doi/abs/10.1164/ajrccm-conference.2016.193.1_MeetingAbstracts.A1088	
York Health Economics Consortium Ltd. NHS Innovation Accelerator. Economic Impact Evaluation Case Study: myCOPD. YHEC. York: York Health Economics Consortium Ltd; 2018. 1-4. Available from: https://nhsaccelerator.com/wp-content/uploads/2018/03/myCOPD-Economic-Case-Study.pdf.	No additional data
Zakrisson AB, Aneros T, Eliason G & Forsberg A 2016. Using a mobile app to motivate exercise in persons with COPD: A mixed method study. European Respiratory Journal, 48 (suppl 60), PA3955. Available from: https://erj.ersjournals.com/content/48/suppl_60/PA3955	Ineligible intervention

ECONOMIC EVIDENCE: CRITIQUE OF THE SUBMISSION SEARCH METHODS

Appendix A of the company economic submission contained a description of the search methodology used to retrieve relevant economic evidence.

Search methods reporting

Although the company submission search reporting did not adhere to all elements of the PRISMA-S (Preferred Reporting Items for Systematic reviews and Meta-Analyses literature search extension) checklist) (Rethlefsen et al. 2021), the overall reporting was reasonably transparent and enough detail was given to enable assessment and reproduction.

Currency of searches

The MEDLINE and Embase searches were conducted on 25/05/2021. The Google Scholar search was conducted between 17/06/2021 and 18/06/2021. The searches therefore had reasonably good currency at the date of submission (02/07/2021).

Information resources searched

The information resources searched were MEDLINE, Embase and Google Scholar. MEDLINE and Embase in particular are commonly regarded as key search resources for systematic reviews. The search methods could have been enhanced by including a wider range of information resources – for example, databases of health technology assessments, multidisciplinary databases, additional databases containing conference abstracts and specialist economics databases containing economic evidence.

Search strategy

The MEDLINE and Embase search strategies were assessed using the Peer Review of Electronic Search Strategies (PRESS) Checklist (McGowan et al. 2016). No spelling or syntax errors were identified. The three-concept structural approach used to retrieve evidence for the topic was relatively focused rather than sensitivity-maximising, and the range of subject heading and free text search terms included for the concepts of interest was limited. The sensitivity of the searches could potentially have been enhanced by using a two-concept structural approach for the topic (COPD AND device – with a published economics search filter applied to reduce record numbers if necessary), and by

including a wider range of variant subject heading and free text search terms for the concepts of interest. The strategies were restricted to studies published in English from 2012 to date. No rationale was given for either restriction.

The Google Scholar search strategy - as reported - also appeared to have limitations. The search terms as reported were: *'myCOPD' or "my COPD"*. When run in Google Scholar this search returns one result (25/07/2021). In Google Scholar the Boolean operator should be in upper case. If the search terms are run in Google Scholar using upper case Boolean OR (*'myCOPD' OR "my COPD"*) 305 results are returned (25/07/2021).

ECONOMIC EVIDENCE: DETAILS OF RE-RUN COMPANY SEARCHES

Economic evidence: re-run company searches - resources searched

The information resources searched for the re-run company searches are shown in Table A5.

Table A5: Economic evidence - re-run company searches - databases and information sources searched

Resource	Interface / URL
MEDLINE(R) ALL	OvidSP
Embase	OvidSP
Google Scholar	https://scholar.google.com/

Economic evidence: re-run company searches - running the search strategies and downloading results

The company searches were re-run using the search methods as reported in the submission.

Results of the searches were downloaded and imported into EndNote reference management software. The records were deduplicated using several algorithms.

Economic evidence: re-run company searches - literature search results

The searches were conducted on 05/07/2021 and identified 458 records (Table A6). Following deduplication, 328 records were assessed for relevance.

Table A6: Economic evidence - re-run company searches - literature search results

Resource	Number of records identified
Databases	
Ovid MEDLINE(R) ALL	145
Embase	312
Google Scholar	1
Total number of records retrieved	**458**
Total number of records after deduplication	**328**

Economic evidence: re-run company searches - full search strategies

A.1: Source: MEDLINE(R) ALL

Interface / URL: OvidSP
Database coverage dates: 1946 to July 02, 2021
Search date: 05/07/2021
Retrieved records: 145
Search strategy:

1 Pulmonary Disease, Chronic Obstructive/ (43112)
2 copd.tw. (49273)
3 coad.tw. (526)
4 1 or 2 or 3 (61674)
5 self management.mp. or Self-Management/ (22345)
6 pulmonary rehabilitation.mp. (4099)
7 5 or 6 (26196)
8 (online or app or application).tw. (1022633)
9 (e-health or ehealth or m-health or mhealth).tw. (9249)
10 8 or 9 (1028685)
11 4 and 7 and 10 (178)
12 limit 11 to (english language and yr="2012 -Current") (145)

A.2: Source: Embase

Interface / URL: OvidSP
Database coverage dates: 1974 to 2021 July 02
Search date: 05/07/2021
Retrieved records: 312
Search strategy:

1 Pulmonary Disease, Chronic Obstructive/ (60943)
2 copd.tw. (94305)

3 coad.tw. (667)
4 1 or 2 or 3 (124693)
5 self management.mp. or Self-Management/ (66511)
6 pulmonary rehabilitation.mp. (9808)
7 5 or 6 (75663)
8 (online or app or application).tw. (1268589)
9 (e-health or ehealth or m-health or mhealth).tw. (10705)
10 8 or 9 (1275590)
11 4 and 7 and 10 (379)
12 limit 11 to (english language and yr="2012 -Current") (312)

A.3: Source: Google Scholar

Interface / URL: https://scholar.google.com/
Database coverage dates: Information not found
Search date: 05/07/2021
Retrieved records: 1
Search strategy:

The company submission search methods reported: " A Google Scholar search was conducted on 17 and 18/6/2021, using the search terms ‘myCOPD’ or “my COPD”.

The following search terms were entered into the interface at: https://scholar.google.com/. All settings were left as default.

‘myCOPD’ or “my COPD” = 1 result returned

ECONOMIC EVIDENCE: DETAILS OF EAC *DE NOVO* SEARCHES

The submission search methods had limitations that could potentially impact on search sensitivity and the identification of relevant evidence. The EAC therefore conducted a *de novo* literature search to identify economic evidence.

Economic evidence: EAC searches - search strategy

A strategy was developed for MEDLINE (Ovid interface). The strategy was designed to identify economic evaluations of myCOPD. The final strategy for MEDLINE used is shown in Figure A3 below.

The main structure of the strategy consisted of three concepts:

1) COPD (search lines 1 – 7)
2) myCOPD (search lines 8 – 45)
3) Economic evaluations (search lines 52 – 68)

The search concepts were combined as follows: COPD AND myCOPD AND economic evaluations.

The strategy also searched on terms related to the technology brand name and manufacturer name (search lines 47 to 50).

The search terms for the COPD and myCOPD concepts reflected those used in the EAC *de novo* clinical search strategy. For details on the search development context for these terms, please see the section above (*Clinical evidence: EAC* de novo *searches – search strategy*).

The strategy excluded animal studies using a standard algorithm (search line 70). The strategy also excluded records indexed as news, editorial and case report publication types, and records with the phrase 'case report' in the title (search line 71). The search was limited to studies published from 2015 to date (search line 73) as myCOPD was understood to be launched then. The company, in its response to the EACs questions on the clinical submission (see correspondence log), confirmed this. The search was limited to studies published in English (search line 74) as project timelines and resources precluded the translation of foreign-language papers.

The final Ovid MEDLINE strategy was peer-reviewed by a second Information Specialist for errors in spelling, syntax and line combinations.

Figure A3: Economic evidence - EAC searches - search strategy for MEDLINE(R) ALL

1	exp Pulmonary Disease, Chronic Obstructive/ (59343)
2	(chronic adj (obstructive pulmonary or obstructive lung or obstructive airway or obstructive air-way or obstructive airflow or obstructive air-flow or obstructive bronchitis or obstructive bronchopulmonary or obstructive broncho-pulmonary or obstructive respiratory)).ti,ab,kf. (58225)
3	(chronic adj (pulmonary obstructi$ or lung obstructi$ or airway obstructi$ or air-way obstructi$ or airflow obstructi$ or air-flow obstructi$ or bronchitis obstructi$ or bronchopulmonary obstructi$ or broncho-pulmonary obstructi$ or respiratory obstructi$)).ti,ab,kf. (1163)
4	(chronic bronchitis or chronic bronchus or bronchitis chronica).ti,ab,kf. (10073)
5	emphysem$.ti,ab,kf. (28854)
6	(COPD or COAD or COBD or AECB).ti,ab,kf. (51339)
7	or/1-6 (115241)
8	Telemedicine/ or Telerehabilitation/ (29461)

9 (mhealth$ or m-health$ or ehealth$ or e-health$).ti,ab,kf. (13822)
10 mobile health$.ti,ab,kf. (5885)
11 Cell Phone/ (9142)
12 (mobile adj (phone$1 or telephone$1 or handset$1 or hand-set$1)).ti,ab,kf. (10808)
13 (cell$ adj (phone$1 or telephone$1 or handset$1 or hand-set$1)).ti,ab,kf. (4085)
14 mobiles.ti,ab,kf. (241)
15 exp Computers, Handheld/ (9850)
16 (smart adj (phone$1 or telephone$1 or handset$1 or hand-set$1)).ti,ab,kf. (1361)
17 smartphone$1.ti,ab,kf. (15127)
18 (iphone$ or i-phone$).ti,ab,kf. (1030)
19 (i-pad$1 or ipad$1).ti,ab,kf. (1679)
20 (smart adj (television$ or tv$)).ti,ab,kf. (22)
21 (digital adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kf. (8092)
22 (mobile adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kf. (9461)
23 (electronic$ adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kf. (18848)
24 (smart adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kf. (3137)
25 ((internet or online or on-line or web) adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kf. (15080)
26 (tablet$ adj3 (device or devices or technolog$)).ti,ab,kf. (812)
27 (smart adj3 (digital$ or mobile$ or electronic$ or internet or online or on-line or web)).ti,ab,kf. (898)
28 (device-based or mobile-based or smart-based).ti,ab,kf. (4060)
29 Mobile Applications/ (8101)
30 (app or apps).ti,ab,kf. (33371)
31 ((digital$ or mobile or electronic$ or smart$ or internet or online or on-line or web or tablet$ or device or devices or software$) adj3 application$1).ti,ab,kf. (33556)
32 ((health$ or medic$) adj application$1).ti,ab,kf. (13353)
33 (android or google play).ti,ab,kf. (3253)
34 (apple or ios).ti,ab,kf. (17284)
35 Online Systems/ (8449)
36 Internet/ (76222)
37 (online or on-line or internet$).ti,kf. (55914)
38 (online or on-line or internet$).ab. /freq=2 (51157)
39 (online based or on-line based or internet based).ti,ab,kf. (9673)
40 ((online or on-line or internet$) adj6 (educat$ or self-manag$ or self-car$ or symptom$ or rehabilit$ or pr or tutorial$ or exercis$)).ab. (7155)
41 ((online or on-line or internet$) adj3 (platform$1 or system$1 or program$ or access$)).ti,ab,kf. (19083)
42 web.ti,kf. (24363)
43 web.ab. /freq=2 (22170)
44 (web-based or webbased or web-site$1 or website$1 or web-page$ or webpage$1).ti,ab,kf. (72220)
45 or/8-44 (367599)
46 7 and 45 (1484)
47 (mycopd$2 or my copd$2).ti,ab,kf. (3)
48 (mypr$2 or my pr$2).ti,ab,kf. (21)
49 (mymhealth$2 or my mhealth$2 or my mobile health$2).ti,ab,kf,in. (4)
50 or/47-49 (25)
51 46 or 50 (1505)
52 Economics/ (27345)

53	exp "costs and cost analysis"/ (246939)
54	Economics, Dental/ (1918)
55	exp economics, hospital/ (25185)
56	Economics, Medical/ (9137)
57	Economics, Nursing/ (4005)
58	Economics, Pharmaceutical/ (2998)
59	(economic$ or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic$).ti,ab. (872163)
60	(expenditure$ not energy).ti,ab. (32151)
61	value for money.ti,ab. (1840)
62	budget$.ti,ab. (31271)
63	or/52-62 (1028495)
64	((energy or oxygen) adj cost).ti,ab. (4313)
65	(metabolic adj cost).ti,ab. (1515)
66	((energy or oxygen) adj expenditure).ti,ab. (26420)
67	or/64-66 (31239)
68	63 not 67 (1021320)
69	51 and 68 (262)
70	exp animals/ not humans/ (4855957)
71	(news or editorial or case reports).pt. or case report.ti. (3014901)
72	69 not (70 or 71) (259)
73	limit 72 to yr="2015 -Current" (156)
74	limit 73 to english language (150)
75	remove duplicates from 74 (150)

Key to Ovid symbols and commands

$	Unlimited right-hand truncation symbol
$N	Limited right-hand truncation - restricts the number of characters following the word to N
ti,ab,kf,in.	Searches are restricted to the Title, Abstract, Keyword Heading Word and Institution fields
pt.	Searches are restricted to the Publication Type field
adj	Retrieves records that contain terms next to each other, in the order shown
adjN	Retrieves records that contain terms (in any order) within a specified number (N) of words of each other
ab. /freq=N	Search is restricted to records where the terms occur at least N times in the abstract
/	Searches are restricted to the Subject Heading field
exp	The subject heading is exploded
or/1-6	Combines sets 1 to 6 using OR
.fs.	Term is searched as a floating subheading

Economic evidence: EAC de novo searches – resources searched

The EAC conducted searches using each database or resource listed in Table A7. The information resources included a range of databases containing research published in the journal literature and elsewhere. The resources included databases of economics literature and databases containing

conference abstacts. The EAC also conducted focused searches of a selection of websites informed by the list of external organisations identified on the NICE final scope document for the technology, and a focused search of the company website. The EAC also conducted a targeted search using Google for research evidence published on NHS websites or produced by NHS organisations.

Table A7: Economic evidence: EAC *de novo* searches - databases and information sources searched

Resource	Interface / URL
MEDLINE(R) ALL	OvidSP
Embase	OvidSP
Database of Abstracts of Reviews of Effects	https://www.crd.york.ac.uk/CRDWeb/
HTA Database	https://database.inahta.org/
Science Citation Index Expanded (SCI-EXPANDED)	Web of Science
Conference Proceedings Citation Index- Science (CPCI-S)	Web of Science
EconLit	OvidSP
NHS Economic Evaluation Database (NHS EED)	https://www.crd.york.ac.uk/CRDWeb/
IDEAS	https://ideas.repec.org/
Royal College of General Practitioners website	https://www.rcgp.org.uk/
Royal College of Nursing website	https://www.rcn.org.uk/
Royal College of Physicians website	https://www.rcplondon.ac.uk/
Primary Care Respiratory Society website	https://www.pcrs-uk.org/
British Thoracic Society website	https://www.brit-thoracic.org.uk/
British Lung Foundation website	https://www.blf.org.uk/
National Association of Primary Care website	https://napc.co.uk/
The Royal College of Emergency Medicine website	https://www.rcem.ac.uk/
British Society for Genetic Medicine website	https://www.bsgm.org.uk/
Association of Respiratory Nurse Specialists website	https://arns.co.uk/
Infection Prevention Society website	https://www.ips.uk.net/
Association for Respiratory Technology & Physiology website	http://www.artp.org.uk/
NARA – The Breathing Charity website	http://naratbc.org.uk/
My mhealth website	https://mymhealth.com/
Google	https://www.google.com/

The following additional search source was also sought, but was not found at date of search: Community Practitioners & Health Visitors Association website

In addition to the above searches, the EAC assessed all studies supplied by the company during the economic submission.

Economic evidence: EAC de novo searches - running the search strategies and downloading results

We conducted searches using each database or resource listed above, translating the Ovid MEDLINE strategy appropriately. Translation included consideration of differences in database interfaces and functionality, in addition to variation in indexing languages and thesauri. The full strategies (including search dates) for all sources searched are shown below.

Where possible, we downloaded the results of searches in a tagged format and loaded them into bibliographic software (EndNote). The results were deduplicated within-set and against the results retrieved by the re-run company searches using several algorithms and the duplicate references held in a separate EndNote database for checking if required. Results from resources that did not allow export in a format compatible with EndNote were saved in Word or Excel documents as appropriate and manually deduplicated.

Economic evidence: EAC de novo searches - literature search results

The searches were conducted between 06/07/2021 and 16/07/2021 and identified 629 records (Table A8). Following deduplication, 404 records were assessed for relevance.

Table A8: Literature search results

Resource	Number of records identified
Databases	
MEDLINE(R) ALL	150
Embase	274
Database of Abstracts of Reviews of Effects	6
HTA Database	40
Science Citation Index Expanded (SCI-EXPANDED)	89
Conference Proceedings Citation Index- Science (CPCI-S)	15
EconLit	34
NHS Economic Evaluation Database (NHS EED)	0
IDEAS	0
Royal College of General Practitioners website	0
Royal College of Nursing website	0
Royal College of Physicians website	0
Primary Care Respiratory Society website	0
British Thoracic Society website	0
British Lung Foundation website	0
National Association of Primary Care website	0
The Royal College of Emergency Medicine website	0
British Society for Genetic Medicine website	0
Association of Respiratory Nurse Specialists website	0
Infection Prevention Society website	0

Association for Respiratory Technology & Physiology website	0
NARA – The Breathing Charity website	0
my mhealth website	2
Google	18
Contact with company	1
Total number of records retrieved	**629**
Total number of records after deduplication	**404**

Economic evidence: EAC de novo searches - full search strategies

A.1: Source: MEDLINE(R) ALL

Interface / URL: OvidSP
Database coverage dates: 1946 to July 02, 2021
Search date: 06/07/21
Retrieved records: 150
Search strategy:

1 exp Pulmonary Disease, Chronic Obstructive/ (59343)
2 (chronic adj (obstructive pulmonary or obstructive lung or obstructive airway or obstructive air-way or obstructive airflow or obstructive air-flow or obstructive bronchitis or obstructive bronchopulmonary or obstructive broncho-pulmonary or obstructive respiratory)).ti,ab,kf. (58225)
3 (chronic adj (pulmonary obstructi$ or lung obstructi$ or airway obstructi$ or air-way obstructi$ or airflow obstructi$ or air-flow obstructi$ or bronchitis obstructi$ or bronchopulmonary obstructi$ or broncho-pulmonary obstructi$ or respiratory obstructi$)).ti,ab,kf. (1163)
4 (chronic bronchitis or chronic bronchus or bronchitis chronica).ti,ab,kf. (10073)
5 emphysem$.ti,ab,kf. (28854)
6 (COPD or COAD or COBD or AECB).ti,ab,kf. (51339)
7 or/1-6 (115241)
8 Telemedicine/ or Telerehabilitation/ (29461)
9 (mhealth$ or m-health$ or ehealth$ or e-health$).ti,ab,kf. (13822)
10 mobile health$.ti,ab,kf. (5885)
11 Cell Phone/ (9142)
12 (mobile adj (phone$1 or telephone$1 or handset$1 or hand-set$1)).ti,ab,kf. (10808)
13 (cell$ adj (phone$1 or telephone$1 or handset$1 or hand-set$1)).ti,ab,kf. (4085)
14 mobiles.ti,ab,kf. (241)
15 exp Computers, Handheld/ (9850)
16 (smart adj (phone$1 or telephone$1 or handset$1 or hand-set$1)).ti,ab,kf. (1361)

17 smartphone$1.ti,ab,kf. (15127)
18 (iphone$ or i-phone$).ti,ab,kf. (1030)
19 (i-pad$1 or ipad$1).ti,ab,kf. (1679)
20 (smart adj (television$ or tv$)).ti,ab,kf. (22)
21 (digital adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kf. (8092)
22 (mobile adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kf. (9461)
23 (electronic$ adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kf. (18848)
24 (smart adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kf. (3137)
25 ((internet or online or on-line or web) adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kf. (15080)
26 (tablet$ adj3 (device or devices or technolog$)).ti,ab,kf. (812)
27 (smart adj3 (digital$ or mobile$ or electronic$ or internet or online or on-line or web)).ti,ab,kf. (898)
28 (device-based or mobile-based or smart-based).ti,ab,kf. (4060)
29 Mobile Applications/ (8101)
30 (app or apps).ti,ab,kf. (33371)
31 ((digital$ or mobile or electronic$ or smart$ or internet or online or on-line or web or tablet$ or device or devices or software$) adj3 application$1).ti,ab,kf. (33556)
32 ((health$ or medic$) adj application$1).ti,ab,kf. (13353)
33 (android or google play).ti,ab,kf. (3253)
34 (apple or ios).ti,ab,kf. (17284)
35 Online Systems/ (8449)
36 Internet/ (76222)
37 (online or on-line or internet$).ti,kf. (55914)
38 (online or on-line or internet$).ab. /freq=2 (51157)
39 (online based or on-line based or internet based).ti,ab,kf. (9673)
40 ((online or on-line or internet$) adj6 (educat$ or self-manag$ or self-car$ or symptom$ or rehabilit$ or pr or tutorial$ or exercis$)).ab. (7155)
41 ((online or on-line or internet$) adj3 (platform$1 or system$1 or program$ or access$)).ti,ab,kf. (19083)
42 web.ti,kf. (24363)
43 web.ab. /freq=2 (22170)
44 (web-based or webbased or web-site$1 or website$1 or web-page$ or webpage$1).ti,ab,kf. (72220)
45 or/8-44 (367599)
46 7 and 45 (1484)
47 (mycopd$2 or my copd$2).ti,ab,kf. (3)
48 (mypr$2 or my pr$2).ti,ab,kf. (21)
49 (mymhealth$2 or my mhealth$2 or my mobile health$2).ti,ab,kf,in. (4)

50 or/47-49 (25)
51 46 or 50 (1505)
52 Economics/ (27345)
53 exp "costs and cost analysis"/ (246939)
54 Economics, Dental/ (1918)
55 exp economics, hospital/ (25185)
56 Economics, Medical/ (9137)
57 Economics, Nursing/ (4005)
58 Economics, Pharmaceutical/ (2998)
59 (economic$ or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic$).ti,ab. (872163)
60 (expenditure$ not energy).ti,ab. (32151)
61 value for money.ti,ab. (1840)
62 budget$.ti,ab. (31271)
63 or/52-62 (1028495)
64 ((energy or oxygen) adj cost).ti,ab. (4313)
65 (metabolic adj cost).ti,ab. (1515)
66 ((energy or oxygen) adj expenditure).ti,ab. (26420)
67 or/64-66 (31239)
68 63 not 67 (1021320)
69 51 and 68 (262)
70 exp animals/ not humans/ (4855957)
71 (news or editorial or case reports).pt. or case report.ti. (3014901)
72 69 not (70 or 71) (259)
73 limit 72 to yr="2015 -Current" (156)
74 limit 73 to english language (150)
75 remove duplicates from 74 (150)

A.2: Source: Embase

Interface / URL: OvidSP
Database coverage dates: 1974 to 2021 July 02
Search date: 06/07/21
Retrieved records: 274
Search strategy:

1 chronic obstructive lung disease/ or chronic bronchitis/ or lung emphysema/ (164005)
2 (chronic adj (obstructive pulmonary or obstructive lung or obstructive airway or obstructive air-way or obstructive airflow or obstructive air-flow or obstructive bronchitis or obstructive bronchopulmonary or obstructive broncho-pulmonary or obstructive respiratory)).ti,ab,kw,dq. (85611)
3 (chronic adj (pulmonary obstructi$ or lung obstructi$ or airway obstructi$ or air-way obstructi$ or airflow obstructi$ or air-flow obstructi$ or bronchitis

obstructi$ or bronchopulmonary obstructi$ or broncho-pulmonary obstructi$ or respiratory obstructi$)).ti,ab,kw,dq. (1559)
4 (chronic bronchitis or chronic bronchus or bronchitis chronica).ti,ab,kw,dq. (12586)
5 emphysem$.ti,ab,kw,dq. (36602)
6 (COPD or COAD or COBD or AECB).ti,ab,kw,dq. (97701)
7 or/1-6 (213270)
8 telehealth/ or telerehabilitation/ (11172)
9 (mhealth$ or m-health$ or ehealth$ or e-health$).ti,ab,kw,dq. (15059)
10 mobile health$.ti,ab,kw,dq. (6042)
11 exp mobile phone/ (34558)
12 (mobile adj (phone$1 or telephone$1 or handset$1 or hand-set$1)).ti,ab,kw,dq. (12848)
13 (cell$ adj (phone$1 or telephone$1 or handset$1 or hand-set$1)).ti,ab,kw,dq. (5606)
14 mobiles.ti,ab,kw,dq. (338)
15 personal digital assistant/ or tablet computer/ (3444)
16 (smart adj (phone$1 or telephone$1 or handset$1 or hand-set$1)).ti,ab,kw,dq. (2817)
17 smartphone$1.ti,ab,kw,dq. (19576)
18 (iphone$ or i-phone$).ti,ab,kw,dq,dv,my. (2192)
19 (i-pad$1 or ipad$1).ti,ab,kw,dq,dv,my. (3581)
20 (smart adj (television$ or tv$)).ti,ab,kw,dq. (32)
21 (digital adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kw,dq. (10149)
22 (mobile adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kw,dq. (12009)
23 (electronic$ adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kw,dq. (21489)
24 (smart adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kw,dq. (3919)
25 ((internet or online or on-line or web) adj3 (device or devices or technolog$ or tool$ or tablet$1)).ti,ab,kw,dq. (20840)
26 (tablet$ adj3 (device or devices or technolog$)).ti,ab,kw,dq. (1484)
27 (smart adj3 (digital$ or mobile$ or electronic$ or internet or online or on-line or web)).ti,ab,kw,dq. (1167)
28 (device-based or mobile-based or smart-based).ti,ab,kw,dq. (4634)
29 exp mobile application/ (16254)
30 (app or apps).ti,ab,kw,dq. (46200)
31 ((digital$ or mobile or electronic$ or smart$ or internet or online or on-line or web or tablet$ or device or devices or software$) adj3 application$1).ti,ab,kw,dq. (38299)
32 ((health$ or medic$) adj application$1).ti,ab,kw,dq. (16117)
33 (android or google play).ti,ab,kw,dq,dv,my. (5134)

34 (apple or ios).ti,ab,kw,dq,dv,my. (34569)
35 online system/ (27373)
36 internet/ (113813)
37 (online or on-line or internet$).ti,kw. (71572)
38 (online or on-line or internet$).ab. /freq=2 (72014)
39 (online based or on-line based or internet based).ti,ab,kw,dq. (13090)
40 ((online or on-line or internet$) adj6 (educat$ or self-manag$ or self-car$ or symptom$ or rehabilit$ or pr or tutorial$ or exercis$)).ab. (11187)
41 ((online or on-line or internet$) adj3 (platform$1 or system$1 or program$ or access$)).ti,ab,kw,dq. (26904)
42 web.ti,kw. (28960)
43 web.ab. /freq=2 (26351)
44 (web-based or webbased or web-site$1 or website$1 or web-page$ or webpage$1).ti,ab,kw,dq. (103018)
45 or/8-44 (494166)
46 7 and 45 (2933)
47 (mycopd$2 or my copd$2).ti,ab,kw,dq,dv,my. (10)
48 (mypr$2 or my pr$2).ti,ab,kw,dq,dv,my. (52)
49 (mymhealth$2 or my mhealth$2 or my mobile health$2).ti,ab,kw,in,dq,dv,my,dm. (6)
50 or/47-49 (63)
51 46 or 50 (2987)
52 Health Economics/ (33514)
53 exp Economic Evaluation/ (320735)
54 exp Health Care Cost/ (305013)
55 pharmacoeconomics/ (8646)
56 (econom$ or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic$).ti,ab. (1167451)
57 (expenditure$ not energy).ti,ab. (43729)
58 (value adj2 money).ti,ab. (2609)
59 budget$.ti,ab. (41316)
60 or/52-59 (1437119)
61 (metabolic adj cost).ti,ab. (1631)
62 ((energy or oxygen) adj cost).ti,ab. (4566)
63 ((energy or oxygen) adj expenditure).ti,ab. (33534)
64 or/61-63 (38592)
65 60 not 64 (1429200)
66 51 and 65 (511)
67 (animal/ or animal experiment/ or animal model/ or animal tissue/ or nonhuman/) not exp human/ (6249863)
68 editorial.pt. or case report.ti. (1015296)
69 66 not (67 or 68) (495)
70 limit 69 to yr="2015 -Current" (291)
71 limit 70 to english language (281)

72 remove duplicates from 71 (274)

A.3: Source: Science Citation Index Expanded (SCI-EXPANDED)

Interface / URL: Web of Science
Database coverage dates: 1900-present
Search date: 06/07/2021
Retrieved records: 89
Search strategy:

All lines except #54: Indexes=SCI-EXPANDED Timespan=All years

54 89
(#53) AND LANGUAGE: (English)
Indexes=SCI-EXPANDED Timespan=2015-2021

53 132
#52 AND #42

52 1,774,571
#47 not #51

51 50,880
#50 OR #49 OR #48

# 50 38,918
TS=((energy or oxygen) near/0 "expenditure")

# 49 2,249
TS=("metabolic" near/0 "cost")

# 48 11,288
TS=(("energy" or "oxygen") near/0 "cost")

47 1,790,997
#46 OR #45 OR #44 OR #43

# 46 92,797
TS=budget*

# 45 1,634
TS=("value for money")

# 44 32,470
TS=(expenditure* not "energy")

# 43 1,703,589
TS=(economic* or "cost" or "costs" or "costly" or "costing" or "price" or "prices" or "pricing" or pharmacoeconomic*)

42 1,064
#41 OR #37

41 8
#40 OR #39 OR #38

# 40 2
ALL=(mymhealth* or "my mhealth*" or "my mobile health*")

# 39 3
TS=("mypr" or "myprr" or "myprtm" or "my pr" or "my prr" or "my prtm")

# 38 3
TS=(mycopd* or "my copd*")

37 1,059
#36 AND #6

36 587,310
#35 OR #34 OR #33 OR #32 OR #31 OR #30 OR #29 OR #28 OR #27 OR #26 OR #25 OR #24 OR #23 OR #22 OR #21 OR #20 OR #19 OR #18 OR #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8 OR #7

# 35 79,978
TS=("web-based" or "webbased" or "web-site*" or website* or "web-page*" or webpage*)

# 34 46,792
TI="web"

# 33 38,676
TS=(("online" or "on-line" or internet*) NEAR/3 (platform* or system* or program* or access*))

# 32 8,926
TS=(("online" or "on-line" or internet*) NEAR/6 (educat* or "self-manag*" or "self-car*" or symptom* or rehabilit* or "pr" or tutorial* or exercis*))

31 10,536

TS=("online based" or "on-line based" or "internet based")

# 30 103,335
TI=("online" or "on-line" or internet*)

# 29 52,558
TS=("apple" or "ios")

# 28 5,753
TS=("android" or "google play")

# 27 20,419
TS=((health* or medic*) NEAR/0 application*)

# 26 121,528
TS=((digital* or "mobile" or electronic* or smart* or "internet" or "online" or "on-line" or "web" or tablet* or "device" or "devices" or software*) NEAR/3 application*)

# 25 43,055
TS=("app" or "apps")

# 24 9,805
TS=("device-based" or "mobile-based" or "smart-based")

# 23 4,736
TS=("smart" NEAR/3 (digital* or mobile* or electronic* or "internet" or "online" or "on-line" or "web"))

# 22 1,375
TS=(tablet* NEAR/3 ("device" or "devices" or technolog*))

# 21 30,531
TS=(("internet" or "online" or "on-line" or "web") NEAR/3 ("device" or "devices" or technolog* or tool* or tablet*))

# 20 12,184
TS=("smart" NEAR/3 ("device" or "devices" or technolog* or tool* or tablet*))

# 19 52,361
TS=(electronic* NEAR/3 ("device" or "devices" or technolog* or tool* or tablet*))

18 24,646

TS=("mobile" NEAR/3 ("device" or "devices" or technolog* or tool* or tablet*))

# 17 16,373
TS=("digital" NEAR/3 ("device" or "devices" or technolog* or tool* or tablet*))

# 16 189
TS=("smart" NEAR/0 (television* or "tv" or "tvs"))

# 15 1,958
TS=("i-pad*" or ipad*)

# 14 1,351
TS=(iphone* or "i-phone*")

# 13 22,580
TS=smartphone*

# 12 3,284
TS=("smart" NEAR/0 (phone* or telephone* or handset* or "hand-set*"))

# 11 940
TS="mobiles"

# 10 7,222
TS=(cell* NEAR/0 (phone* or telephone* or handset* or "hand-set*"))

# 9 17,707
TS=("mobile" NEAR/0 (phone* or telephone* or handset* or "hand-set*"))

# 8 4,941
TS="mobile health*"

# 7 12,662
TS=(mhealth* or "m-health*" or ehealth* or "e-health*")

6 110,910
#5 OR #4 OR #3 OR #2 OR #1

# 5 65,321
TS=("COPD" or "COAD" or "COBD" or "AECB")

# 4 25,929
TS=emphysem*

# 3 8,948
TS=("chronic bronchitis" or "chronic bronchus" or "bronchitis chronica")

# 2 1,066
TS=("chronic" NEAR/0 ("pulmonary obstructi*" or "lung obstructi*" or "airway obstructi*" or "air-way obstructi*" or "airflow obstructi*" or "air-flow obstructi*" or "bronchitis obstructi*" or "bronchopulmonary obstructi*" or "broncho-pulmonary obstructi*" or "respiratory obstructi*"))

# 1 53,019
TS=("chronic" NEAR/0 ("obstructive pulmonary" or "obstructive lung" or "obstructive airway" or "obstructive air-way" or "obstructive airflow" or "obstructive air-flow" or "obstructive bronchitis" or "obstructive bronchopulmonary" or "obstructive broncho-pulmonary" or "obstructive respiratory"))

A.4: Source: Conference Proceedings Citation Index- Science (CPCI-S)

Interface / URL: Web of Science
Database coverage dates: 1990-present
Search date: 07/07/21
Retrieved records: 15
Search strategy:

All lines except #54: Indexes=CPCI-S Timespan=All years

54 15
(#53) AND LANGUAGE: (English)
Indexes=CPCI-S Timespan=2015-2021

53 23
#52 AND #42

52 648,674
#47 not #51

51 7,752
#50 OR #49 OR #48

# 50 3,714
TS=((energy or oxygen) near/0 "expenditure")

# 49 256
TS=("metabolic" near/0 "cost")

# 48 3,907
TS=(("energy" or "oxygen") near/0 "cost")

47 653,146
#46 OR #45 OR #44 OR #43

# 46 27,025
TS=budget*

# 45 276
TS=("value for money")

# 44 5,602
TS=(expenditure* not "energy")

# 43 630,818
TS=(economic* or "cost" or "costs" or "costly" or "costing" or "price" or "prices" or "pricing" or pharmacoeconomic*)

42 208
#41 OR #37

41 2
#40 OR #39 OR #38

# 40 2
ALL=(mymhealth* or "my mhealth*" or "my mobile health*")

39 0 TS=("mypr" or "myprr" or "myprtm" or "my pr" or "my prr" or "my prtm")

38 0 TS=(mycopd* or "my copd*")

37 207
#36 AND #6

36 389,536
#35 OR #34 OR #33 OR #32 OR #31 OR #30 OR #29 OR #28 OR #27 OR #26 OR #25 OR #24 OR #23 OR #22 OR #21 OR #20 OR #19 OR #18 OR #17 OR #16 OR #15 OR #14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8 OR #7

35 51,300

TS=("web-based" or "webbased" or "web-site*" or website* or "web-page*" or webpage*)

# 34 44,826
TI="web"

# 33 34,373
TS=(("online" or "on-line" or internet*) NEAR/3 (platform* or system* or program* or access*))

# 32 5,346
TS=(("online" or "on-line" or internet*) NEAR/6 (educat* or "self-manag*" or "self-car*" or symptom* or rehabilit* or "pr" or tutorial* or exercis*))

# 31 5,066
TS=("online based" or "on-line based" or "internet based")

# 30 65,170
TI=("online" or "on-line" or internet*)

# 29 10,166
TS=("apple" or "ios")

# 28 13,261
TS=("android" or "google play")

# 27 9,149
TS=((health* or medic*) NEAR/0 application*)

# 26 101,621
TS=((digital* or "mobile" or electronic* or smart* or "internet" or "online" or "on-line" or "web" or tablet* or "device" or "devices" or software*) NEAR/3 application*)

# 25 14,555
TS=("app" or "apps")

# 24 4,538
TS=("device-based" or "mobile-based" or "smart-based")

# 23 5,994
TS=("smart" NEAR/3 (digital* or mobile* or electronic* or "internet" or "online" or "on-line" or "web"))

# 22 1,643
TS=(tablet* NEAR/3 ("device" or "devices" or technolog*))

# 21 32,284
TS=(("internet" or "online" or "on-line" or "web") NEAR/3 ("device" or "devices" or technolog* or tool* or tablet*))

# 20 14,512
TS=("smart" NEAR/3 ("device" or "devices" or technolog* or tool* or tablet*))

# 19 25,014
TS=(electronic* NEAR/3 ("device" or "devices" or technolog* or tool* or tablet*))

# 18 38,420
TS=("mobile" NEAR/3 ("device" or "devices" or technolog* or tool* or tablet*))

# 17 15,932
TS=("digital" NEAR/3 ("device" or "devices" or technolog* or tool* or tablet*))

# 16 335
TS=("smart" NEAR/0 (television* or "tv" or "tvs"))

# 15 814
TS=("i-pad*" or ipad*)

# 14 1,003
TS=(iphone* or "i-phone*")

# 13 19,177
TS=smartphone*

# 12 6,462
TS=("smart" NEAR/0 (phone* or telephone* or handset* or "hand-set*"))

# 11 1,548
TS="mobiles"

# 10 5,549
TS=(cell* NEAR/0 (phone* or telephone* or handset* or "hand-set*"))

# 9 15,449
TS=("mobile" NEAR/0 (phone* or telephone* or handset* or "hand-set*"))

# 8 1,703
TS="mobile health*"

# 7 5,787
TS=(mhealth* or "m-health*" or ehealth* or "e-health*")

6 13,879
#5 OR #4 OR #3 OR #2 OR #1

# 5 8,849
TS=("COPD" or "COAD" or "COBD" or "AECB")

# 4 2,069
TS=emphysem*

# 3 567
TS=("chronic bronchitis" or "chronic bronchus" or "bronchitis chronica")

# 2 58
TS=("chronic" NEAR/0 ("pulmonary obstructi*" or "lung obstructi*" or "airway obstructi*" or "air-way obstructi*" or "airflow obstructi*" or "air-flow obstructi*" or "bronchitis obstructi*" or "bronchopulmonary obstructi*" or "broncho-pulmonary obstructi*" or "respiratory obstructi*"))

# 1 4,727
TS=("chronic" NEAR/0 ("obstructive pulmonary" or "obstructive lung" or "obstructive airway" or "obstructive air-way" or "obstructive airflow" or "obstructive air-flow" or "obstructive bronchitis" or "obstructive bronchopulmonary" or "obstructive broncho-pulmonary" or "obstructive respiratory"))

A.5: Source: HTA database

Interface / URL: https://database.inahta.org/

Database coverage dates: Information not found. The former database was produced by the CRD until March 2018, at which time the addition of records was stopped as INAHTA was in the process of rebuilding the new database platform. In July 2019, the database records were exported from the CRD platform and imported into the new platform that was developed by INAHTA. The rebuild of the new platform was launched in June 2020.

Search date: 07/07/21

Retrieved records: 40

Search strategy:

13 #12 AND #11 40

12 * FROM 2015 TO 2021 3198

11 #10 OR #6 196

10 #9 OR #8 OR #7 1

9 mymhealth* 0

8 mypr* 1

7 mycopd* 0

6 #5 OR #4 OR #3 OR #2 OR #1 195

5 ((COPD OR COAD OR COBD OR AECB)) 108

4 (emphysem*)30

3 (("chronic bronchitis" OR "chronic bronchus" OR "bronchitis chronica")) 2

2 (chronic AND (pulmonary OR lung OR airway OR "air-way" OR airflow* OR "air-flow" OR bronchitis OR bronchopulmonary OR "broncho-pulmonary" OR respiratory) AND obstructi*) 131

1 "Pulmonary Disease, Chronic Obstructive"[mhe] 121

Search notes:

It is not possible to search on the term *my* in the HTA database. Searching on this term returns zero results with the message: "Sorry please make your search terms a minimum of 3 characters". It was therefore not possible to search on the following previously included terms:

*my pr**
*my mhealth**
*my mobile health**

A.6: Source: Database of Abstracts of Reviews of Effects (DARE)
Interface / URL: https://www.crd.york.ac.uk/CRDWeb/

Database coverage dates: Information not found. Bibliographic records were published on DARE until 31st March 2015. Searches of MEDLINE, Embase, CINAHL, PsycINFO and PubMed were continued until the end of the 2014.
Search date: 07/07/21
Retrieved records: 6
Search strategy:

1 (MeSH DESCRIPTOR Pulmonary Disease, Chronic Obstructive EXPLODE ALL TREES) 555

2 (((chronic adj1 (obstructive pulmonary or obstructive lung or obstructive airway or obstructive air-way or obstructive airflow or obstructive air-flow or obstructive bronchitis or obstructive bronchopulmonary or obstructive broncho-pulmonary or obstructive respiratory)))) 712

3 (((chronic adj1 (pulmonary obstructi* or lung obstructi* or airway obstructi* or air-way obstructi* or airflow obstructi* or air-flow obstructi* or bronchitis obstructi* or bronchopulmonary obstructi* or broncho-pulmonary obstructi* or respiratory obstructi*)))) 5

4 (((chronic bronchitis or chronic bronchus or bronchitis chronica))) 72

5 ((emphysem*)) 93

6 (((COPD or COAD or COBD or AECB))) 552

7 ((#1 or #2 or #3 or #4 or #5 or #6)) 993

8 ((mycopd* or my copd*)) 0

9 ((mypr* or my pr*)) 1

10 ((mymhealth* or my mhealth* or my mobile health*)) 0

11 ((#8 or #9 or #10)) 1

12 ((#7 or #11)) 994

13 ((#7 or #11)) FROM 2015 TO 2021 35

14 ((#7 or #11)) IN DARE FROM 2015 TO 2021 6

A.7: Source: NHS Economic Evaluation Database (NHS EED)
Interface / URL: https://www.crd.york.ac.uk/CRDWeb/

Database coverage dates: Information not found. Bibliographic records were published on NHS EED until 31st March 2015. Searches of MEDLINE, Embase, CINAHL, PsycINFO and PubMed were continued until the end of the 2014.
Search date: 07/07/21
Retrieved records: 0
Search strategy:

1 (MeSH DESCRIPTOR Pulmonary Disease, Chronic Obstructive EXPLODE ALL TREES) 555

2 (((chronic adj1 (obstructive pulmonary or obstructive lung or obstructive airway or obstructive air-way or obstructive airflow or obstructive air-flow or obstructive bronchitis or obstructive bronchopulmonary or obstructive broncho-pulmonary or obstructive respiratory)))) 712

3 (((chronic adj1 (pulmonary obstructi* or lung obstructi* or airway obstructi* or air-way obstructi* or airflow obstructi* or air-flow obstructi* or bronchitis obstructi* or bronchopulmonary obstructi* or broncho-pulmonary obstructi* or respiratory obstructi*)))) 5

4 (((chronic bronchitis or chronic bronchus or bronchitis chronica))) 72

5 ((emphysem*)) 93

6 (((COPD or COAD or COBD or AECB))) 552

7 ((#1 or #2 or #3 or #4 or #5 or #6)) 993

8 ((mycopd* or my copd*)) 0

9 ((mypr* or my pr*)) 1

10 ((mymhealth* or my mhealth* or my mobile health*)) 0

11 ((#8 or #9 or #10)) 1

12 ((#7 or #11)) 994

13 ((#7 or #11)) FROM 2015 TO 2021 35

14 (((#7 or #11))) IN NHSEED FROM 2015 TO 2021 0

A.8: Source: Econlit
Interface / URL: OvidSP

Database coverage dates: 1886 to June 24, 2021
Search date: 07/07/21
Retrieved records: 34
Search strategy:

1 (chronic adj (obstructive pulmonary or obstructive lung or obstructive airway or obstructive air-way or obstructive airflow or obstructive air-flow or obstructive bronchitis or obstructive bronchopulmonary or obstructive broncho-pulmonary or obstructive respiratory)).af. (56)
2 (chronic adj (pulmonary obstructi$ or lung obstructi$ or airway obstructi$ or air-way obstructi$ or airflow obstructi$ or air-flow obstructi$ or bronchitis obstructi$ or bronchopulmonary obstructi$ or broncho-pulmonary obstructi$ or respiratory obstructi$)).af. (0)
3 (chronic bronchitis or chronic bronchus or bronchitis chronica).af. (15)
4 emphysem$.af. (5)
5 (COPD or COAD or COBD or AECB).af. (45)
6 or/1-5 (85)
7 (mycopd$2 or my copd$2).af. (0)
8 (mypr$2 or my pr$2).af. (2)
9 (mymhealth$2 or my mhealth$2 or my mobile health$2).af. (0)
10 or/7-9 (2)
11 6 or 10 (87)
12 limit 11 to yr="2015 -Current" (34)
13 limit 12 to english (34)
14 remove duplicates from 13 (34)

A.9: Source: IDEAS

Interface / URL: https://ideas.repec.org/
Database coverage dates: Information not found.
Search date: 15/07/21
Retrieved records: 0
Search strategy:

The following targeted searches were conducted separately using the interface at: https://ideas.repec.org/search.html. Search settings were left at default.

mycopd = 0 results
"my copd" = 0 results
mypr = 0 results
"my pr" = 0 results

A.10: Source: Google

Interface / URL: https://www.google.com/
Database coverage dates: n/a

Search date: 15/07/21
Retrieved records: 18
Search strategy:

The 16 results from the Google searches conducted for the review of the clinical submission (see CLINICAL EVIDENCE: DETAILS OF EAC DE NOVO SEARCHES) were retrieved for assessment.

The following searches were conducted to identify additional studies. Two additional results were retrieved for assessment.

The following targeted searches for research evidence published on NHS sites or produced by NHS organisations were conducted using Google. The first 5 pages of returned results (or all results if less than 5 pages) for each search were rapidly screened by the Information Specialist for potential relevance. Order of returned results was determined by the Google ranking algorithm. The decision as to which results should be opened and explored further was based on the Information Specialist's judgement. Links within results were followed, as judged appropriate. Results which reported economic evidence on myCOPD were retrieved.

1. allintitle: mycopd OR "my copd" site:.nhs.uk = "About 26 results" returned

Repeated the search "with the omitted results included" = "About 26 results" returned

2. allintitle: mypr OR "my pr" site:.nhs.uk = 1 result returned

3. allintitle: mycopd OR "my copd" filetype:pdf = "About 93 results" returned

Repeated the search "with the omitted results included" = "About 93 results" returned

4. allintitle: mypr OR "my pr" filetype:pdf = "About 23 results" returned

5. allintitle: mycopd OR "my copd" filetype:doc = 0 results returned

6. allintitle: mypr OR "my pr" filetype:doc = 1 result returned

7. allintitle: mycopd OR "my copd" filetype:ppt = 0 results returned

8. allintitle: mypr OR "my pr" filetype:ppt = 0 results returned

9. mycopd site:.nhs.uk filetype:pdf = "About 877 results" returned

10. mycopd site:.nhs.uk filetype:doc = 6 results returned

11. mycopd site:.nhs.uk filetype:ppt = 2 results returned

12. "my copd" site:.nhs.uk filetype:pdf = "About 263 results" returned

13. "my copd" site:.nhs.uk filetype:doc = "About 4 results" returned

14. "my copd" site:.nhs.uk filetype:ppt = "About 2 results" returned

15. mypr site:.nhs.uk filetype:pdf = 7 results returned

16. mypr site:.nhs.uk filetype:doc = 0 results returned

17. mypr site:.nhs.uk filetype:ppt = 0 results returned

18. "my pr" site:.nhs.uk filetype:pdf = 4 results returned

19. "my pr" site:.nhs.uk filetype:doc = 0 results returned

20. "my pr" site:.nhs.uk filetype:ppt = 0 results returned

21. allintitle: mycopd cost = 3 results returned

22. allintitle: mycopd costs = 0 results returned

23. allintitle: mycopd economic = 1 results returned

24. allintitle: "my copd" cost = 0 results returned

25. allintitle: "my copd" costs = 0 results returned

26. allintitle: "my copd" economic = 0 results returned

27. allintitle: mypr cost = 4 results returned

28. allintitle: mypr costs = 2 results returned

29. allintitle: mypr economic = 5 results returned

30. allintitle: "my pr" cost = 7 results returned

31. allintitle: "my pr" costs = 0 results returned

32. allintitle: "my pr" economic = 0 results returned

A.11: Source: my mhealth website

Interface / URL: https://mymhealth.com/
Database coverage dates: n/a
Search date: 15/07/21
Retrieved records: 2
Search strategy:

The 2 results from the my mhealth website search conducted for the review of the clinical submission (see CLINICAL EVIDENCE: DETAILS OF EAC DE NOVO SEARCHES) were retrieved for assessment.

The following search was conducted to identify additional studies. No additional results were retrieved for assessment.

Navigated to Studies page at: https://mymhealth.com/studies

The page content was browsed by the Information Specialist for studies on myCOPD. Studies reporting economic evidence on myCOPD were checked against records already retrieved via searches of other sources. Duplicate studies were not retrieved.

Navigated to myCOPD page at https://mymhealth.com/mycopd. Navigated to "myCOPD Studies and Evaluations"

Studies reporting economic evidence on myCOPD were checked against records already retrieved via searches of other sources. Duplicate studies were not retrieved.

A.12: Source: Royal College of General Practitioners website

Interface / URL: https://www.rcgp.org.uk/
Database coverage dates: n/a
Search date: 16/07/2021
Retrieved records: 0
Search strategy:

A site wide search was conducted using the search interface at https://www.rcgp.org.uk/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM

myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.13: Source: Royal College of Nursing website
Interface / URL: https://www.rcn.org.uk/
Database coverage dates: n/a
Search date: 16/07/2021
Retrieved records: 0
Search strategy:

A site wide search was conducted using the search interface at https://www.rcn.org.uk/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.14: Source: Royal College of Physicians website
Interface / URL: https://www.rcplondon.ac.uk/
Database coverage dates: n/a
Search date: 16/07/2021
Retrieved records: 0
Search strategy:

A site wide search was conducted using the search interface at https://www.rcplondon.ac.uk/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.15: Source: Primary Care Respiratory Society website
Interface / URL: https://www.pcrs-uk.org/
Database coverage dates: n/a
Search date: 16/07/2021
Retrieved records: 0
Search strategy:

A site wide search was conducted using the search interface at https://www.pcrs-uk.org/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.16: Source: British Thoracic Society website
Interface / URL: https://www.brit-thoracic.org.uk/
Database coverage dates: n/a
Search date: 16/07/2021
Retrieved records: 0
Search strategy:

A site wide search was conducted using the search interface at https://www.brit-thoracic.org.uk/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.17: Source: British Lung Foundation website
Interface / URL: https://www.blf.org.uk/
Database coverage dates: n/a
Search date: 16/07/2021
Retrieved records: 0
Search strategy:

A site wide search was conducted using the search interface at https://www.blf.org.uk/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.18: Source: National Association of Primary Care website
Interface / URL: https://napc.co.uk/
Database coverage dates: n/a
Search date: 16/07/2021
Retrieved records: 0
Search strategy:

A site wide search was conducted using the search interface at https://napc.co.uk/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.19: Source: The Royal College of Emergency Medicine website
Interface / URL: https://www.rcem.ac.uk/
Database coverage dates: n/a
Search date: 16/07/2021

Retrieved records: 0
Search strategy:

A site wide search was conducted using the search interface at https://www.rcem.ac.uk/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.20: Source: British Society for Genetic Medicine website
Interface / URL: https://www.bsgm.org.uk/
Database coverage dates: n/a
Search date: 16/07/2021
Retrieved records: 0
Search strategy:

A site wide search was conducted using the search interface at https://www.bsgm.org.uk/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.21: Source: Association of Respiratory Nurse Specialists website
Interface / URL: https://arns.co.uk/
Database coverage dates: n/a
Search date: 16/07/2021
Retrieved records: 0
Search strategy:

A site wide search was conducted using the search interface at https://arns.co.uk/. The following terms were searched on separately:

myCOPD
myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.22: Source: Infection Prevention Society website
Interface / URL: https://www.ips.uk.net/
Database coverage dates: n/a
Search date: 16/07/2021
Retrieved records: 0
Search strategy:

No site wide search found at http://naratbc.org.uk/. A search was conducted via Google (https://www.google.com/) using the following terms:

site:https://www.ips.uk.net/ myCOPD
site:https://www.ips.uk.net/ myCOPDR
site:https://www.ips.uk.net/ myCOPDTM
site:https://www.ips.uk.net/ myPR
site:https://www.ips.uk.net/ myPRR
site:https://www.ips.uk.net/ myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.23: Source: Association for Respiratory Technology & Physiology website
Interface / URL: http://www.artp.org.uk/
Database coverage dates: n/a
Search date: 16/07/2021
Retrieved records: 0
Search strategy:
A site wide search was conducted using the search interface at http://www.artp.org.uk/. The following terms were searched on separately:

myCOPD

myCOPDR
myCOPDTM
myPR
myPRR
myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

A.24: Source: NARA – The Breathing Charity website

Interface / URL: http://naratbc.org.uk/
Database coverage dates: n/a
Search date: 16/07/2021
Retrieved records: 0
Search strategy:

No site wide search found at http://naratbc.org.uk/. A search was conducted via Google (https://www.google.com/) using the following terms

site:http://naratbc.org.uk/ myCOPD
site:http://naratbc.org.uk/ myCOPDR
site:http://naratbc.org.uk/ myCOPDTM
site:http://naratbc.org.uk/ myPR
site:http://naratbc.org.uk/ myPRR
site:http://naratbc.org.uk/ myPRTM

Any returned results were assessed by the searcher for potential relevance. After assessment, 0 records were retrieved.

Details of the EAC's Study Selection

Full details of the eligibility criteria for the economic review are presented in Table A9. The records were screened by a single reviewer.

Table A9: EAC selection criteria – economic evidence

	Inclusion criteria	Exclusion criteria
Population	People with a diagnosis of COPD	Patients with other health conditions Animal and in vitro studies
Intervention	MyCOPD (alone or in combination with 'standard of care')	Other self-management apps for COPD
Comparator	Anything (for example standard of care)	
Outcomes	Not specified to maximise sensitivity	

Study design	Health economic studies (myCOPD v. comparator) • cost-effectiveness • cost-utility • cost-benefit • cost-minimisation • cost-consequence	Non-comparative cost analyses including cost of illness studies. Clinical studies reporting on cost of treatment in the discussion only without more formal analyses
Limits	English language	

A PRISMA diagram of record selection by the EAC is provided in Figure A4 and the reason for exclusion of full papers provided in Table A10. The included studies were also assessed for their generalisability to the decision problem.

Figure A4: PRISMA flow diagram of the EAC published study selection (economic)

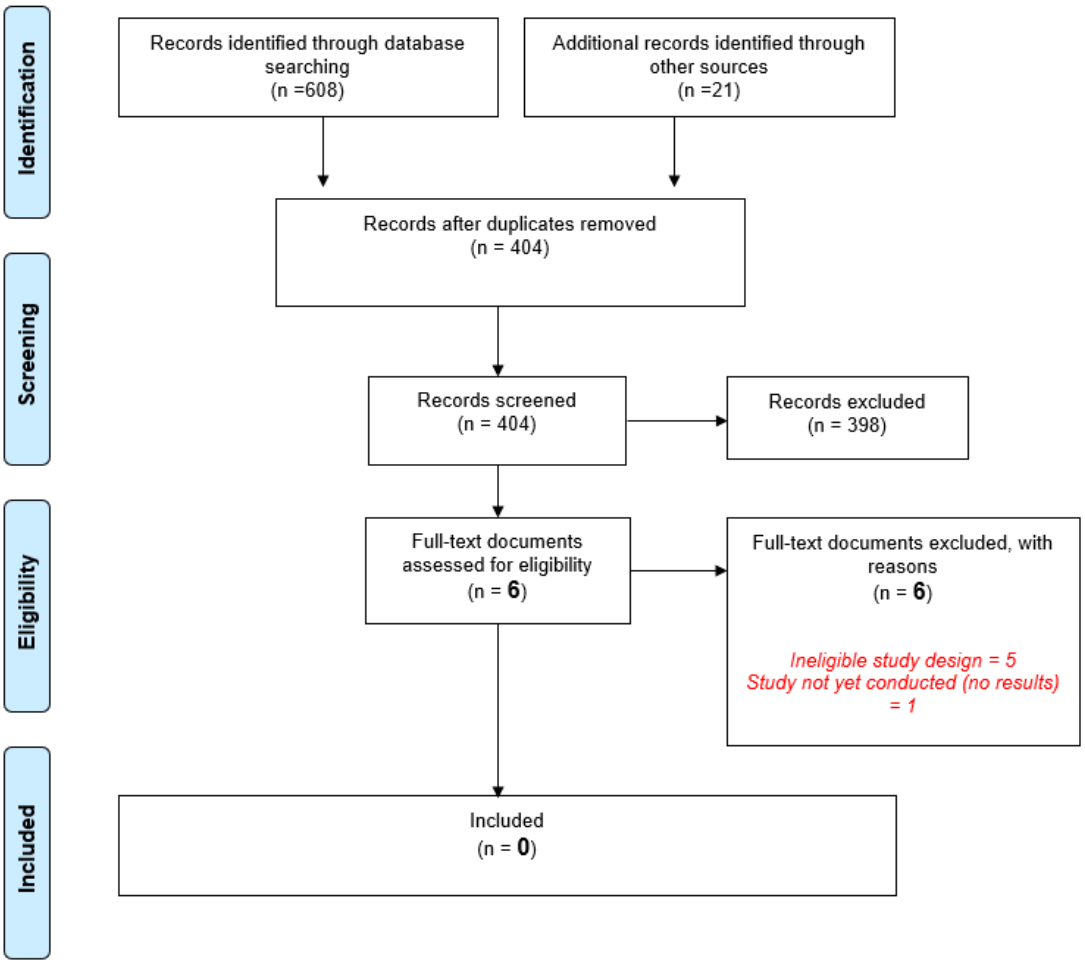


Table A10: Excluded studies at full text selection (n=6) (economic)

Reference	Exclusion reason
Boer, Lonneke Bischoff, Erik van der Heijden, Maarten Lucas, Peter Akkermans, Reinier Vercoulen, Jan Heijdra, Yvonne Assendelft, Willem Schermer, Tjard A Smart Mobile Health Tool Versus a Paper Action Plan to Support Self-Management of Chronic Obstructive Pulmonary Disease Exacerbations: Randomized Controlled Trial	Ineligible study design
Van Zelst, Cathelijne In't Veen, Hans Van Noort, Esther Chavannes, Niels Kasteleyn, Marise Blended care results in an improved adherence of an eHealth Platform by COPD patients	Ineligible intervention
Mymheallth. myCOPD universal guidance. Available at: https://www.innovationagencyexchange.org.uk/sites/default/files/myCOPD%20universal%20guidance%20-v.1.0_0.pdf	Ineligible study design
York Health Economic Consortium. NHS Innovation Accelerator. Economic Impact Evaluation Case Study: myCOPD. 2018. Available at:https://nhsaccelerator.com/wp-content/uploads/2018/03/myCOPD-Economic-Case-Study.pdf	Ineligible study design
A Cox, K Speigelhalter, R Marangozov, J Hanlon, M Gabbay. NHS Innovation Accelerator Evaluation. Final Report. Institute of Employment Studies. Available at: https://www.employment-studies.co.uk/system/files/resources/files/nia0318-NHS_Innovation_Accelerator_Evaluation.pdf	Ineligible study design
Ian Megson, Beth Sage, Adam Giangreco. Evaluation of a chronic obstructive pulmonary disease self-management tool for NHS Highland. Available at: https://pure.uhi.ac.uk/en/projects/evaluation-of-a-chronic-obstructive-pulmonary-disease-self-manage	Study not yet conducted (no results)

Appendix B: Risk of bias assessment

Table B1: Risk of Bias Assessment: RCTs

Bourne S et al. (2017), TROOPER, UK	
Was randomisation carried out appropriately?	Yes – Randomisation was achieved using a computerised permuted block randomise sequencer via an online randomisation system hosted by My mHealth. Randomisation was done in the ratio of 2:1 to myPR and face-to-face PR respectively to reduce the numbers of patients in the more costly face-to-face intervention while maintaining the power. A stratified approach was used to ensure even distribution of severity of COPD in both arms. Disease severity was defined by the GOLD classification of COPD severity.
Was the concealment of treatment allocation adequate?	Yes – An online system hosted by My mHealth was used for concealed allocation.
Was the outcome accurately measured to minimise bias?	Unclear – The primary outcomes (6MWD and impact on health status) were measured according to national standards (British Thoracic Society Quality Standards 2014) and a validated test (CAT score). Secondary outcome measures were assessed using standard questionnaires or scales (SGRQ, HADS), but participant responses are more subjective. AEs were recorded and assessed by the clinical study team.
Were the groups similar at the outset of the study in terms of prognostic factors, for example, severity of disease?	Unclear – There were more participants in the myPR group than in the face-to-face group as a consequence of the 2:1 randomisation used to reduce the number of patients in the more costly face-to-face group while maintaining power. The patients appeared to be reasonably balanced for important baseline characteristics and also comorbidities, although there was a higher proportion of current smokers in the face-to-face group (23% vs 14%). However, P values were not provided and also no statistical analysis was undertaken to demonstrate how balanced the groups were.
Were the care providers, participants and outcome assessors blind to treatment allocation? If any of these people were not blinded, what might be the likely impact on the risk of bias (for each outcome)?	No, for providers and participants; Yes, for outcome assessors – The study personnel were divided into two teams to ensure they remained blinded to treatment allocation: one team was responsible for the initial assessment and randomisation of participants onto the study, while the other team was responsible for subsequent assessment. A separate 'non-'blinded team member who was not involved in pre- or post-study assessments answered participants' questions and dealt with AEs. Participants were not blinded and were requested not to discuss their PR programme during assessment. Outcome assessors were blinded to the treatment allocation. Patients not being blinded could have an impact as for most the outcomes questionnaires were used, which are subjective and could be prone to bias if patients are aware of their treatment allocation.

Were there any unexpected imbalances in drop-outs between groups? If so, were they explained or adjusted for?	Unclear – There were more participants who were lost to follow up, withdrew or did not complete the final study assessment because exacerbation in the myPR arm compared with the face-to-face PR arm. Details are given below:- myPR [n(%)]: Lost to follow up: 4(6) Withdrawals: 11 (17) Exacerbation: 3(5) Face-to-face PR: Lost to follow up: 2(8) Withdrawals: 3 (12) Exacerbation: 0 Both ITT and per protocol analyses were done. The frequency, patterns and predictors of missing data were explored, and multiple imputation done. Analyses of participants with complete data only were compared with those done with missing data imputed.
Is there any evidence to suggest that the authors measured more outcomes than they reported?	Yes – The authors reported all the primary and secondary objective mentioned in the study methods section. However, they also compared the modified MRC dyspnoea score and adherence to the PR programme between the two groups which was not stated as one of the study's objectives, although these were specified as secondary outcomes in the trial registry record.
Did the analysis include an intention-to-treat analysis? If so, was this appropriate and were appropriate methods used to account for missing data?	Yes – The study carried out ITT analysis which included all randomised participants in the arm they were assigned to irrespective of adherence to the intervention. Data at follow-up was imputed regardless of the reason for missing. Multiple imputation was implemented based on chained equation model and using age, gender, baseline scores and COPD severity assuming unobserved measurements were missing at random.
North M (2019), RESCUE	
Was randomisation carried out appropriately?	Yes – Patients were randomised to myCOPD or usual care in a 1:1 ratio using permuted blocks via an online randomisation system, with stratification by disease severity (FEV1% predicted) defined by the GOLD classification of COPD severity.
Was the concealment of treatment allocation adequate?	Unclear – An online system was used for randomisation. It was likely, though not explicit, that this system was also used to allocate treatments to the patients.
Was the outcome accurately measured to minimise bias?	Unclear – Outcome measures were assessed using validated tools, questionnaires or scales (CAT, SGRQ, PAM, HADS, VSAQ, WPAI), but participant responses are more subjective. AEs were recorded by the

	research team and recoded using terms of the clinical investigators choosing; Common Terminology Criteria for Adverse Events (CTCAE) do not appear to have been used.
Were the groups similar at the outset of the study in terms of prognostic factors, for example, severity of disease?	Unclear – The two groups were broadly comparable in terms of the patients' baseline characteristics with a few exceptions. The MyCOPD group contained higher proportions of patients with severe COPD (55% vs 29%), male participants (65% vs 52%), and current smokers (35% vs 24%) than the conventional care group. No statistical analysis was undertaken to determine the significance of these differences.
Were the care providers, participants and outcome assessors blind to treatment allocation? If any of these people were not blinded, what might be the likely impact on the risk of bias (for each outcome)?	No for providers and participants; Yes for outcome assessors – The study personnel were divided into two teams to ensure they remained blinded as to which am each participant was randomised to. One team (unblinded) was responsible for the initial assessment, randomisation, and liaison with participants to respond to queries and deal with adverse events during the study. A separate blinded team member executed the final study visit and patients were requested not to mention their group assignment during assessment. Inhaler technique was evaluated by both a blinded and unblinded assessor. An independent blinded statistician did the analysis according to an a priori SAP.
Were there any unexpected imbalances in drop-outs between groups? If so, were they explained or adjusted for?	No for imbalance; Yes for adjustment – The number (proportion) of withdrawals from the study was the same in both groups. The mean differences for effectiveness outcomes between the two arms were adjusted for baseline score and stratification variables (smoking status and COPD severity). A Poisson regression was used to model count data, if there was evidence of over dispersion a negative binomial was used instead. Model assumptions for all analyses were assessed thorough residuals and deviance for Poisson regressions.
Is there any evidence to suggest that the authors measured more outcomes than they reported?	Unclear – – All pre-specified outcomes appear to have been reported. Although App usage, which was not a pre-specified outcome, was reported. Improvement in treatment adherence which was stated as a hypothesis but it was not stated as an outcome
Did the analysis include an intention-to-treat analysis? If so, was this appropriate and were appropriate methods used to account for missing data?	Unclear – Analysis was reported to have been undertaken using the intention-to-treat principle , that is participants analysed in the arm to which they were randomised regardless of whether they subsequently, use of intervention. However, some analyses appear to have been based on treatment completers. The proportion of missing data by timepoint was calculated for key study variables, but it was unclear how they were taken account for in the analyses
Crooks MG et al. (2020)	
Was randomisation carried out appropriately?	Yes - Participants were randomised 1:1 (myCOPD: usual care) via an online system (my mhealth). Randomisation was stratified by COPD severity and used permuted blocks.
Was the concealment of treatment allocation adequate?	Unclear - An online system was used for randomisation. It was likely, though not explicit, that this system was also used to allocate treatments to the patients.

Was the outcome accurately measured to minimise bias?	Unclear - Outcome measures were assessed using validated tools, questionnaires, or scales (CAT, PAM, SEAMS, EQ5D 5L), but participant responses are more subjective.
Were the groups similar at the outset of the study in terms of prognostic factors, for example, severity of disease?	Unclear - The two groups were broadly comparable in terms of the patients' baseline characteristics but there was baseline imbalance between groups for exacerbation frequency and CAT score. No statistical analysis was undertaken to determine the significance of these differences.
Were the care providers, participants and outcome assessors blind to treatment allocation? If any of these people were not blinded, what might be the likely impact on the risk of bias (for each outcome)?	No for providers and participants. No for outcome assessors except for those assessing inhaler technique - Open label trial. Inhaler technique was evaluated by two assessors: one blinded and one unblinded to the intervention. The unblinded assessor observed technique at the baseline visit and the blinded assessor at end of study
Were there any unexpected imbalances in drop-outs between groups? If so, were they explained or adjusted for?	Yes for imbalance Unclear for adjustment There were more participants who were lost to follow up, withdrew or did not complete the final study assessment because exacerbation in the myCOPD arm compared with the standard care arm. Details are given below. myCOPD [n(%)]: Incomplete follow up: 5 (17.24) Standard care [n(%)]: Incomplete follow up: 1 (3.2) [withdrawn no reason) ITT analysis, defined as participants randomised with at least one post-baseline measurement was undertaken. Participants with missing baseline data were included in ITT analysis, using mean imputation for continuous or binary baseline measurements. For categorical data participants were assigned to the group closest to the mean. However for a lot of outcomes like (inhaler error, compliance average cause effect, EQ5D) the analysis included only participants who were present at the final study visit (n=54) instead of the modified ITT (n=58).
Is there any evidence to suggest that the authors measured more outcomes than they reported?	Yes - Authors did not specify number of exacerbation and adverse event as study outcomes but they were reported in the result section.
Did the analysis include an intention-to-treat analysis? If so, was this appropriate and were appropriate	Unclear - ITT analysis, defined as participants randomised with at least one post-baseline measurement was undertaken. Participants with missing baseline data were included in ITT analysis, using mean imputation for continuous or binary baseline measurements. For categorical data participants were assigned to the group closest to the mean.

methods used to account for missing data?	However for a lot of outcomes like (inhaler error, compliance average cause effect, EQ5D) the analysis included only participants who were present at the final study visit (n=54) instead of the modified ITT (n=58). The company confirmed that this was because some outcomes needed the complete data set.

Table B2: Risk of Bias Assessment: Observational

	North M (2015), uk
Was the cohort recruited in an acceptable way?	No – Patients were recruited through requests for volunteers in the local newspaper.
Was the exposure accurately measured to minimise bias?	Unclear – The method (criteria or guidelines) used to diagnose COPD were not reported.
Was the outcome accurately measured to minimise bias?	Unclear – The CAT score was used to measure impact on patient's quality of life, but the method used to assess inhaler technique from a video recording was not reported.
Have the authors identified all important confounding factors?	Unclear – The authors made no mention of confounding factors.
Have the authors taken account of the confounding factors in the design and/or analysis?	Unclear – This was a service development project to explore the efficacy of the online self-management system compared with the paper-based system, and was most likely not designed or done to enable full analysis of the outcomes.
Was the follow-up of patients complete?	Yes – The patients undertook a 3-month programme and no further follow-up was planned.
How precise (for example, in terms of confidence interval and p values) are the results?	Unclear – Results were scant and limited in nature, and were not reported on a similar basis in both groups.

Appendix C: Adherence to myCOPD (PR) from TROOPER

Table C1 replicates table 6 from the study report (Bourne et al. 2017).

Table C1: Adherence to myCOPD (PR) from TROOPER

	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6
Face-to-face (n=26) numbers (%)						
Zero sessions	3 (11)	8 (31)	5 (19)	6 (23)	6 (23)	7 (27)
One session	3 (11)	3 (11)	4 (15)	1 (4)	5 (19)	1 (4)
Two sessions	20 (77)	15 (58)	17 (65)	19 (73)	15 (58)	18 (69)
Mean	1.6	1.3	1.5	1.5	1.3	1.4
Online groups (n=64) numbers (%)						
Zero sessions	9 (14)	12 (19)	13 (20)	14 (22)	18 (28)	18 (28)
One session	2 (3)	2 (3)	4 (6)	6 (9)	2 (3)	4 (6)
Two sessions	6 (9)	5 (8)	7 (11)	8 (13)	6 (9)	11 (17)
Three sessions	4 (6)	7 (11)	5 (8)	8 (13)	11 (17)	8 (13)
Four sessions	11 (17.2)	6 (9)	9 (14)	5 (8)	6 (9)	9 (14)
Five sessions	17 (27)	25 (39)	18 (28)	17 (27)	17 (27)	9 (14)
Six sessions	11 (17)	6 (9)	8 (13)	4 (6)	3 (5)	5 (8)
Seven sessions	4 (6)	1 (2)	0 (0)	2 (3)	1 (2)	0 (0)
Mean	3.9	3.5	3.2	3.0	2.8	2.5

Appendix D: RESCUE, North, 2020 - App usage and mean days used for the MyCOPD arm in participants who did not withdraw from the study

Table D1: RESCUE, North 2020 – App usage and mean days used for the myCOPD arm in participants who did not withdraw from the study

Week of Trial	Total (N=20)	
	Users, n (%)	Days used, mean (SD)
Week 1	17 (85%)	4.5 (2.37)
Week 2	13 (65%)	5 (1.83)
Week 3	12 (60%)	4.4 (2.39)
Week 4	10 (50%)	5.4 (1.78)
Week 5	10 (50%)	4.9 (1.91)
Week 6	11 (55%)	4.3 (2.2)
Week 7	10 (50%)	4.6 (2.12)
Week 8	10 (50%)	6 (1.33)
Week 9	9 (45%)	5.1 (2.09)
Week 10	8 (40%)	5.6 (1.77)
Week 11	9 (45%)	4.4 (2.65)
Week 12	8 (40%)	5.6 (2.13)

Users are participants who accessed the app on at least one day in the week under evaluation. This shows the minimum amount of participant usage.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

Assessment report overview

myCOPD for self-management of chronic obstructive pulmonary disease (COPD)

This assessment report overview has been prepared by the Medical Technologies Evaluation Programme team to highlight the significant findings of the External Assessment Centre (EAC) report. It includes **brief** descriptions of the key features of the evidence base and the cost analysis, any additional analysis carried out, and additional information, uncertainties and key issues the Committee may wish to discuss. It should be read along with the company submission of evidence and with the EAC assessment report. The overview forms part of the information received by the Medical Technologies Advisory Committee when it develops its recommendations on the technology.

Key issues for consideration by the Committee are described in section 6, following the brief summaries of the clinical and cost evidence.

This report contains information that has been supplied in confidence and will be redacted before publication. This information is highlighted in yellow. This overview also contains:

- Appendix A: Sources of evidence
- Appendix B: Comments from professional bodies
- Appendix C: Comments from patient organisations
- [Appendix D: Additional analyses carried out by External Assessment Centre] [delete if no appendix D]

1 The technology

myCOPD is a digital tool to help people manage their chronic obstructive pulmonary disease (COPD). It has been designed to be used by people at any stage of their disease progression.

myCOPD is an integrated online platform covering elements of education, self-management, symptom reporting and pulmonary rehabilitation. It has a dashboard of self-care tools and educational resources to teach people how to take their inhalers correctly; a self-management plan to help people understand what medication to take and when; a prescription assessment function to check whether there are conflicts with prescribed medication; and a COPD assessment test to enable patients to track their symptoms to help optimise symptom control. People can also access an online 6-weeks pulmonary rehabilitation course consisting of an incremental exercise programme with education sessions to help promote self-management of COPD.

Data collected via the app can be reviewed by clinicians, helping clinical decision-making. People can access myCOPD on any digital device such as smart phones and tablets that connect to the internet. For the Evidence Standards Framework, myCOPD is classified as active monitoring and is therefore a tier 3b technology. The app was released in 2015, and there are over 11,000 users across the UK now. The technology was supported by the innovation and technology tariff in 2017.

2 Proposed use of the technology

2.1 Disease or condition

COPD is a long-term respiratory condition. In the UK, an estimated 1.2 million people are living with COPD. It is the second most common lung disease in the UK after asthma and on average, 115,000 people are diagnosed with COPD each year. In England, the prevalence of COPD was 1.9% in 2019 using GP recorded data (NHS digital 2020). Most people are not diagnosed

until they are 50 years of age or older. It is more common in men than in women (British Lung Foundation 2019).

Typical COPD symptoms include breathlessness when active, a persistent cough and frequent chest infections. Without treatment, the symptoms are likely to gradually get worse. Some patients may periodically experience sudden and acute worsening of symptoms knowns as exacerbations which may be triggered by infection. Optimal treatment can help control symptoms, slow the progression of the disease and prevent exacerbations, but the condition is not curable.

In the UK, it is estimated that 1.4 million GP consultations are related to COPD each year. It is the second most common cause of emergency admissions with an estimated 1 in 8 emergency hospital admissions for COPD.

2.2 Patient group

myCOPD is intended to be used by people with COPD to better understand their condition and to support shared care process, with clinicians and patients having access to the clinical information for managing and monitoring the condition.

2.3 Current management

The majority of people (90%) with COPD live at home and their management is likely to be shared between healthcare professionals in primary and secondary care (NICE guideline on COPD, 2010). Most people with mild and moderate symptoms and those who are not experiencing frequent exacerbations will be managed predominately in primary care. People with severe COPD are likely to have frequent exacerbations leading to hospital admissions.

The NICE guideline for chronic obstructive pulmonary disease over 16s: diagnosis and management provides recommendations on the management of stable COPD covering smoking cession, 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 are given training.

The NICE guideline recommends the development of an individualised self-management plan to include education and an action plan for managing the risk of exacerbations including a cognitive behavioural component being considered in the self-management plan to help those who feel frightened when experiencing symptoms of breathlessness. For some people with COPD such as those who are functionally breathless or those who have had a recent hospitalisation because of an acute exacerbation, pulmonary rehabilitation is recommended to help better manage symptoms and improve exercise capacity and quality of life (British Thoracic Society 2014)

NICE recently published a COVID-19 rapid guideline on community-based care of patients with COPD. The guideline recognised the need to reduce face-to-face contacts, recommending people access online resources.

2.4 Proposed management with new technology

The adoption of myCOPD in the NHS is unlikely to substantially change the care pathway for people with COPD. Face-to-face appointments are likely to remain the gold standard of care. The company noted that some clinical commissioning groups (CCGs) have already adopted myCOPD alongside existing care pathways. This is consistent with the views of the experts that myCOPD enables service providers to offer a blended service, combining access to digital tools with face-to face support. The use of myCOPD can respond to people' preferences and service availabilityand so if face-to-face services cannot be delivered at a time when people need the service, myCOPD may be substituted.

The company suggested that, it is possible that myCOPD could replace some elements of the existing care for some people with COPD. For example, pulmonary rehabilitation (PR) delivered by myCOPD could replace face-to-

face programmes. Similarly, using the app's monitoring features by clinicians could possibly replace some face-to-face appointments; for example appointments where inhaler use or the self-management plan is reviewed. The company also advised that many NHS services have used myCOPD to support people during the COVID pandemic, with the platform replacing face-to face appointments.

3 Company claimed benefits and the decision problem

The company has not proposed any changes to the scope. The decision problem is described in Appendix D..

4 The evidence

4.1 Summary of evidence of clinical benefit

Evidence from clinical studies

The company provided 5 publications on 4 completed studies and 1 ongoing study.

- 3 RCTs (TROOPER, RESUE, EARLY)
- 1 observational study (North et al. 2014)
- 1 ongoing study (Chmiel et al 2020) (see section 6)

The EAC's search did not identify any additional clinical study that was not stated in the company's submission. It identified the full text publication of the observational study which was included in the assessment (North et al. 2015),

The EAC critiqued 3 RCTs and 1 observational study. TROOPER used a 'non-'inferiority design (Bourne et al. (2017) and RESCUE was a feasibility trial (North et al 2020). The sample sizes were relatively small, ranging from 41 to 90. The baseline characteristics of the study populations in the intervention groups were matched reasonably well but there were some

noticeable differences; for instance, RESCUE had more people with severe COPD in the myCOPD group than the usual care group. Study populations were followed up between 6 weeks and 3 months. The comparator varied across the RCTs but was described as standard care. Little detail was provided in RESCUE and EARLY studies. All trials are UK studies. The EAC considered that the results from the trials were generalisable to people with COPD in the NHS. The EAC concluded that the overall quality of the trials was moderate because of risk of bias in relation to unclear outcome measurement and a lack of blinding. It acknowledged that the blinding may not possible due to the nature of the interventions.

The quality of the observational study was considered to be low because the study was a single site service development project done in the UK with limited information on its methodology and poor reporting of results.

Real-world evidence

The company submitted 6 published local evaluations (RWE) of myCOPD, 9 unpublished evaluations, myCOPD usage data and results of a company questionnaire.

In additional to real world evidence(RWE) provided by the company, the EAC identified further 5 published evaluations. Therefore the RWE includes a total of 20 documents describing local evaluations across 10 sites:

- Coventry primary care
- Dorset CCG evaluation
- Ipswich and East Suffolk (2 documents)
- Kent community health NHS Foundation Trust
- Leeds community Healthcare, Leeds Chest Clinic and Primary Care
- Mid and South Essex case study
- NHS Grampian evaluation (2 documents)
- NHS West Lothian (3 documents)
- NHS Highland (3 documents)

- Southend CCG (5 documents)

Several of these reported limited data or were a poster. Many were interim evaluations designed to inform commissioning decisions or service developments, and not published in peer-reviewed journals.

No validated checklists are available to critically appraise RWE. The EAC considered that most of the evaluations were poor quality, with many not reporting the methodology, patient numbers or characteristics, clinical outcomes and follow-up period. Despites the limitations, the EAC concluded that RWE reflect the use of myCOPD in clinical practice and the findings of the local evaluations could be generalisable to local health services.

The results of the clinical studies and local evaluations are summarised here. Table 1 presented the clinical studies. Details of the real-world evidence were presented in Table 4.2a of the assessment report.

COPD symptoms assessment (CAT score)

All 4 comparative studies showed a greater improvement of COPD symptoms people using myCOPD compared with those having usual care. A reduction in CAT score indicates an improvement in COPD symptoms with a difference of 2 points or more in a CAT score suggesting a clinically important change in health status. RESCUE showed that a difference of 2.94 (95% CI -6.924 to 1.05) in favour of myCOPD at the 3-months follow-up (North et al. 2020).

RWE also reported clinical important improvements in CAT scores (Southend CCG evaluations, NHS Grampian evaluation; Mid and South Essex evaluation).

Acute exacerbation

The changes in the number of exacerbations varied in the studies. The RESCUE trial showed that people in the myCOPD group were less likely to have exacerbations (relative risk, RR= 0.58, 95% CI 0.32 to 1.04) compared with people having usual care in the 90-days period. The EARLY trial reported the RR (adjusted for disease COPD severity, baseline values and centre) of

2.55 (95% CI 1.17 to 5.54), indicating that people in the myCOPD group were more likely to have exacerbations compared with those in usual care group for 3 months follow-up.

RWE reported a reduction of the number of people reporting exacerbations after 6 months using myCOPD (NHS Grampian Evaluation),

Hospital admissions

People using myCOPD had fewer hospital readmissions compared with those having usual care, with the adjusted odd ratio of 0.38 (95% CI 0.07 to 1.99) (North et al. 2020).

RWE reported a decrease in the number of hospital admissions in people who used myCOPD from 6 at baseline to 0 at 5 months (NHS Grampian evaluation). A 12-months follow up study reported no statistically significant differences in hospital admissions, inpatient bed days, or other health service utilisation before and after myCOPD activation (Cooper et al. 2021).

Inhaler error

Three comparative studies showed a greater reduction in the number of inhaler errors in people used myCOPD compared with those having usual care. The difference was statistically significant in the RESCUE trial (RR= 0.38, 95% CI 0.18 to 0.80).

RWE reported an improvement in technique using the inhaler (Leeds evaluation) and the number of “Good inhaler technique” practices increased from 48% to 91% (n=64) at 5 months, with a reduction in mean rescue inhaler use from 3.17 to 2.13 (NHS Grampian evaluation).

Walking test - 6MWT

TROOPER reported outcome data for the 6MWT (Bourne et al. 2017). An increase in test score indicates an improvement in symptoms. There was no statically significant difference in the intervention groups. Designed as a non-inferiority trial, the lower 95% CI for the adjusted mean difference between

groups was well above the 'non-'inferiority threshold and, therefore, the non-inferiority of myCOPD was demonstrated.

RWE reported an improvement in the 6MWT in people using myCOPD (Mid and South Essex evaluation; Southend CCG evaluation).

Adherence and usage of myCOPD

Adherence

The RCT evidence showed that a decline in adherence of the app during the study period. After 6 weeks, 22% of people used myCOPD completed the recommended 5 or more sessions compared with 77% of people in comparator group attended their face-to-face sessions (Bourne et al. 2017).

RWE suggested an improvement in the completion of pulmonary rehabilitation (PR) programme (Southend CCG evaluation, Kent CHFT evaluation). The company data showed that of a potential [redacted].

Usage

Both RESCUE and EARLY trials reported a continuing decline in using myCOPD. EARLY reported people's experience of using the app, and found that exercise videos, education videos, inhaler videos and medication diaries were most useful. Other domains of the app like self-management plan, appointment dairy, chest clearance videos and weather and pollution forecast were less popular.

The use of the app varied in the real-world evidence, which largely reported the percentage of people by different domains within myCOPD.

Other outcomes

The evidence from the RCTs showed that no statistically significant differences in quality of life, self-efficacy for appropriate medication use and patient activation measure (PAM) test which assesses patient knowledge, skill, and confidence for self-management.

RWE reported fewer unscheduled GP appointments after using myCOPD (NHS Grampian evaluation).

Summary of clinical evidence

The EAC concluded that the evidence suggests that using myCOPD was associated with greater improvements in COPD assessment test (CAT) scores, 6-minute walking test (6MWT) and inhaler techniques but evidence was inconclusive on rates of exacerbations. The use of the app fell over time in all 3 RCTs and in the real-world data. The RCTs had a 3-month follow-up period and sample sizes were relatively small, and the EAC considered that these studies could be underpowered to detect statistical significance differences. Two RCTs were not designed to detect superiority of myCOPD over usual care for clinical endpoints. Of the 3 robust RCTs, benefits are shown in 2 population populations (people discharged from hospital with AECOPD and people referred for PR). All studies are done in the UK and the real-world data across 10 settings indicated that myCOPD could be a useful addition to usual care as part of a blended approach to encourage self-management.

Table 1: Clinical studies included by the EAC.

<table>
<tr><th>Study and design</th><th>Participants/ population</th><th>Intervention & comparator</th><th>Outcome measures and follow up</th><th>EAC Comments</th></tr>
<tr><td colspan="5">Randomised controlled trial</td></tr>
<tr>
<td>Bourne et al. (2017)
A single site prospective, parallel group, single blind, ‘non-’inferiority RCT.
UK
Follow-up: 6 weeks
NCT02706613
Funding: SBRI grant from NHS England

(publications include full text, abstract and clinical trial record)</td>
<td>People aged ≥40 years with a diagnosis of COPD who had a modified MRC dyspnoea of grade ≥2 and referred for PR, with internet access and ability to use a web platform. Note that this is a subgroup of the overall COPD population.

Minor imbalances between groups in baseline characteristics, most notably in smoking status with a higher proportion of current smokers in the face-to-face group compared with the online group (23% vs 14%).</td>
<td>Intervention: 'myPR' – the PR elements of myCOPD. Referred to as myCOPD going forward. (n=64, intention to treat ITT)

Comparator: face-to-face class-based PR programme for 6 weeks, delivered in a conventional community setting. (n=26, ITT)
was not reported despite these being</td>
<td>Primary outcomes
<table>
<tr><td></td><td>myPR</td><td>Face-to-face</td><td>Adjusted differ</td></tr>
<tr><td colspan="4">6-minute walk test, 6MWT) (miles)</td></tr>
<tr><td>baseline</td><td>388.7 (104.4)</td><td>416.5 (118.3)</td><td rowspan="2">23.8 (−4.5 to 52.2)</td></tr>
<tr><td>7 weeks</td><td>433.6 (102.9)</td><td>445.1 (124.9)</td></tr>
<tr><td colspan="4">COPD assessment test (CAT)</td></tr>
<tr><td>baseline</td><td>18.1 (7.9)</td><td>17.3 (6.7)</td><td rowspan="2">−1.0 (−2.9 to 0.86)</td></tr>
<tr><td>7 weeks</td><td>14.9 (7.0)</td><td>16.2 (6.7)</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
</table>
Adverse events: myCOPD (n=2), face to face PR (n=3).

Usage data: 18 out of 26 people completed 2 sessions at the week 6 (69%); and 14 out of 64 (22%) people used myCOPD completed the recommended 5 or more sessions.</td>
<td>Single centre study

Study partially matches scope.
The app only was used for PR. Patients in myCOPD arm did not receive all components of usual care as in the comparison arm.

This was a ‘non-’inferiority trial which needs fewer participants than a superiority or equivalence study.</td>
</tr>
<tr>
<td>North et al. (2020)
A single site, single-blind, parallel arm feasibility RCT.
UK
Follow-up: 3 months
NCT027066000</td>
<td>People aged >45 years with a primary COPD diagnosis using an inhaled device and a current or ex-smoker for over 10 years. Included patients who had been admitted to a single NHS Acute Trust or managed by the local COPD Admission Avoidance Team in a home-based environment with an acute exacerbation of COPD.</td>
<td>Intervention: myCOPD (n=20)

Comparator: Usual care with additional written support (education booklet plus self-management plan) (n=21)</td>
<td>
<table>
<tr><td></td><td>myCOP</td><td>Usual care</td><td>Differ (95%CI)</td></tr>
<tr><td>CAT score</td><td>20.7 (7.35)</td><td>25.1 (7.24)</td><td>Mean=-2.94 (-6.92 to 1.04)</td></tr>
</table>
</td>
<td>Single centre study
Patients in myCOPD arm did not receive all components of usual care as in the comparison arm. This was a feasibility trial with a relatively small sample size (<50 participants).
The 2 groups were broadly comparable in terms of the participants’ baseline characteristics with a few exceptions.</td>
</tr>
</table>

<table>
<tr>
<td>Funding: SBRI grant from Innovate UK
(publications include full text, abstract and clinical trial record)</td>
<td>Internet access and ability to use a web platform, use a written action plan, or both, was also needed. Note that this is a subgroup of the overall COPD population.</td>
<td></td>
<td>
<table>
<tr><td>Readmission rate</td><td>0.24 (0.44)</td><td>0.39 (0.55)</td><td>OR=0.38 (0.07 to 1.99)</td></tr>
<tr><td>no. of exacerbations</td><td>1.06 (0.83)</td><td>1.88 (1.84)</td><td>RR=0.58 (0.32 to 1.07)</td></tr>
<tr><td>no. of critical errors</td><td>1.17 (1.70)</td><td>4.00 (4.97)</td><td>RR=0.38 (0.18 to 1.04)</td></tr>
</table>

Adverse events: myCOPD (n=3), face to face PR (n=1).

Usage data: 17 (85%) people activated the app in the first week. The proportion of users was highest in the first week and lowest in the last week of the study with 8 (40%) users.
</td>
<td>The myCOPD group contained higher proportions of people with severe COPD (55% vs 29%), male (65% vs 52%), and current smokers (35% vs 24%) than the usual care group. There was no statistical analysis of these differences. The prevalence of comorbidities such as anxiety and depression was not reported.</td>
</tr>
<tr>
<td>Crooks et al. (2020)
multiple sites, open label, parallel arm RCT. UK
Follow-up: 90 days
NCT03620630
Funding: UKRI Innovate UK Grant to my mhealth

(Published as full text, abstract and clinical trial record)</td>
<td>Patients aged 40 to 80 years with either mild to moderate COPD (FEV1 >50% predicted and FEV1/forced vital capacity ratio <70%) or COPD of any severity diagnosed within the past 12 months.</td>
<td>Intervention: myCOPD (n=29)

Comparator: Usual care for 3 months (the study did not provide details about usual care) (n=31)</td>
<td>Primary outcomes
<table>
<tr><td></td><td>myCOPD</td><td>Usual care</td><td>Adjusted differ</td></tr>
<tr><td colspan="4">COPD assessment test (CAT)</td></tr>
<tr><td>baseline</td><td>21.5 (8.0)</td><td>19.8 (5.4)</td><td rowspan="3">-1.3 (-4.5 to 1.9)</td></tr>
<tr><td>90 days</td><td>19.2 (9.0)</td><td>19.8 (7.5)</td></tr>
<tr><td>Difference</td><td>-1.8 (5.8)</td><td>0 (5.5)</td></tr>
<tr><td colspan="4">1 or more inhaler error</td></tr>
<tr><td>Difference from baseline to 90 days</td><td>-0.3 (0.7)</td><td>0.1 (0.7)</td><td>OR=0.3 (0.1 to 1.1)</td></tr>
<tr><td colspan="4">Mean number of inhaler error</td></tr>
<tr><td>Difference from baseline to 90 days</td><td>-0.3 (1.6)</td><td>-0.1 (1.2)</td><td>IRR=0.97 (0.52 to 1.81)</td></tr>
</table>
</td>
<td>3 UK primary care centres.

This was a superiority trial but had a small sample size (60 participants).

The 2 groups were broadly comparable for some characteristics including COPD severity, age and smoking status. There was imbalance in others but no statistical analysis of these differences..

The authors added the study was underpowered to demonstrate significant effects in the primary outcomes at 90 days.</td>
</tr>
</table>

			Exacerbations: myCOPD=18; usual care=11 (post baseline); myCOP=13; usual care=3 (baseline). **Adverse events**: myCOPD=5; usual care=7. Two participants, both in usual care, reported multiple adverse events. No serious adverse events were reported during the study.	
Comparative observational study				
North 2015 single site, observational (cohort) study. UK Follow-up: 3 months Funding: SBRI for Healthcare contract.	People with a confirmed COPD diagnosis who were recruited through a request for volunteers in a local newspaper.	**Intervention:** 'myCOPD' followed for 3 months. (n=27) **Comparator:** Paper-based system (n=9) Baseline characteristics not reported	**CAT score** -Most (95%) of the participants who used the system showed a mean decrease in their COPD assessment tool (CAT) score of 4.5. -The patient group who did not use the system had a mean increase in their CAT score of 2.4 points **Inhaler error** - at the start of our first study, 98% of patients used their inhalers incorrectly (based on all 36 people in the study). - By the end of the study, 98% of patients who used the online system were using their inhalers correctly.	Single centre study in UK Patients in myCOPD arm did not receive all components of usual care as in the comparison arm. Small study (<50 patients). The brief article had limited details of the study methods. Poor reporting of outcome data.

4.2 Summary of economic evidence

The company and the EAC did not find any published economic evidence.

De novo analysis

The company submitted 2 cost models which compared the costs and health outcomes associated with using myCOPD and standard care in 2 different population groups:

1) people who were discharged from hospital admission for acute exacerbation of COPD (AECOPD) and
2) people who were eligible for pulmonary rehabilitation (PR).

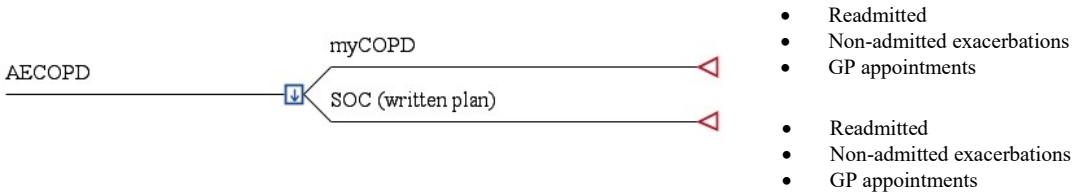
The EAC noted the population in the decision problem is all people with a diagnosis of COPD but agreed with the company's decision to model only subgroups of people where clinical benefit has been demonstrated.

AECOPD model

Company model

The company's model is a cost calculator and the structure is illustrated in Figure 1. The company modelled a typical CCG purchasing an unlimited myCOPD license package based on the CCG population. The base case analysis is presented over a 1-year time horizon, with 3 months of outcomes (hospital re-admissions for COPD, non-admitted exacerbations, and GP appointments) were compared using myCOPD and standard of care (a written self-management plan at discharge). The company noted that there are some discharge services available (for example, early supported discharge or community respiratory services) for people with COPD but these were not modelled as they are either not universal or poorly implemented.

Figure 1: Company model diagram AECOPD



EAC critique of the model

The EAC considered the company's model structure to be appropriate. No errors or discrepancies were identified in the base case analysis. But the EAC thought not all people eligible for myCOPD would agree to be registered for it because the evidence showed that 46% of people eligible for myCOPD agreed to use it (North et al. 2020). Therefore, the EAC added an input for the uptake of myCOPD in the model to reflect this.

Pulmonary rehabilitation (PR) model

Company model

The company developed a decision tree model including all people who are eligible for a PR programme. This model also assumed the CCG purchasing the myCOPD license package as in the AECOPD model, and was intended to estimate the potential additional benefits of using myCOPD as an alternative option for delivering PR. An alternative costing scenario was included in the model whereby a PR service provider could purchase the myCOPD license specifically for PR services.

Patient choice was considered in the model with 3 options available: face-to-face PR (6 weeks), hybrid (1 face-to-face session per week for 6 weeks plus use of the myCOPD app) or myCOPD alone (6 weeks). The analysis compared the cost between offering PR with myCOPD and without, and was presented over approximately a 1-year time horizon with all people receiving an initial face-to-face assessment for their eligibility of PR. Then the number of exacerbations was modelled depending on whether people completed the PR programme they chose or not.

EAC critique of the model

The EAC considered the company's PR model structure to be appropriate. No errors or discrepancies were identified. The EAC noted that the company included the cost of a face-to-face assessment for all people referred to PR regardless of their completion of PR programme but no additional cost was included for those who did not finish a programme. The EAC included a cost

for those starting but not completing their programme for all treatment groups in the model. The EAC also changed the decision point in the model from time when people were referred to PR service, to the point at which people have opted in for or shown they would be willing to use myCOPD (see Figure 2a and Figure 2b). This change was to align the decision point in the AECOPD model and the population in the evidence (Bourne et al. 2017), and also enabled to calculate the cost on the basis of an individual using myCOPD rather each CCG.

Figure 2a: Company's PR model structure

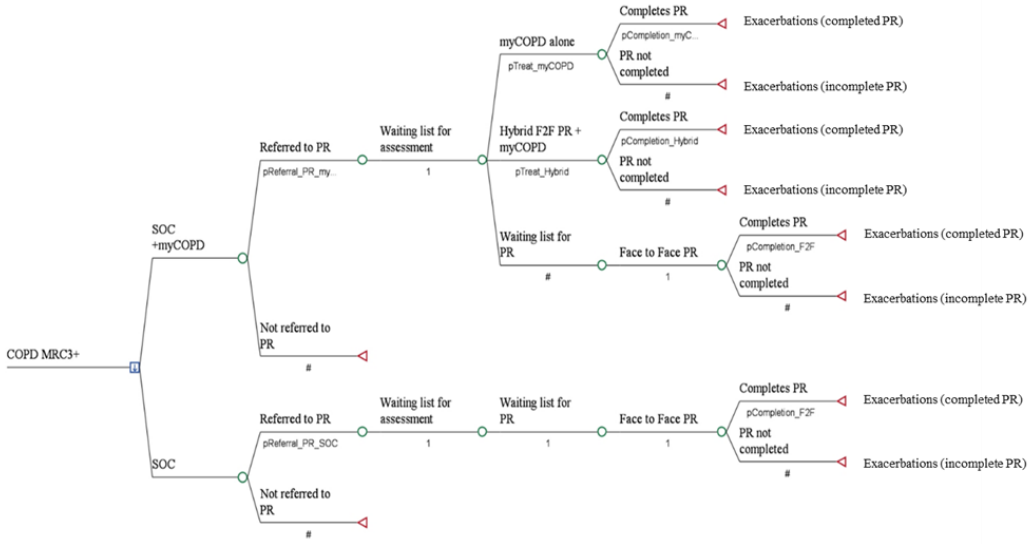
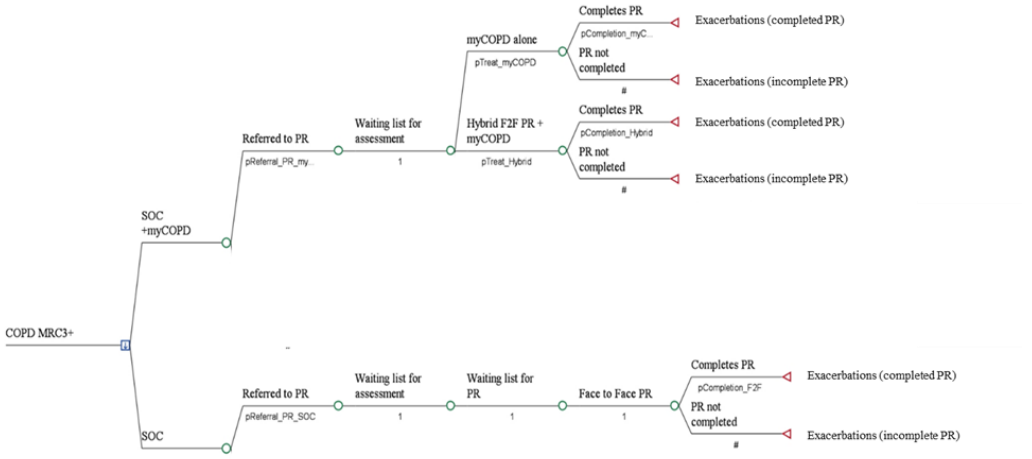


Figure 2b: EAC modified PR model structure



Model parameters

AECOPD model

The clinical parameters included in the company's AECOPD model included population size in a CCG, the number of hospital admission for AECOPD, the number of events including number of exacerbations, GP appointments and readmissions after hospital discharge due to AECOPD. The EAC accepted these estimates with 3 amendments to reflect the evidence base (North et al 2020):

- An inclusion of 46% myCOPD uptake rate;
- Changed the number exacerbations after hospital discharge in people using myCOPD from 1.06 to 1.09;
- Changed readmission rate in people using myCOPD from 0.24 to 0.20.

PR model

The clinical parameters included in the company's PR model included the prevalence of COPD, the percentage of people who were eligible for PR referrals, the probability of people having possible treatment options, the probability of completing PR course, waiting time for PR course and the annual number of exacerbations. The EAC considered most estimates to be reasonable with the following changes:

- Changed the probability of being treated with hybrid (combined myCOPD with face-to face sessions) or myCOPD alone from 11% to 12% by taking into account of the completion of PR courses.
- Changed the number of people in this model from 2,577 to 127 because decision point in model changed. The number of people in the scenario of PR service provider changed from 495 to 121.

Costs and resource use

AECOPD model

The annual cost of a 3-year myCOPD license for a CCG is £0.25 cost per person registered with a GP in the CCG. The EAC updated the health service use costs including the cost of exacerbation self-managed or managed in primary care and emergency hospital admission for acute exacerbation using the most update to date NHS reference costs. In the company submission, the cost of registering a person for a myCOPD licence was £9.75, the EAC changed this to £19.50 to reflect a longer registration time (30 mins instead of 15) suggested by the clinical experts.

PR model

The base case PR model was an additional subgroup of people in the CCG who could be included for the same contract, administration and training costs. Therefore, the cost of myCOPD was not included in this model. The only set-up cost related to myCOPD in the PR model was the cost of registering the additional PR patients on the myCOPD app. This cost was updated by the EAC as described for the AECOPD model. Other changes that EAC made to parameters (see Table 9.2 in the assessment report) include:

- Cost of exacerbations was changed from £283 to £328 to reflect the costs of admitted and non-admitted exacerbation;
- Costs of starting the PR course and not completing: £26 for face-to-face PR; £13 for combined myCOPD and face to face PR; and £2 for myCOPD alone.

Results

AECOPD model

The company base case results showed a saving of £204,641 per CCG over 1 year time period. The EAC made changes to the model resulted in a reduced cost saving, with a saving of £86,297 per CCG (see Table 2). The differences were the registration cost of myCOPD and the resource use costs

(exacerbations, readmissions and GP appointments). This cost saving was influenced by the myCOPD uptake. The cost difference between myCOPD and standard care would decrease if the uptake decreased.

The EAC notes that the licence cost for myCOPD is based on everyone registered with GPs in a CCG, and it is possible that people other than those in the population modelled could benefit from myCOPD. Any potential additional benefits would be incurred with only the additional cost of registering a patient for myCOPD (at £19.50 per patient).

The EAC also calculated the results per person with a saving of £170 per person when using myCOPD (see table 9.22 in the Assessment Report)

Table 2: Summary of base case results for the AECOPD model

	Company's results			**EAC results**		
	myCOPD	**Standard of care (SoC)**	**Incremental cost per CCG**	**myCOPD**	**SoC**	**Incremental cost per CCG**
myCOPD contract costs	£111,866	£0	£111,866	£111,866	£0	£111,866
myCOPD registration costs	£10,774	£0	£10,774	£9,914	£0	£4,957
myCOPD training costs	£1,950	£0	£1,950	£1,950	£0	£1,950
myCOPD administration	£360	£0	£360	£360	£0	£360
GP appointments	£79,742	£98,278	-£18,535	£36,682	£45,208	-£8,526
Exacerbations	£62,783	£111,352	-£48,568	£45,399	£78,140	-£32,741
Readmissions	£419,984	£682,473	-£262,490	£172,100	£341,221	-£169,121
Total	**£687,462**	**£892,102**	**-£204,641**	**£378,271**	**£464,568**	**-£86,297**

PR model

The company base case results showed a saving of £20,27 per CCG over 1 year time period. The EAC made changes to the model resulted in an increased cost saving, with a saving of £22,78 per CCG (see Table 4). In the alterative cost scenario (when the license was purchased by the PR service providers), the company results showed a saving of £8,707 per PR service provider and the EAC's results showed £11,093 saving per PR service provider (see Table 4). The differences between the company results and the

EAC results were mainly driven by the decision point used which impacts on the number of people who eligible for PR and chose preferred treatment options. Other changes include minor changes to the clinical parameters and changes to the costs/resources associated with referral to PR, and those who start but do not finish their PR courses.

The EAC also calculated results per person with a saving of £179 per person when using myCOPD (see table 9.23 in the Assessment Report

Table 4: Summary of base case results for the PR model – per CCG and the alterative cost scenario – per PR service provider.

	Company's results			EAC results		
Base case (per CCG)						
	myCOPD	**SoC**	**Incremental cost**	**myCOPD**	**SoC**	**Incremental cost**
Licence and registration of myCOPD	£1,117	£0	£1,117	£2,485	£0	£2,485
myCOPD support/face-to-face assessments	£4,228	£0	£4,228	£10,553	£5,851	£4,703
Face-to-face assessments	£126,672	£151,703	-£25,031	£9,280	£37,119	-£27,839
Starting and not completing PR	£23,912	£23,912	£0	£546	£1,923	-£1,377
Exacerbations	£2,343,048	£2,343,631	-£583	£117,176	£117,926	-£751
Total	**£2,498,978**	**£2,519,246**	**-£20,269**	**£140,040**	**£162,819**	**-£22,779**
Alterative cost scenario – per PR service provider						
Licence and registration of myCOPD	£11,617	£0	£11,617	£12,917	£0	£12,917
myCOPD support/face-to-face assessments	£26,742	£22,724	£4,018	£10,029	£5,560	£4,469
Face-to-face assessments	£120,379	£144,166	-£23,787	£8,819	£35,275	-£26,456
Starting and not completing PR	£0	£0	£0	£519	£1,828	-£1,309
Exacerbations	£395,142	£395,696	-£554	£111,354	£112,068	-£713
Total	**£553,879**	**£562,586**	**-£8,707**	**£142,456**	**£154,730**	**-£11,093**

Scenario and sensitivity analyses

AECOPD model

The company provided a best- and worst-case scenarios which used the most and least beneficial clinical parameter vales for myCOPD to explore the range of economic outcomes that might results from implementing myCOPD (see

details of the parameters in Table 9.7 and Table 9.8 of the assessment report). The results of the scenario analysis showed that using myCOPD remains cost saving in the best-case scenario but became cost incurring in the worst-base scenario. The company identified the key driver of cost saving from the sensitivity analysis was the readmission rate over 90 days post AECOPD. The 90-day rate of readmissions in the myCOPD arm at which the base case model changed from cost saving to cost-neutral/cost-incurring was 0.357 per person (base-case 0.24).

The EAC updated the best and worst case scenarios and also proposed a scenario whereby the benefits of myCOPD continue for the 9 months following the 3 months of benefits seen in the clinical trial. In the best-case scenario the EAC included the benefits of myCOPD continuing for 9 months, and in the worst-case scenario the EAC set the rate of admissions and exacerbations to be equal in both arms and used a 12% uptake of myCOPD.. The EAC best-case scenario resulted a saving of £4,143,428 per CCG and the worst-case scenario incurred an additional £58,928 per CCG. The scenario where only the myCOPD benefits were extended (and all other base case inputs remained the same) led to a cost saving of £658,312 per CCG.

The EAC conducted deterministic sensitivity analysis and threshold analysis. The rates at which the parameters in the myCOPD arm changed from cost saving to cost-neutral/incurring were: 26.2% of uptake rate of myCOPD and 0.3 per person of 90-day rate of readmissions in the myCOPD group. The EAC conducted PSA of the base case model. The analysis was run for 5,000 iterations and resulted in an average cost decrease per CCG of £86,059. The estimated probability that using myCOPD to be cost saving is 73.5%.

PR model

The company presented an additional scenario for the PR model where no impact on resource use was included due to the uncertainty around PR outcomes. In this scenario costs for exacerbations were removed. The company also presented the results of the PR costing scenario (whereby a PR

service purchased the myCOPD license for their PR service only). The estimated results from the company ranged from an £8,707 cost saving per CCG (PR service contract scenario) to a £19,685 cost saving per CCG (scenario excluding costs for exacerbation).

In the EAC's updated model the scenario result where no impact on resource use was included resulted in a cost saving of £22,029 per CCG and £10,379 per PR service when considering the PR service costing scenario.

The EAC conducted deterministic sensitivity analysis and threshold analysis on key drivers in the PR costing scenario.

Table 6: Threshold analysis for PR model (per CCG)

Input parameter	Base case value	Threshold value*	EAC comments
Probability of being treated with myCOPD	12.2%	1.9% when hybrid model uptake is 12.2% Or 9.8% if hybrid model uptake is assumed 0%	If a hybrid model is not being used, uptake of myCOPD needs to be higher to demonstrate a cost saving. There is still a paucity of data around uptake in real world settings in the appropriate setting.
Probability of being treated with hybrid model	12.2%	NA, still cost saving at 0% when myCOPD alone uptake is 12.2% Or 15.2% if myCOPD alone uptake is assumed 0%	If use of myCOPD alone is not accepted, acceptance of the hybrid model needs to be higher in the model to demonstrate cost savings. A two-way sensitivity analysis on uptake is provided below.
Number of patients referred to PR service	495	240	myCOPD may not be cost saving in PR services with fewer than 240 referrals per year.

The EAC conducted PSA. The model was run for 1,000 iterations and resulted in an average cost saving of £22,913 per CCG, and £11,384 in the PR service costing scenario. The estimated probability that the intervention is cost saving is 86% in the CCG model and 87% in the PR service costing scenario.

Summary of economic evidence

There are no published economic evaluations of myCOPD. The EAC considered that cost models focused on 2 subgroups of people with COPD (people were discharged after hospital admission for acute exacerbation; people were eligible for PR service) were appropriate. Both company and EAC's models demonstrated an economic benefit using myCOPD.

5 Patient survey

NICE's public involvement programme circulated a survey to explore people's experience using myCOPD between April to July 2021. A total of 390 responses were received. Results from responders were extracted and are summarised Appendix C.

6 Ongoing research

The company advised undertaking ongoing work looking at the contribution myCOPD to big data, with a Horizon 2020 BigMedilytics grant. BigMEdilytics is a 3-year project which aims to enhance patient outcomes and increase productivity in the health care sector by applying big data technologies to complex datasets. The company has developed a real time database and user interface which enables prospective review of aggregated, anonymised data on app registration, app access and clinical outcomes.

The company provided full text of the study by Chmiel et al. (2020), which has not been peer reviewed (Chmiel et al. 2020). The study is a part of this ongoing project and was undertaken in partnership with the University of Southampton. The Chmiel at study used self-reported data from myCOPD to predict exacerbation events using a machine learning model. The study analysed data from 2,374 people with COPD, who entered 68,139 self-reported symptoms. Heuristic and machine-learnt models were applied to the entered symptom data. Results showed that both a baseline model and a machine learnt model showed moderate ability in predicting exacerbation events occurring within 3 days of a given self-report. Further studies are underway to improve the accuracy of such models

The company also noted that several NHS sites are conducting on-going evaluations of myCOPD but none are sufficiently mature to inform this assessment.

7 Issues for consideration by the Committee

Clinical evidence

- The evidence from RCTs and real-world evaluations suggests that using myCOPD was associated with an improvement in clinical outcomes including CAT scores, 6MWT and inhaler techniques in people with COPD. However, evidence on rates of exacerbations was inconclusive. Most outcomes were not statistically significant different in people using myCOPD and those having usual care.
- Clinical benefits were shown in 2 patient populations (people discharged from hospital with AECOPD and people referred for PR) but the sample sizes are small with short study follow-ups. RWE suggests some benefits may extend to 12 months.
- The use of the app fell over time but some local evaluations reported an improvement in the PR course completion. The EAC noted that clinical experts had concerns with attrition and adherence with myCOPD, highlighting the need for evidence to demonstrate using the app changes behaviour and outcomes. The importance of adherence was reported in a subgroup analysis of a local evaluation (NHS Highland), suggesting that individuals with greater adherence had a reduction in bed days (Cooper et al. 2021b).
- The real-world evidence reflected the use of the app in clinical practice, reporting positive feedback from people with COPD and clinicians. The evidence provided snapshots and there are considerable inconsistencies and uncertainties when they were used to inform outcome measures.

Cost evidence

- The company submitted the cost models included in 2 subgroups of people with COPD. The EAC considered the model structures, assumptions and time horizon to be appropriate. But it noted a small overlap in people included in the AECOPD model and the PR model. It is possible that some of the benefits demonstrated from using myCOPD in the PR model may be

overestimated when compared with standard of care. However, the company thought this would be approximately 5%. The EAC agreed the models would be combined because of the potential to double-count benefits if combined.

- Both models have shown that using myCOPD would be cost-saving. But there are uncertainties in the models, particularly around the uptake rates of myCOPD because of lack of real-world evidence and no consensus from clinical experts.
- The PR model can be considered as an add-on to the AECOPD model, if a license is to be purchased only for use for PR services, uptake and the number of referrals need be sufficient to ensure the cost savings to outweigh the license fees.

8 Authors

Health technology assessment analyst: YingYing Wang

Health technology assessment adviser: Bernice Dillon

NICE Medical Technologies Evaluation Programme

September 2021

Appendix A: Sources of evidence considered in the preparation of the overview

A Details of assessment report:

Angaja P, Stephanie W, Judith S et al. DHT001 myCOPD: External Assessment Centre report, August 2021.

B Submissions from the following sponsors:

- mymHealth Ltd

C Related NICE guidance

- Chronic obstructive pulmonary disease in over 16s: diagnosis and management. NICE clinical guideline 115 (2019). Available from https://www.nice.org.uk/guidance/ng115.
- COVID-19 rapid guideline: community-based care of patients with chronic obstructive pulmonary disease (COPD). NICE guidance 169 (2020). Available from https://www.nice.org.uk/guidance/ng168.

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Appendix B: Comments from professional bodies

Expert advice was sought from experts who have been nominated or ratified by their Specialist Society, Royal College or Professional Body. The advice received is their individual opinion and does not represent the view of the society.

Professor Nawar Bakerly

Consultant respiratory physician and clinical chief information officer, Salford Integrated Care Organisation, Salford Royal NHS Foundation Trust.

Dr Alex Hicks

Respiratory consultant, Portsmouth Hospitals NHS Trust.

Lisa Ward

Lead respiratory nurse practitioner, Southend University Hospital NHS Foundation Trust.

Dr Beth Sage

Consultant Respiratory Physician, NHS Highland.

Ms Jennifer Robson

COPD Specialist Team Lead at Queen Alexandra Hospital, Portsmouth Hospitals NHS Trust.

Professor Tom Wilkinson

Professor of Respiratory Medicine and Honorary NHS Consultant Physician at the University of Southampton and myhealth, founder of myCOPD.

For full details, please see the expert adviser questionnaire (EAQ) responses which are included in the committee pack.

Appendix C: Patient survey

Results of NICE PIP patient survey

During April–July 2021, NICE's public involvement programme posted an online survey, 390 responses were received including:

- 358 people with COPD and used the app
- 2 people with COPD but not used the app
- 1 carer of a person with COPD who used the app
- 28 people did not specify.

All responders confirmed that they read the information sheet provided which explains the purpose of the survey and how the information will be used. All responders consented to NICE using the information as described.

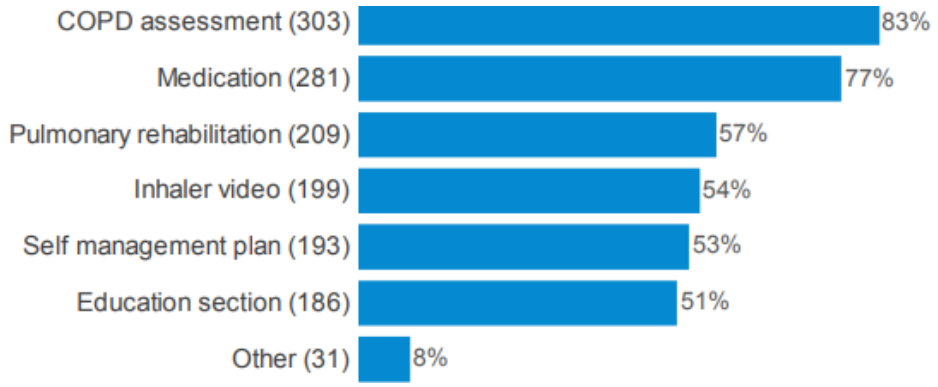
1. Responder demographics

Mean age of responders was 66.8 years, range 43–93 years (n=335 provided data). 54.6% of responders were male (n=213) and 40.5%% were female (n=158).

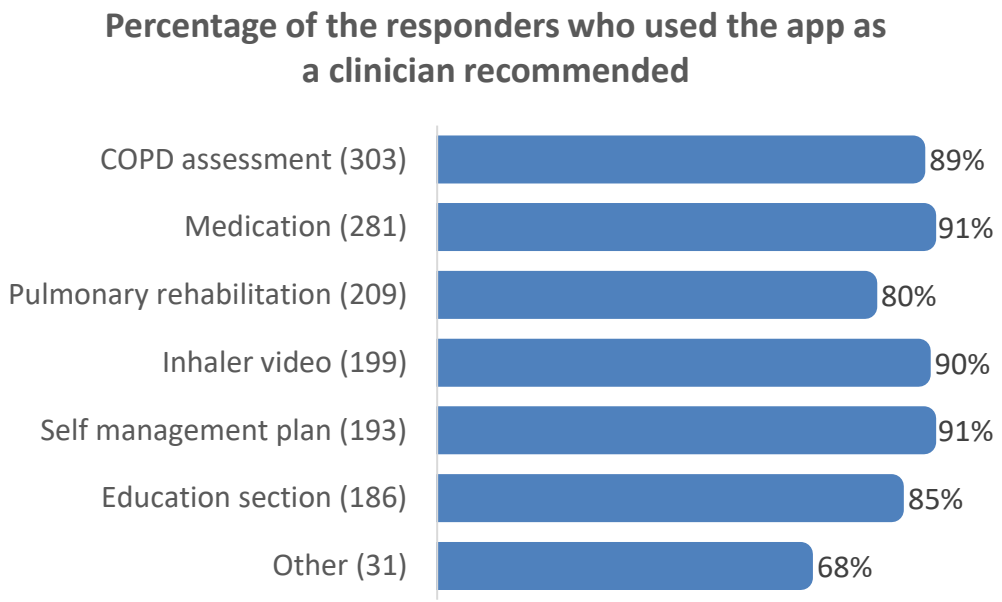
2. myCOPD for self-management

On average, people had COPD for about 9 years (n=328 respondents).

The functions that the responders used myCOPD included:

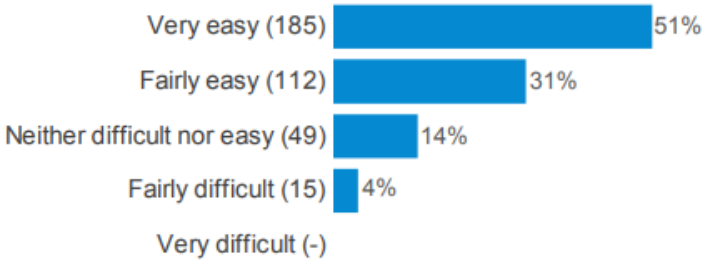


Of different functions within the app, most responders used the app as the clinicians recommended



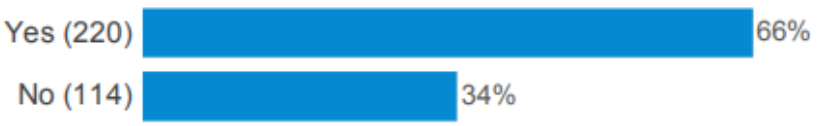
3. Experience of using the app

Most responders (n=297/359, 82.7%) found easy to use myCOPD and a small number of responders found difficult (n=15/359, 4%). Around 14% of responders found neither easy nor difficult.

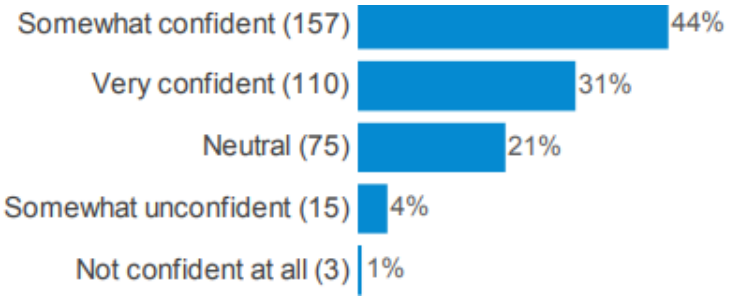


Over 70% of responders (n=254/356, 71.3%) had an introduction with a healthcare professional when being prescribed the app, providing support for registering or activating the app.

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.



Three quarters of responders (n=267/358, 74.6%) felt confident in manging COPD symptoms after using the app.



Main positive effects

"*MyCOPD encourages me to exercise on a regular basis. I have created my half hour exercise routine based on the app and alternate this with a 4 to 5 mile fast walk. I stopped smoking back in 2012. I used to smoke cigars but the app doesn't allow you to say that it only talks of cigarettes and pipes and also only goes back to 2017.*"

"using my copd makes me more aware of my symptoms, and makes me look after my health better than i did before."

"*The medication diary is helpful to make sure I keep to schedule. The other facilities I dip into from time to time to refresh my knowledge of how to cope with COPD.*"

"*I find doing the pulmonary exercises is beneficial to my breathing, which is somewhat helpful to doing daily activities, also having done exercises give me a good feeling.*"

"*My symptoms continue to worsen, however having the app helps me to feel more confident in that the app is always with me which contains lots of info about my condition. If needed it's at my fingertips which gives a little peace of mind which goes a long way. If anything I'm guilty of not using it as much as I should but I'm still a busy person working long hours.*"

"*Some very good advice information, useful to revisit from to time. Pulmonary rehab videos useful a few times but too boring, they have prompted me to exercise more regularly tho which has been beneficial. Inhaler videos good esp with advice from clinician. I manage my health better than I used to and have had less exacerbations.*"

"*Only use it once a month to record current condition as at the moment everything is under control."*

“Before I used this app I couldn't breathe without oxygen, now I can manage some things without oxygen, and perform a few tasks at home on my own. I feel more confident and I haven't had an exacerbation during lockdown. I feel as If I am not alone with this app. It has been the single most useful thing since I was diagnosed with COPD”

Main negative effects

“*..I often forget to do it*”

“*I used the app very thoroughly for about a year but felt there was a big lack of interest in it from the healthcare side if things my own cops nurse didn't even know of it. When covid-19 and the pandemic kicked in it seemed pretty pointless using it as apart from 2 brief phone calls I have heard nothing at all from my copd nurse or and copd related professionals*”

“*The exercises are very boring and time consuming makes me feel old. I do other activities that I enjoy encluding weight exercise and dance. I have only just started to feel out of breath a little. I would like face to face contact with a specialist at least once a year so I could express how I feel and get help, if I need it.*”

“*No input from clinician. No idea if the data is meaningful. Does anybody else see my data?*”

”

Appendix D: decision problem from scope

Population	People with a diagnosis of COPD	
Intervention	myCOPD as an add-on intervention to standard care	
Comparator(s)	Standard care without MyCOPD as an add-on intervention	
Outcomes	The outcome measures should include: ●COPD symptoms assessment (COPD assessment test [CAT] score) ●Rates of acute exacerbation ●Rates of hospital admissions, readmissions or emergency admissions ●Number of consultations with healthcare professionals in primary and secondary care ●Rates of inhaler error ●Compliance (adherence) to the use of myCOPD including pulmonary rehabilitation (rate of course completed), education, inhaler technique improvement and exercise. ●Health-related quality of life ●Patient activation measurement ●Self-efficacy for appropriate medication use ●Walking test (a 6-minute walking test) ●Device-related adverse events	
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.	
Subgroups to be considered	●Severity of COPD (mild, moderate or severe COPD) ●Time since COPD diagnosis	
Special considerations, including those related to equality	myCOPD is only accessible to people who have access to and are able to use devices that connect to the internet. Digital technologies such as myCOPD may be unsuitable for people with visual or cognitive impairment, problems with manual dexterity or learning disabilities. People who are unable to read or understand health related text, including those unable to read English, may not be suitable for using the technology. Disability and race are protected characteristics under the Equality Act. COPD is linked with deprivation and is more common in the most deprived communities. Access to electronic devices, access to the internet and user engagement with the technology may be more difficult for the people in deprived communities. COPD is most common in people over 50 years. Men tend to be at higher risk than women. Age and sex are protected characteristics under the Equality Act.	
Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No
Any other special considerations	Not applicable	

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technology guidance

SCOPE

myCOPD for self-management of chronic obstructive pulmonary disease (COPD)

1 Technology

1.1 Description of the technology

myCOPD is a digital tool to help people manage their chronic obstructive pulmonary disease (COPD) .It has been designed to be used by people at any stage of their disease progression including those who are newly diagnosed with COPD, those being discharged from hospital, those at their annual review and those unable to attend class-based pulmonary rehabilitation. People can access myCOPD on any digital device such as smart phones and tablets that connect to the internet.

myCOPD is an integrated online education, self-management, symptom reporting and pulmonary rehabilitation system. It has a dashboard of self-care tools and educational resources to teach people how to take their inhalers correctly; a self-management plan to help people understand what medication to take and when; a prescription assessment function to check whether there are conflicts with prescribed medication; and a COPD assessment test to enable patients to track their symptoms to help optimise symptom control. The technology provides online tutorials on a range of topics such as smoking cessation and the role of exercise in managing their COPD. People can also access an online 6-week pulmonary rehabilitation course consisting of an incremental exercise programme with education sessions to help promote self-management of COPD.

Patients using myCOPD can allow clinicians access to their data to enable management decisions and monitoring to be done remotely. Clinicians can access and review the patient's profile including medications and the assessment reports. Clinicians are also able to suggest a change to a patient's medications such as inhaler/device prescription, and any changes are communicated automatically to patients as notifications.

myCOPD is listed on the NHS app library. It is currently being reassessed following an update of the technology. The technology was supported by the innovation and technology tariff in 2017. For the Evidence Standards Framework, myCOPD is classified as active monitoring and is therefore a tier 3b technology.

1.2 Regulatory status

myCOPD is CE-marked as a class I medical device.

1.3 Relevant diseases and conditions

COPD is a long-term respiratory condition. In the UK, an estimated 1.2 million people are living with COPD. It has also been estimated that there are over 2 million people living with COPD undiagnosed. It is the second most common lung disease in the UK after asthma and on average, 115,000 people are diagnosed with COPD each year. Most people are not diagnosed until they are 50 years of age or older. It is more common in men than in women (British Lung Foundation 2019).

Typical COPD symptoms include breathlessness when active, a persistent cough and frequent chest infections. Without treatment, the symptoms are likely to gradually get worse. Some patients may periodically experience sudden and acute worsening of symptoms knowns as exacerbations which may be triggered by infection. Optimal treatment can help control symptoms, slow the progression of the disease and prevent exacerbations, but the condition is not curable.

In the UK, it is estimated that 1.4 million GP consultations are related to COPD each year. It is the second most common cause of emergency admissions with an estimated 1 in 8 emergency hospital admissions for COPD in the UK. COPD also accounts for approximately 30,000 deaths every year in the UK (NICE Clinical Knowledge Summaries, 2019). People with COPD are more likely to experience worse psychological functioning and greater psychological distress compared with people with other chronic diseases (Dury 2016). Anxiety and depression are common comorbidities in patients with COPD, having a negative effect on mortality, exacerbation rates and length of hospital stay (Pumar et al. 2014).

1.4 Current management

The majority of people (90%) with COPD live at home and their management is likely to be shared between healthcare professionals in primary and secondary care (NICE guideline on COPD, 2010). Most people with mild and moderate symptoms and those who are not experiencing frequent exacerbations will be managed predominately in primary care. People with severe COPD are likely to have frequent exacerbations leading to hospital admissions.

The NICE guideline for chronic obstructive pulmonary disease over 16s: diagnosis and management provides recommendations on the management of stable COPD covering smoking cession, 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. All people with COPD should be followed up, the frequency of which depends on the severity of symptoms. Follow-up visits should review the need for referral to specialist care, smoking status, symptom control, presence of complications, effects of medication and inhaler technique. The guideline notes that most people with COPD can develop adequate inhaler technique if they are given training.

The NICE guideline recommends the development of an individualised self-management plan to include education and an action plan for managing the risk of exacerbations including a cognitive behavioural component being considered in the self-management plan to help those who feel frightened when experiencing symptoms of breathlessness. For some people with COPD such as those who are functionally breathless or those who have had a recent hospitalisation because of an acute exacerbation, pulmonary rehabilitation is recommended to help better manage symptoms and improve exercise capacity and quality of life.

1.5 Claimed benefits

The benefits to people using myCOPD claimed by the company are:

- Improvement in self-management of COPD symptoms
- Increased quality of life
- Enabling shared care between primary care and secondary care

The benefits to the healthcare system claimed by the company are:

- Reduction in emergency admissions
- Increased efficiency in patient management
- Improvement in coordination of patient care or services

2 Statement of the decision problem

Population	People with a diagnosis of COPD
Intervention	myCOPD as an add-on intervention to standard care
Comparator(s)	Standard care without MyCOPD as an add-on intervention
Outcomes	The outcome measures should include: • COPD symptoms assessment (COPD assessment test [CAT] score) • Rates of acute exacerbation • Rates of hospital admissions, readmissions or emergency admissions • Number of consultations with healthcare professionals in primary and secondary care • Rates of inhaler error • Compliance (adherence) to the use of myCOPD including pulmonary rehabilitation (rate of course completed), education, inhaler technique improvement and exercise. • Health-related quality of life • Patient activation measurement • Self-efficacy for appropriate medication use • Walking test (a 6-minute walking test) • Device-related adverse events
Cost analysis	Costs will be considered from an NHS and personal social services perspective. The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.
Subgroups to be considered	• Severity of COPD (mild, moderate or severe COPD) • Time since COPD diagnosis
Special considerations, including those related to equality	myCOPD is only accessible to people who have access to and are able to use devices that connect to the internet. Digital technologies such as myCOPD may be unsuitable for people with visual or cognitive impairment, problems with manual dexterity or learning disabilities. People who are unable to read or understand health related text, including those unable to read English, may not be suitable for using the technology. Disability and race are protected characteristics under the Equality Act. COPD is linked with deprivation and is more common in the most deprived communities. Access to electronic devices, access to the internet and user engagement with the technology may be more difficult for the people in

	deprived communities. COPD is most common in people over 50 years. Men tend to be at higher risk than women. Age and sex are protected characteristics under the Equality Act.	
Special considerations, specifically related to equality	Are there any people with a protected characteristic for whom this device has a particularly disadvantageous impact or for whom this device will have a disproportionate impact on daily living, compared with people without that protected characteristics?	No
	Are there any changes that need to be considered in the scope to eliminate unlawful discrimination and to promote equality?	No
	Is there anything specific that needs to be done now to ensure MTAC will have relevant information to consider equality issues when developing guidance?	No
Any other special considerations	Not applicable	

3 Related NICE guidance

Published

- NICE guideline 115: Chronic obstructive pulmonary disease in over 16s: diagnosis and management.

4 External organisations

4.1 Professional organisations

The following societies have been alerted to the availability of the draft scope for comment:

- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Physicians
- Primary Care Respiratory Society
- British Thoracic Society
- British Lung Foundation
- National Association of Primary care
- British Association of Emergency Medicine
- British Society for Genetic Medicine
- Association of Respiratory Nurse Specialists
- Community Practitioners' & Health Visitors Association
- Infection Prevention Society
- The Association for Respiratory Technology and Physiology (UK)

4.2 Patient organisations

NICE's Public Involvement Programme contacted the following organisations for patient commentary and alerted them to the availability of the draft scope for comment:

- British Lung Foundation
- The Breathing Charity

NICE National Institute for Health and Care Excellence

Adoption report: DHT001 myCOPD for self-management of chronic obstructive pulmonary disease (COPD)

Summary

Adoption levers identified by contributors

- Provides an option for self-management and help for people with COPD. Importance of self-management will increase in the current climate due to COVID.
- Enables pulmonary rehabilitation to be provided and completed remotely at a time it cannot be delivered in person.
- Enables self-assessment and production of a CAT score. This may save appointment time.

Adoption barriers identified by contributors

- Lack of evidence to support routine use.
- Patient adherence: users reported that many people did not access or continue to access the app therefore benefits were not realised.
- Equitable access: use of the app requires an internet connected device, IT literacy and confidence.
- Not linked to the patient electronic record.

1 Introduction

The adoption team has collated information from 5 healthcare professionals (3 clinicians and 2 commissioners) with expertise in COPD, working within NHS organisations. One has experience of using myCOPD and another of commissioning use of myCOPD within their area. It has been developed for the medical technologies advisory committee (MTAC) to provide context from current practice and an insight into the potential levers and barriers to adoption. It does not represent the opinion of NICE or MTAC.

This adoption report includes some of the adoption considerations for the routine NHS use of the technology.

2 Contributors

Details of contributing individuals are listed in the below table.

Job title	Organisation	Experience of myCOPD
Consultant Respiratory Physician	NHS Foundation Trust	Evaluated for use locally
PMO Manager; leading on long term conditions	CCG	Currently commissions myCOPD locally
Respiratory consultant	NHS Trust	Aware of but not used app
Advanced Practice Respiratory Nurse	NHS Healthboard	Used as part of pilot
Head of Planned Care	CCG	Commissioned as part of pilot

3 Current practice in clinical area

Most people with COPD are managed in primary care. Specialist respiratory services, based in secondary care, see people who need more intense care or rehabilitation. These people are more at risk of needing unscheduled care (mostly in the form of hospital admission) because of their COPD. If, following the provision of secondary care, which includes signposting and referral to other services, care needs are reduced, people are discharged back to management within primary care. A large part of secondary care provision is to provide education and support.

4 Use of myCOPD in practice

One commissioner had commissioned the app (along with other apps for other conditions provided by the same company) for adoption within their area.

The other professionals spoken to by the adoption team had assessed the app for use or implemented its use on a pilot basis. None of these went on to commission the app for routine use.

The cost of the app is £40 per licence per person and contributors reported that they commissioned its use across the CCG or secondary care respiratory service (either on a pilot basis or for routine use).

The app:

- was generally accessed on a smart phone rather than on a computer.

5 Reported benefits

The potential benefits of adopting myCOPD, as reported to the adoption team by the contributors to this report are:

- Potential for improved self-help/management
- Possible reduced unscheduled care admissions and associated costs through improved self-management (not yet seen by contributors)

- Ability to provide pulmonary rehabilitation remotely
- Ability for patients to complete COPD assessment and provide CAT score, possibly saving appointment time
- Ability for clinicians to log in and monitor patients' progress

6 Insights from the NHS

Care pathway

Contributors thought that myCOPD could be a useful additional resource to support people with COPD to self-manage their condition. It has been offered as an adjunct to the care pathway and does not replace anything. It was reported that the pulmonary rehabilitation course provided on the app, could potentially replace group sessions (currently delivered remotely due to COVID), but this has not yet happened.

Patient selection

Two of the three contributors who had or were currently offering use of the app, reported that their service or CCG did not apply a patient selection process. myCOPD was offered to all people with COPD at any NHS contact or appointment.

One contributor who implemented the app on a pilot basis, explained that they offered the app to those with a COPD diagnosis and at increased risk of an unscheduled care admission. These are people who had:

- an MRC (mMRC Dyspnea Scale) grade of 3 and above
- a CAT (COPD assessment test) score of 10 and above
- a previous admission with an exacerbation
- been categorised as in the top tier of need.

Those who implemented use of the app on a pilot basis indicated that if they were to adopt it, they would apply a triage and patient selection process. which would include

offering the app to those with an appropriate level of IT literacy and confidence with training to those who needed it.

Interestingly, one contributor said that people at risk of unscheduled care and therefore more likely to benefit from using the app were more unlikely to use it. They explained that they would attempt to uncover the rational for this and target this group if they were to use this or apps like this in the future.

Contributors also commented on the potential for increasing inequalities in more vulnerable groups who might not have access to an internet connected device and that these may be the groups with the highest incidence of COPD.

One contributor who had not used the app indicated that it may be a useful resource for patients who use a lot of healthcare resources, or those with anxiety who need lots of reassurance, as it may help to bridge the gap for these people.

Clinician confidence and engagement

Contributors who assessed the app for use or who implemented it on a pilot basis highlighted that its lack of evidence is an issue in terms of adoption for routine use.

The information collected within the app is not linked to the patient's electronic record. Red flags or deterioration in COPD are shown in the self-assessment test section and these are not seen or acted upon unless clinicians log in to review them. Most clinicians spoken to did not log in and review this and referred to the app as a self-management tool.

No contributors were able to report benefits in terms of patient outcomes following use of myCOPD.

Patient adherence and motivation

Two of the three organisations who had offered the app to people with COPD explained that only a small number of patients were getting maximum benefit out of it. Some didn't access the app at all, and many who used it initially tapered off relatively quickly. Reasons given for not accessing the app included: forgetting the

password, not ticking the correct boxes at sign up and simply forgetting. Like all self-help applications motivation is a key requirement and contributors recommended that this should be assessed before offering myCOPD to ensure maximum benefit.

Reports providing information on the number and frequency of patient log ins, as well as usage can be requested and obtained from the company.

Use of the app requires a level of IT literacy and confidence. Users without this were more likely to reduce and stop use.

Contributors reported that people accessed the parts of the app most relevant to them. Few people used all the functionality and content and therefore maximum benefit was not achieved.

Resource impact

All contributors reflected that with regular and correct use of the app, savings should be seen from fewer unscheduled care admissions. This benefit has not been realised to date.

As the app is offered as an adjunct to the current care pathway, it would represent an additional cost and contributors reported that it would need to be supported with a business case.

Capacity

Contributors reported that users needed a lot of initial support to help them navigate the system. This could have an impact on clinic capacity as it may require a longer appointment.

If patients can complete the CAT (COPD assessment test) themselves within the app shortly before this could save appointment time.

One potential benefit of the app identified by contributors is its use for pulmonary rehabilitation. If this module on the app is completed it could prevent the need for

people to attend a course in person which would result in cost and capacity savings (These sessions are currently being delivered remotely due to COVID).

Contributors reported a concern about the increase in resource use without improvements being seen in patient outcomes.

Training

Face to face training for clinicians is provided by the company who offer to support patient training if needed. Contributors reported that most clinicians provided this to patients themselves. Without significant initial support, contributors reported that patients were less likely to access and use the app.

The contributor who has commissioned use of the app has co-commissioned a digital health advisor with the company to train clinicians to advise patients on how to use the app (and the other apps commissioned and provided by the same company) and help with trouble shooting.

Monitoring

Contributors all highlighted that without information inputted into the app linking to the patient's electronic record deteriorations and red flags could be missed. However, they also stressed that as this was offered primarily as a self-management tool and an adjunct to the care pathway these issues should still be picked up. Patients were instructed that if a red flag is prompted by myCOPD, they should contact their service.

One contributor said that the company have indicated they are developing functionality to enable links with EMIS or System one.

Patient experience

Contributors reported that the app provides people with a wealth of information and resources to support them in their COPD self-management. Contributors said that the resources were of high quality with user-friendly language.

Contributors reported that the self-assessment and exacerbations scores can be helpful and motivating. However, as this is a subjective measurement some people continually obtain a red score with a request to contact their service leaving patients feeling they have tried everything and that their condition will not improve and thus act as a demotivator. The app is reported to be not subtle enough for some patients.

Contributors reported that myCOPD has been well received by people who need pulmonary rehabilitation but do not like group therapy and provides an alternative remote version for use during COVID.

7 Comparators

Contributors indicated that some patients use other apps and websites to help them self-manage their COPD. These included:

Florence Telehealth

My Lungs My Life

Contributors stated that whilst much of the information contained within myCOPD can be accessed at no cost online it is useful to be contained within a single log in on an app.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technologies guidance

DHT001 MyCOPD for self-management of chronic obstructive pulmonary disease (COPD)

Company evidence submission

Part 1: Decision problem, clinical evidence and outline of economic evidence

Company name	my mhealth Limited
Submission date	October 2019
Regulatory documents attached	Please list regulatory documents submitted (e.g. CE certificate, instructions for use, etc.) MHRA Class 1; CE marked December 2016 (MDD)
Contains confidential information	Yes

August 2019 v1.0

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1 Decision problem

	Scope issued by NICE	Variation from scope (if applicable)	Rationale for variation
Population	People with a diagnosis of COPD	Enter text.	Enter text.
Intervention	myCOPD as an add-on intervention to standard care	Enter text.	Enter text.
Comparator(s)	Standard care without myCOPD as an add-on intervention	Enter text.	Enter text.
Outcomes	-COPD symptoms assessment (COPD assessment test [CAT] score) -Rates of acute exacerbation -Rates of hospital admissions, readmissions or emergency admissions -Number of consultations with healthcare professionals in primary and secondary care -Rates of inhaler error -Compliance (adherence) to use of myCOPD including pulmonary rehabilitation (rate of course completion), education, inhaler techniques improvement and exercise.	Enter text.	Enter text.

	-Health-related quality of life -Patient activation measurement -Self-efficacy for appropriate medication use -Walking test (a 6-minute walking test) -Device-related adverse events		
Cost analysis	Costs will be considered from an NHS and personal social services perspective The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.	Enter text.	Enter text.
Subgroups to be considered	- Severity of COPD (Mild, moderate or severe COPD) - Time since COPD diagnosis	Enter text.	Enter text.

Functional classification and risk category	Self-Manage	Enter text.	Enter text.
Special considerations, including issues related to equality	No special considerations were submitted in the NICE scoping document	Enter text.	Enter text.

2 The technology

2.1 Overview of the technology

Give the brand name, approved name and details of any different versions of the same technology (including future versions in development and due to launch within 12 months). Please also provide links to (or send copies of) the instructions for use for each version of the technology.

Brand name	myCOPD
Approved name	myCOPD
CE mark class and date of authorisation	MHRA Class 1, CE marked; December 2016 (MDD)
Main function	To support the management of COPD by patients and their healthcare team
Development stage	Live
Current availability in the UK	Yes. Via website www.mymhealth.com; Google play; Apple store

Version(s)	Launched	Features
1.7.12	20 Sept 2019	Bluetooth medical device integration UX improvements Bug fixes and performance improvements
1.7.1	16 July 2019	Bug fixes and performance improvements.
1.7.0	15 July 2019	Bug fixes and performance improvements

1.6.5	17 May 2019	Fixed issues with new account creation experienced by some users Simplified Forgotten password and user authentication Performance and usability improvements
1.6.2	2 May 2019	Performance and usability improvements Fixed some issues on iOS 12.2 preventing some videos from playing properly
1.5	2 Apr 2019	Updated Lifetime Licence pricing from 1 April 2019
1.4.1	7 Feb 2019	Bug fixes and performance improvements
1.4	15 Dec 2018	Bug fixes and performance improvements
1.3.1	20 Nov 2018	Bug fixes and performance improvemence
1.2.1	10 Oct 2018	Fixed issue where video sounds were not playing while device was in silent mode
1.2	11 Sept 2018	Bug fixes and performance improvements
1.0.1	15 May 2018	Bug fixes and performance improvements
1.0	6 May 2018	Release

Briefly describe the technology (no more than 1,000 words). Include details on how the technology works, functionality, integration with other systems, any innovative features, and if the technology must be used alongside another treatment or technology. Include diagrams if appropriate.

myCOPD is a digital tool to help people manage their chronic obstructive pulmonary disease (COPD) .It has been designed to be used by people at any stage of their disease progression including those who are newly diagnosed with COPD, those being discharged from hospital, those at their annual review and those unable to attend class-based pulmonary rehabilitation. People can access myCOPD on any digital device such as smart phones and tablets that connect to the internet.

myCOPD is an integrated online education, self-management, symptom reporting and pulmonary rehabilitation system. It has a dashboard of self-care tools and educational resources to teach people how to take their inhalers correctly; a self-management plan to help people understand what medication to take and when; a prescription assessment function to check whether there are conflicts with prescribed medication; and a COPD assessment test to enable patients to track their symptoms to help optimise symptom control. The technology provides online tutorials on a range of topics such as smoking cessation and the role of exercise in managing their COPD. People can also access an online 6-week pulmonary rehabilitation course consisting of an incremental exercise programme with education sessions to help promote self-management of COPD.

Patients using myCOPD can allow clinicians access to their data to enable management decisions and monitoring to be done remotely. Clinicians can access and review the patient's profile including medications and the assessment reports. Clinicians are also able to suggest a change to a patient's medications such as inhaler/device prescription, and any changes are communicated automatically to patients as notifications.

myCOPD is listed on the NHS app library. It is currently being reassessed following an update of the technology. The technology was supported by the innovation and technology tariff in 2017. For the Evidence Standards Framework, myCOPD is classified as active monitoring and is therefore a tier 3b technology.

2.2 Claimed benefits of the technology

What are the claimed benefits for patients and the NHS of using the technology for the decision problem described in Section 1?

Claimed benefit	Supporting evidence	Rationale
Patient benefits		
Improvement in self-management of COPD symptoms	Rescue data - Reduction in the CAT score by 4 (p=0.025)	Improving the patient's well-being and reducing their ill-health and its impact on them and their surroundings
Correction of Inhaler techniques	Trooper study and Rescue – reduced number of critical errors (p=0.008)	Improved delivery of inhaled medication
Reduction in Exacerbations	Rescue Data (p=0.047)	Exacerbations are related to morbidity and mortality in COPD patients
Reduced admissions to hospital	Topol Health Care Review 2019	Reduced periods of ill-health and time spent in hospital
Reduced readmissions to hospital	Rescue Data (p=0.029)	Significant reduction in the return to hospital following a in-patient period
System benefits		
Reduction in admissions	Topol Healthcare Review 2019 – as above	Reduced periods of ill-health and time spent in hospital
Reduction in readmissions to hospital	Rescue data – as above	Reduced returns following discharge from hospital – as above
Safe scalability of pulmonary rehabilitation	Trooper data – showing non-inferior outcomes of PR associated with digital delivery	Enables upscaling of a service to meet the demands from the population, without a requirement for a large increase in the

		workforce required to deliver it.
Cost benefits		
Scalability for the provision of pulmonary rehabilitation	Trooper Study – as above	Increasing service requirements can be met without a large workforce escalation nor overhead
Reduction in non-elective demands from COPD patients – admissions and readmissions	Trooper and Rescue data	As above
Sustainability benefits		
Reduced carbon footprint	No formal evidence yet	Remote working reducing the need for patients to travel
Reduced infrastructural demand on providers	No formal evidence yet	Having patients at home means demands on local infrastructure (public transport) and provision of parking etc.

2.3 Other considerations

Describe any training (for healthcare professionals and patients or their carers) that would be needed if the NHS were to adopt the technology (no more than 500 words).

Access and training of the healthcare professions using the platform is usually undertaken face-to-face by a my mhealth with the procuring user group. This takes approximately 3 hours and is supported by in-app “how to” videos that explain how the functionalities in the app work. This is supplemented by written explanations too.

For patients, the same “how to” videos are available, alongside written explanations. No formal face-to-face training is undertaken, although my mhealth provides phone support during the working day and an email that users can access and ask questions. There are also FAQs to assist.

Briefly describe the environmental impact of adopting the technology across the NHS, including for example the impact of the manufacturing process and waste disposal process, and any sustainability considerations (no more than 500 words).

The apps my mhealth produce are all web-enabled. This means they are available on any internet-connected device with a browser 4years or younger. There is no waste from this point of view.

Using the app as a patient may enable them to reduce the healthcare visits required and support them becoming more engaged and empowered, whilst receiving some medical oversight (if consented to). This is in turn reduces the visits to healthcare environments, reducing carbon footprint through reduced travel, but also not placing unnecessary pressure on carparks and infrastructure to support patients moving around for appointments.

As published in the Topol Healthcare Review 2019 (admission reduction of 19%), reducing admissions has a significant impact on the use of medical equipment and consumables to treat exacerbating patients. By reducing this and subsequent readmissions (Rescue Study data – to be published), these costs and demands on the system are significantly reduced.

If the technology provides any health information, such as advice to users, briefly describe how this is aligned with best available sources such as NICE guidance or guidance from other relevant professional organisations or bodies. Describe how this is kept up to date and accurate (no more than 500 words).

The content of the app is aligned with the BTS guidelines on the management of COPD. Maintenance of the content's clinical currency is done through specialist review of changes to the guidelines. This is a manual process executed by specialists working the field. When updates are required, changes to the content of myCOPD are implemented within three months of the alteration to the guideline.

If peer-support or other similar communication functions are available within the technology please describe what safeguarding measures are in place to ensure the safety of users, for example user agreements or moderation. Describe who has access to the platform and their roles and why these people are suitable and qualified to have access (no more than 500 words).

The platform is created from a Top-Level Account (TLA) that is provided for the procuring group. This enables them to create manager's account from where they can then create clinicians' accounts. Patients' licences come from the clinicians signing them up to the platform.

Access to personal data is only available to the patients themselves and their healthcare team, having been granted access by the patient. This then means patients and their healthcare team can write, report and edit the content of the platform. Managers and more senior, non-clinical, account holders do not have access to personal data as they do not hold a clinical role. Data available to them is anonymised aggregated data reporting on the licence distribution metrics and use of the sections of the app.

Does the technology use recognised behaviour change techniques or frameworks? If yes, please provide details of these and provide academic references supporting the use of these techniques or frameworks. Please state how the principles of these techniques or frameworks have been incorporated into the technology and how the technology will be updated/aligned with best practice going forward (no more than 1,000 words).

The app provides content in accessible, bite-size chunks, to support simple messages being provided and received. It challenges established user behaviours by using repeated messaging and facilitating the co-creation of targets and goals aligned with best practice or personal aims. These goals are supported by in-app simple functionalities, such as identifiable colour coding (illustrating in target or not) or by the use of notifications generated by either the clinician or targets that nudge the user with a call to action.

Does the effectiveness of the technology rely on the use of artificial intelligence (AI)? If yes, please describe how AI is embedded into the technology, the type(s) of AI used and how the technology will be updated/aligned with best practice going forward (no more than 1,000 words). Provide any relevant references.

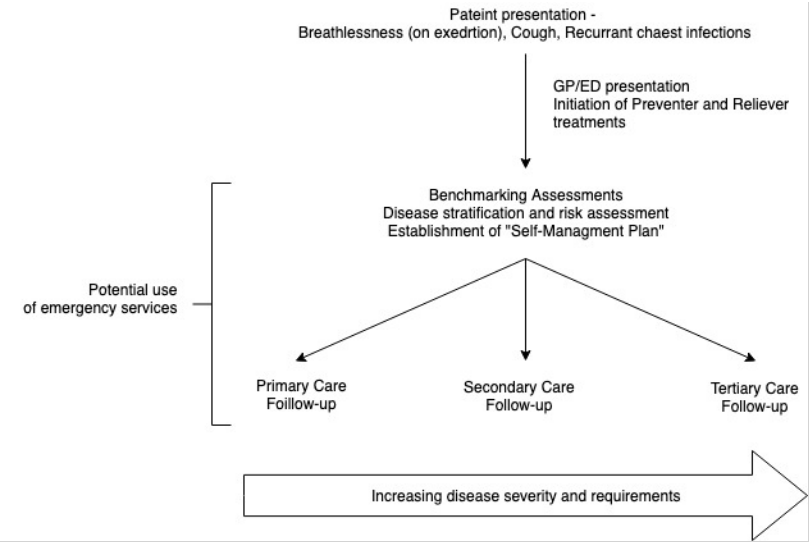
Currently there is no artificial intelligence embedded in the technology. We are exploring the possibility of doing so as the nature of the apps and the data would combine well to support this intervention.

3 Clinical context

3.1 Clinical care pathways

Describe the existing clinical care pathway(s) and the new clinical care pathway(s) that includes the proposed use of the technology, ideally using a diagram or

flowchart. If there are multiple options for new care pathways all should be detailed below.



Management includes: -

- Holistic approach to care
- Non-blame ; causes such as smoking may create difficult feelings
- Treatment – medical/non-medical
- Education
    - Disease
    - Management
    - Collateral – Co-morbidities, others
- Physical improvement

3.2 Validation of pathways

Provide information for new pathways to demonstrate that UK health/social care professionals have been involved in the design/development/testing and/or sign-off of the technology, and that the technology has been successfully piloted or implemented within the NHS (no more than 500 words).

In many regions of England, myCOPD was used alongside existing COPD patient management pathways. There were many successful integrations within CCGs in the UK. Notable examples were

- myCOPD being adopted into the Information Technology Tariff (ITT) 2017-2019. Through this opportunity, my mhealth were able to build relationships with NHS Digital and more than 50% of the English CCG's. From this much was learnt about developing and distributing the apps to patients via a clinician base. Real world data is continuously developing.
- Southend CCG created and trialled a hybrid model of pulmonary rehabilitation. Project lead – Sarah Mills (Integrated Commissioning Manager); Lead Clinician – Leanne Durdle (Respiratory Nurse Specialist). Patients were divided into three groups i) centre-based option, where all activity was delivered face-to-face: ii) the hybrid option, providing a mixture of face-to-face and home materials (included myCOPD or BLF material, if not internet available) and iii) the home-based option where an initial assessment was followed by home myCOPD (or BLF material), concluding with a final face-to-face assessment at the end.
  The results of this study reported improvements in patient outcomes for those using the App/hybrid model of care delivery.

3.3 System changes

Describe any system changes (for example staff changes, IT infrastructure and changes to clinical protocols) that would be needed if the NHS were to adopt the technology (no more than 500 words).

At this stage, there are no changes required to the NHS systems that are in place.
It would be advantageous for the existing systems to be updated to an operating system that is sufficiently advanced to be able to run the app but also from a cybersecurity standpoint, the older systems are a risk to patient/hospital security.

In the future, it would be envisaged that myCOPD (and the other my mhealth apps) would be linked with NHS data. Which one(s) is unclear at this stage, particularly while the NHS app is being developed and the "open API policy" is coming into effect.

To support the use of the app to deliver a service to a larger population, it would be envisaged that a service may need to increase its workforce, but the size of that increase would be nowhere near the size of the service increase. It could be a single person responsible for oversight of the app and the onboarding required.

3.4 Reducing health inequalities and improving access

Describe any contribution the technology makes to improving health inequalities in the UK health and social care system, or improving access to care among hard-to-reach populations (no more than 500 words).

Access to myCOPD is made possible by providing a licence for the app and having an internet connected device (with internet availability) to access and use the app. Once given access, some of the common healthcare inequalities are removed and some of the less common ones too.

1. The app is not influenced by human factors, so the delivered quality and content is not affected by external influences.
2. The content of the app is always aligned with best practice and clinically accurate and current.
3. Ability to access the resources on the app is not influenced by local infrastructure to support patient/healthcare provider movement to attend face-to-face activities such as meeting specialist nurses for updates/assessments or consultations. Examples of infrastructure would include public transport, the regional terrain and parking and its cost and availability.
4. The content is always presented in an accessible format to ensure optimum utility.

5. Pulmonary rehabilitation is supported by specific components in the app that are maintained to ensure myCOPD is an accurate and reliable source of information to support this intervention.
6. The Trooper study reported there not to be a significant difference in outcomes in those that used the app versus those receiving face-to-face pulmonary rehabilitation. No increase safety signals were observed in the study. This enables safe scalability of services, but also ensures those using the app do not suffer as a consequence, due to the outcomes being less good.
7. Inhaler videos are maintained and kept up to date, supporting all inhalers, including new-to-market inhalers. This supports the best personal technique for inhaled medication administration.

4 Evidence search

Undertake a systematic literature search to identify clinical and economic evidence on the technology. Also present any unpublished evidence.

Identification and selection of studies

Complete the following information about the number of studies identified.

Please provide a detailed description of the search and study identification strategy used, and a detailed list of any excluded studies, in appendix A.

Number of studies identified in a systematic search.		Text
Number of **clinical** studies identified as being relevant to the decision problem.		Text
Number of **economic** studies identified as being relevant to the decision problem[1].		Text
Of the relevant **clinical** studies identified:	Number of published **clinical** studies (included in table 1).	Text
	Number of **clinical** abstracts, unpublished clinical studies or other clinical data sources (included in table 2).	Text
	Number of **clinical** ongoing studies (included in table 3).	Text
Of the relevant **economic** studies identified:	Number of published **economic** studies (to be included in company submission part 2).	Text
	Number of **economic** abstracts, unpublished **economic** reports (to be included in company submission part 2).	Text
	Number of economic ongoing studies (to be included in company submission part 2).	Text

5 Clinical evidence

5.1 List of relevant clinical studies

In the following tables, give brief details of all studies identified as being relevant to the decision problem.

- Summarise details of published clinical studies in table 1.
- Summarise details of clinical abstracts, unpublished clinical studies and other clinical data sources in table 2.
- Summarise details of ongoing clinical studies in table 3.
- List the results of all clinical studies and data sources (from tables 1, 2 and 3) in table 4

Economic studies will be presented in part 2 of the submission. An overview of economic evidence is required in Section 10.

[1] Further detail about economic studies is required in Section 10

For any unpublished clinical studies, please provide a structured abstract in appendix A. If a structured abstract is not available, you must provide a statement from the authors to verify the data.

Any data that is submitted in confidence must be correctly highlighted. Please see section 1 of the user guide for how to highlight confidential information. Include any confidential information in appendix C.

Table 1 Summary of all relevant published clinical studies

Author, year and location	Study design	Patient population, setting, and withdrawals/lost to follow up	Intervention (and version(s))	Comparator(s)	Main outcomes
Bourne S, DeVos R, North M, et al. Online versus face-to-face pulmonary rehabilitation for patients with chronic obstructive pulmonary disease: randomised controlled trial. BMJ Open 2017;7:e014580. doi:10.1136/ bmjopen-2016-014580 NCT02706613	Randomised controlled Non inferiority study	COPD Patients MRC 2. Online arm carried out pulmonary rehab in their own home and the face to face arm in a local pulmonary rehabilitation centre Withdrawals 6 Lost to follow up 6	myPR online 6 week pulmonary rehabilitation programme	Face to face 6 week pulmonary rehabilitation	Co primary outcomes six minute walk test (6MWT) and COPD Assessement Test (CAT) Secondary outcomes Hospital Anxiety and Depression Score (HAD St Georges Respiratory Questionnaire (SGRQ) Safety – incident of Adverse events Results The adjusted mean difference for the 6 min walk test (6MWT) between groups for

					the intention-to-treat (ITT) population was 23.8 m with the lower 95% CI well above the non-inferiority threshold of −40.5 m at −4.5 m with an upper 95% CI of +52.2 m. This result was consistent in the per-protocol (PP) population with a mean adjusted difference of 15 m (−13.7 to 43.8). The CAT score difference in the ITT was −1.0 in favour of the online intervention with the upper 95% CI well below the non-inferiority threshold of 1.8 at 0.86 and the lower 95% CI of −2.9. The PP analysis was consistent

					with the ITT.

Table 2 Summary of all relevant clinical abstracts, unpublished clinical studies or other clinical data sources

Author, year and location	Study design	Patient population, setting, and withdrawals/lost to follow up	Intervention (and version(s))	Comparator(s)	Main outcomes
A Randomised controlled trial of E-health platform Supported Care vs Usual care after Exacerbation of COPD**: The RESCUE trial** Authors: Mal North, Simon Bourne, Ben Green, Anoop Chauhan, Tom Brown Jonathan Winter Matt Johnson, David Culliford, Jack Elkes, Victoria Cornelius Tom Wilkinson TO BE PUBLISHED NCT02706600	Randomised controlled feasibility study	Patient with a COPD diagnosis admitted with an exacerbation of COPD into secondary care. Withdrawals 6 Lost to follow up 0	myCOPD Self-management application	Written self-management plan and advice	Primary outcome measurement COPD Assessment Test Secondary outcome Inhaler technique Patient Activation Measurement (PAM) St Georges Respiratory Questionnaire (SGRQ) Hospital Anxiety and depression Score (HAD) Vetrans Specific Activity Questionnaire (VSAQ)

					Work and Productivity Activity Impairment (WPAI) Safety – Incident of adverse events Average app usage Results Improvement in CAT score -4.8 in favour of digitally enhanced care. Exacerbations were less frequent as were re admissions rates in the digital arm. Inhaler technique improved in the digital arm from 101 to 20 compared to the usual care arm of 100 to 72. P.0.021. There were no

					significant improvements in HAD, PAM, SGRQ, WPAI,VSAQ between arms. Average app usage 5 times per week over 3 month period.
North M, Bourne S, Green B*, et al* P238 A randomised controlled feasibility trial of an E-health platform supported care vs usual care after exacerbation of COPD. (RESCUE COPD) *Thorax* 2018;**73:**A231. ABSTRACT NCT02706600	Randomised controlled feasibility study	Patient with a COPD diagnosis admitted with an exacerbation of COPD into secondary care. Withdrawals 6 Lost to follow up 0	myCOPD Self-management application	Written self-management plan and advice	Primary outcome CAT Secondary outcome Inhaler technique Patient Activation Measurement (PAM) St Georges Respiratory Questionnaire (SGRQ) Hospital Anxiety and depression Score (HAD)

					Vetrans Specific Activity Questionnaire (VSAQ) Work and Productivity Activity Impairment (WPAI) Safety – Incident of adverse events Average app usage Results Improvement in CAT score -4.8 in favour of digitally enhanced care. Exacerbations were less frequent as were re admissions rates in the digital arm. Inhaler technique improved in the digital arm from

					101 to 20 compared to the usual care arm of 100 to 72. P.0.021. There were no significant improvements in HAD, PAM, SGRQ, WPAI,VSAQ between arms. Average app usage 5 times per week over 3 month period.
Real World Evidence Generation	Pragmatic real world data analysis of data generated by the app myCOPD	myCOPD app users	myCOPD	No comparator	App licences issued App licences activated Trends in how people are feeling (emoji VAS) CAT scores and various time

					points from initial access Percentage of Pulmonary Rehab programme completed No chest infections per year Percentage of educational programme completed App usage over a period of time. Medication adherence Smoking status COPD severity MRC score

Table 3 Summary of all relevant ongoing clinical studies

Principal investigator, and location [ClinicalTrials Identifier where appropriate]	Year (expected completion date)	Study design	Patient population, setting, and withdrawals/lost to follow up	Intervention (and version(s))	Comparator(s)	Outcomes
Evidence GenerAtion for the Clinical Efficacy and Cost Effectiveness of myCOPD in patients with mild, moderate and newly diagnosed COPD The EARLY COPD Study **REC No 18/SS/0112 IRAS ID 24921** NCT03620630	Sept 2019	Randomised Controlled Evidence generation study	Newly diagnosed COPD patients, Patients with mild and moderate COPD	myCOPD	Usual care	Mean CAT score Inhaler technique improvement in critical errors PAM mean change in activation level and score Exacerbation rates Hospital admission Change in activity improvement in total step count. Completion of educational content.

5.2 Details of relevant clinical studies

Please give details of all relevant clinical studies (all studies in tables 1, 2 and 3). Copy and paste a new table into the document for each study. Please use 1 table per study.

TROOPER	
How are the findings relevant to the decision problem?	The TROOPER Study published in BMJ open demonstrated that the myCOPD app offered equivalent outcomes to face to face pulmonary rehabilitation in terms of improvement in exercise capacity as measured by six-minute walk test and symptom control measured by CAT score.
Does this evidence support any of the claimed benefits for the technology? If so, which?	Yes- this study supports the claim that myCOPD can increase capacity to deliver PR. It also supports the claim that myCOPD improves self-management and symptom control.
Is any information from this study likely to be used in the economic model?	Yes, to establish value of additional PR delivery and improvement in health-related quality of life.
What are the strengths and limitations of this evidence?	This is a formal RCT delivered by an NHS centre and compared to usual NHS face to face PR. It is a single centre study and validation in other centres may be required.
How was the study funded?	Innovate UK SBRI Grant

RESCUE	
How are the findings relevant to the decision problem?	The RESCUE Study in submission for publication was performed in patients recently discharged from hospital with an acute exacerbation of COPD. IT demonstrated that the myCOPD app offered significant improvements in recovery symptom control measured by CAT score. myCOPD also reduced exacerbation frequency, improved inhaler technique and risk of hospital admission.
Does this evidence support any of the claimed benefits for the technology? If so, which?	Yes- this study supports the claim that myCOPD can improve symptom control, reduce exacerbation risk, reduce service use, reduce hospital admission risk and improve medication use
Is any information from this study likely to be used in the economic model?	Yes – reduction in exacerbation and hospitalisation incidence plus improvements in health-related quality of life.
What are the strengths and limitations of this evidence?	This is a formal RCT delivered by an NHS centre and compared to usual NHS care. It is a single centre study.
How was the study funded?	Innovate UK SBRI Grant

EARLY	
How are the findings relevant to the decision problem?	The EARLY Study which has recently completed - 29.9.19 and is currently in analysis (estimated report date December 19) has explored the impact of myCOPD on symptom control measured by CAT score, inhaler technique and patient activation in patients with mild or newly diagnosed COPD and will complement the previous two studies which have been performed in patients with more established disease.
Does this evidence support any of the claimed benefits for the technology? If so, which?	Yes- this study supports the claim that myCOPD improves self-management and symptom control, improves inhaler technique and medication adherence.
Is any information from this study likely to be used in the economic model?	Yes, improvement in health-related quality of life across the disease spectrum with EQ5D as a quality of life and health use questionnaire.
What are the strengths and limitations of this evidence?	This is a formal RCT delivered by 3 NHS centres and compared to usual NHS care. It is generalizable to UK primary care patients. A limitation is that the study duration was only 3 months and may underestimate the long term benefits of app usage.
How was the study funded?	Innovate UK Grant

5.3 Results of relevant clinical studies

Table 4 Results of all relevant studies (from tables 1, 2 and 3)

Please provide results of all relevant studies in a table format. Example tables are presented below and can be adapted.

Example Table A – present results by study

Study	Result with intervention	Result with comparator	Company comments
TROOPER	Six Minute Walk Test change = 433.6 metres	Six Minute Walk Test change = 445.1 metres	Primary outcome, non-inferiority was demonstrated, threshold at -40.5 metres.
TROOPER	Mean CAT Score at 7 Weeks = 14.9	Mean CAT Score at 7 Weeks = 16.2	Non-inferiority demonstrated, results favoured intervention, CAT Score difference = -1.0 (95%CI -2.9, 0.68).
RESCUE	Mean CAT Score 3 Months = 20.7	Mean CAT Score 3 Months = 25.1	Primary outcome was statistically significant. Lower CAT Score = Better
RESCUE	Inhaler Technique, Mean Critical Errors = 1.2	Inhaler Technique, Mean Critical Errors = 4	It was noted that errors were duplicated across inhalers, this was adjusted for in analysis, the Poisson baseline adjusted rate was 0.377
RESCUE	Exacerbation rate = 1.1	Exacerbation rate = 1.9	A baseline adjusted Poisson regression showed a rate ratio of 0.581 (95% CI: 0.3147, 1.0723) in favour of the Intervention.
RESCUE	Admission rate mean rate post intervention = 0.24	Admission rate mean rate post intervention 0.77	An odds-ratio of hospital re-admissions was 0.3 (95% CI 0.10, 0.88) in favour of the intervention.

Example Table B – present result by outcome

CAT Score	Result with intervention	Result with comparator	Company comments
TROOPER	14.9	16.2	Both studies showed consistent results with the direction of the CAT Score improvement. Text
RESCUE	20.7	25.1	

6 Ongoing use and data collection

Briefly describe any ongoing or planned data collection which is aimed at demonstrating the effectiveness of the technology. Provide details of the patients included and the setting where these data are collected and the planned duration. Provide details of any NHS partners involved in the data collection.

Briefly describe if data is collected on an ongoing basis to demonstrate usage of the technology in the target population and improvement in user outcomes or user satisfaction with the technology, where applicable. Provide details of the patients included and the setting where these data are collected and comment on whether ongoing usage data reflects usage required to achieve outcomes reported in the clinical evidence (no more than 1000 words).

We have recently re-structured our information technology infrastructure to support in-app activity capture and analysis. By coding for and capturing all activity within the app, anonymised analysis of the data generated can be undertaken. This information will link in-app activities with the in-app targets (or nationally accepted target ranges) to determine the on-going effectiveness of the technology. All patients' data will be incorporated into this data set to facilitate big data analysis, but the my mhealth analytics platform will also support more targeted reviews. Examples of anonymous data linkage would include pulmonary rehabilitation usage, education usage or use of inhaler videos with CAT scores.

Ongoing data acquisition currently taking place is the Early Study (Evidence GenerAtion foR the CLinical EfficacY and Effectiveness of myCOPD in patients with mild, moderate and newly diagnosed COPD) that is completing and currently being written up for publication. The primary endpoints for this study were a reduction in CAT score and a reduction in critical errors in inhaler technique.

By way of consent, we plan to work with our NHS partners, such as the North West London Collaborative, to link the my mhealth data set with HES data to understand the health impact of the technology on users, but also to gain insight into the health economic impact our intervention.

As stated above, data is collected on an on-going basis and utilises in-app analysis. This data is used to evidence usage, identify areas that may be less used and required adjustments and provide evidence of positive outcomes. Alongside the in-app functionality to investigate usage, we provide customer support where all feedback is welcomed. This

information forms part of on-going drive to improve and provide all users with a positive beneficial experience,

.

7 Adverse events

Describe any adverse events and outcomes associated with the technology in national regulatory databases such as those maintained by the MHRA and FDA (Maude). Please describe the search in appendix B and provide links and references.

To date we have had no adverse events.

Describe any adverse events and outcomes associated with the technology in the clinical and data usage evidence.

Not applicable.

8 Evidence synthesis and meta-analysis

If a quantitative evidence synthesis is not considered appropriate, please instead complete the section on qualitative review.

8.1 Quantitative review

If a quantitative evidence synthesis is appropriate, describe the methods used. Include a rationale for the studies selected.

The trials data available currently is from two randomised controlled trials. The RCTS explored different impacts of the app in the context of Pulmonary Rehabilitation and hospital discharge. Outcome measures collected were therefore different in each study. Here we present the outcomes from the studies and a narrative synthesis of the common outcome captured across trials- COPD assessment test.

Report all relevant results, including diagrams if appropriate.

TROOPER Study Primary Outcomes:
Six-minute walk test and CAT score- both non-inferior to usual pulmonary rehabilitation.

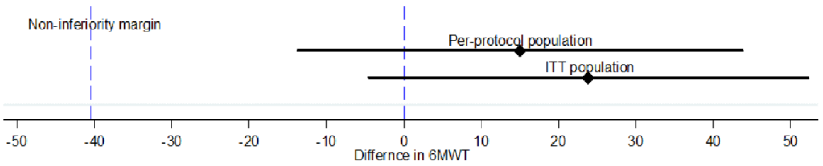


Figure 2A Adjusted mean difference and 95% CI for 6 min walk test (6MWT) in the intention-to-treat (ITT) and per-protocol (PP) population.

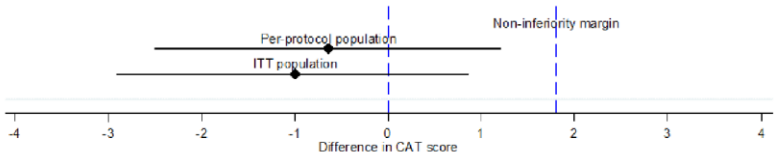


Figure 2B Adjusted mean difference and 95% CI for COPD assessment test (CAT) score in the intention-to-treat (ITT) and per-protocol (PP) population.

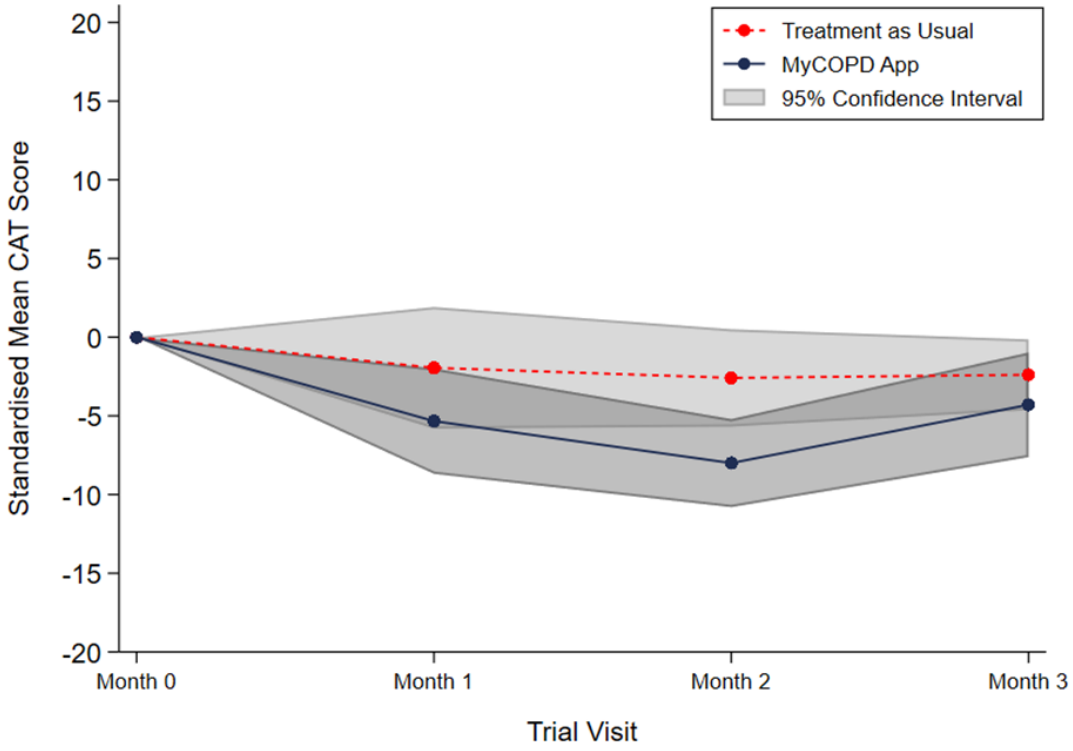
Table 3 Between-group differences in primary and secondary outcomes

	Mean value (SD), n		Regression analysis (ITT population)		Regression analysis (PP population)	
	Face-to-face PR (n=26)	Online PR (n=64)	Adjusted difference (95% CI)	p Value	Adjusted difference (95% CI)	p Value
6 min walk test (m)						
Baseline	416.5 (118.3)	388.7 (104.4)	23.8 (–4.5 to 52.2)	0.098	15.0 (–13.7 to 43.8)	0.300
7 weeks	445.1 (124.9)	433.6 (102.9)				
COPD assessment test score						
Baseline	17.3 (6.7)	18.1 (7.9)	–1.0 (–2.9 to 0.86)	0.373	–0.64 (–2.5 to 1.2)	0.569
7 weeks	16.2 (6.7)	14.9 (7.0)				
Hospital Anxiety and Depression Scale						
Baseline	10.0 (6.0–18.0)	10.0 (6.0–16.5)	–0.74 (–3.5 to 0.9)	0.263	–1.2 (–3.5 to 1.2)	0.320
7 weeks	10.5 (5.0–13.0)	7.0 (4.0–15.0)				
St Georges Respiratory Questionnaire						
Baseline	37.7 (17.2)	42.4 (18.6)	–3.72 (–10.7 to 3.3)	0.291	–2.5 (–9.3 to 4.4)	0.474
7 weeks	39.3 (18.5)	39.3 (18.5)				
Modified Medical Research Council Dyspnoea score						
Baseline	2.0 (1.0–2.0)	2.0 (1.0–3.0)	0.03 (–0.56 to 0.63)	0.909	0.04 (–0.54 to 0.63)	0.885
7 weeks	1.5 (1.0, 2.0)	1.0 (1.0, 2.0)				

ITT, intention to treat; PP, per -protocol; PR, pulmonary rehabilitation.

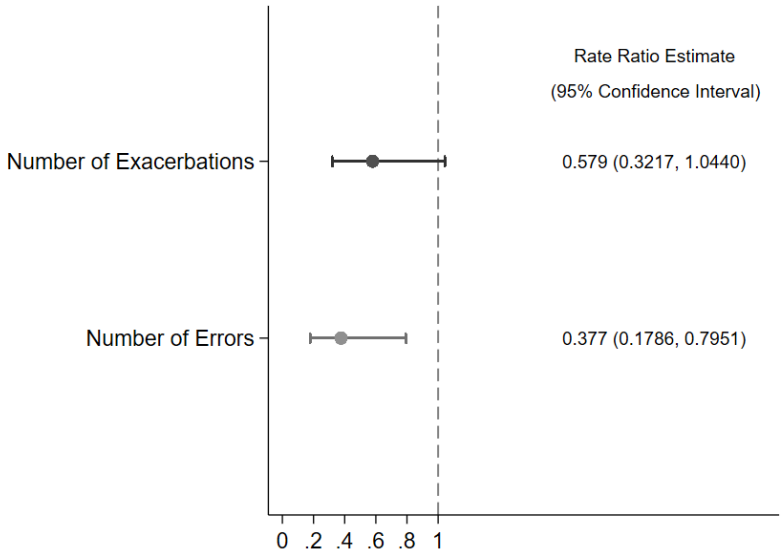
The improvement in CAT Score in TROOPER was 3.2 points against a minimally important clinical difference of 2 points.

In the RESCUE study clinically important improvements in CAT score were also seen:



The adjusted CAT improvement at 3 months was 2.9 points- comparable to the effect size seen in TROOPER.

In addition, improvements in inhaler technique – reduction in critical errors, and reduction in exacerbation frequency was also seen.



No. of Exacerbations usual care 1.9 (1.84) myCOPD 1.1 (0.83) rate ratio 0.581 (0.3147, 1.0723)
Similarly, inhaler technique improved significantly in the myCOPD arm of Rescue:

No. of Critical Errors – app vs usual care rate ration 0.377 (0.1786, 1.0440).

Explain the main findings and conclusions drawn from the quantitative evidence synthesis.

The main findings are that there is clear consistency in effect of myCOPD in terms of direction and quantity of benefit over usual care on symptom and disease control measure CAT, well above the minimally important clinical difference. Similarly, significant improvements in inhaler technique were seen across the evidence from two trials.

In addition, improvements in functional capacity, exacerbation frequency and hospitalisation seen in the different trials points to a dramatic overall benefit of myCOPD usage in COPD patients.

8.2 Qualitative review

Please only complete this section if a quantitative evidence synthesis for all relevant outcomes is not appropriate.

Explain why a quantitative review is not appropriate for all relevant outcomes.

In addition to the trials data patient feedback has been obtained from a range of clinical groups using myCOPD in the NHS the findings were independently presented by local clinical services and are summarised in the appendix.

Provide a qualitative review for outcomes where a quantitative review is not appropriate. This review should summarise the overall results of the individual studies with reference to the information in Section 5.

Enter text.

9 Summary and interpretation of clinical evidence

Summarise the main clinical evidence, highlighting the clinical benefits and any risks relating to adverse events from the technology.

The evidence base for myCOPD has established in two separate clinical trials that the app is safe and effective as an adjunct to the management of COPD in the UK. Importantly it has shown strong and statistically significant impacts on a range of important clinical outcomes including disease control and symptoms- measured by the MHRA and EMEA approved PRO CAT. The effect size was greater than the MCID in both studies and greater than that delivered by the the prescribed interventions in COPD currently in use. The app was able to show clear clinical benefit against hard endpoints- exacerbations and hospital readmissions which few existing therapies and no existing digital therapies have shown. In addition, the non-inferiority of the app in delivering PR outcomes demonstrates its suitability as a platform to build capacity and extend access to deliver this mandated aspect of COPD care. The studies also demonstrate clear evidence for improvements in inhaler technique – vitally reducing the number of critical errors, these are errors in technique which are common but so fundamental that they mean the inhaled drug is not reaching the patients lungs and so will not carry the clinical benefit required.

	The app use is able to correct this and results in much fewer critical errors hence ensuring improved efficacy of the expensive prescribed therapy.

Briefly discuss the relevance of the evidence base to the decision problem. This should focus on the claimed benefits proposed by the company and the quality and quantity of the studies in the evidence base.

The evidence base supports each and every claim for the efficacy and value of the myCOPD app. The studies were performed across 4 different NHS sites in total with a wide geographical spread and although relatively small generated clear, significant signals of benefit against all claims- patient benefit through improved symptom control, improved self-management including inhaler technique and reduced exacerbations, Reduced NHS service needs through reduced admissions and increased PR capacity and similarly decreased costs of care. In addition, improved inhaler technique and adherence dramatically reduces medication wastage.

Identify any factors which might be different between the patients in the presented evidence and patients having routine care in the NHS in England.

The patients studied were all recruited from active NHS centres in all studies. In addition, the emergence of real-world evidence would suggest that the use of the app in the NHS as part of routine care reproduces the impact and benefit of the app seen in clinical trials (Southend PR outcomes).

Describe any criteria that would be used in clinical practice to select patients for whom the technology would be most appropriate.

The technology is suitable for all patients with a diagnosis of COPD who are able to use the app on any device that connects to the internet.

Briefly summarise the strengths and limitations of the clinical evidence for the technology.

As with any new technology the myCOPD app has a limited evidence base- however the evidence generated by separate, NHS delivered studies is robust and convincing- that there is a clear benefit to patients and health services. Furthermore, the app is now in use nationally and real-world evidence studies demonstrate reproducible results – reinforcing the clinical and economic value of the app in routine use.

10 Outline of economic evidence

10.1 Population benefiting

Provide an estimate of the numbers of people likely to benefit from use of the technology in year 1 and how uptake will change over time to year 5. Explain assumptions and evidence sources informing your estimate.

The numbers of patients that stand to benefit is all patients with COPD. This would be 1.2mil people. This statement is made from the standpoint that the app offers many different elements in many different forms to facilitate accessibility. Rate limiting factors affecting that would be the ability to distribute the licences to patients and the app's utilisation (as dependent on the user's activation).

Examples of areas that might support multiple groups includes

- Education
- Pulmonary rehabilitation
- Tracking of symptoms and signposting

10.2 List price of technology

Provide the unit list price(s) for the technology, including all related charges such as licence fees and subscription charges (all charges excluding VAT). The cost of the technology used in the base case of the economic modelling must be publicly available. Companies can present additional economic analyses using other technology costs to support their case for adoption. Please highlight any confidential information as explained at the start of the user guide.

Costings of the app depends on how the access to an app was provided. Models and costs currently in place include

1. Buying myCOPD as a single unit. myCOPD directly from Google, Apple or our website would currently cost £39.99, which would provide a 30year licence.
2. Buying myCOPD as part of a my mhealth Package. For myCOPD, these are known as Pulmonary Rehabilitation Packages. The aim of these is to supply sufficient licences to support a small to medium sized project, looking at the impact of myCOPD. The cost of this model is £10,000 for 200 licences, that includes set-up, training and pathway integration with clinical specialist input (working with the local team).
3. Buying myCOPD as part of The Unlimited contract – this is a 3-year contract providing the maximum number of licences to the CCG that equates to those people with registered diagnoses in that CCG's catchment area. The price of the contract is based on the population serviced by that CCG. See below for worked example.

Worked Example: - The Unlimited contract
CCG population – 100,000

Cost of contract; based on population serviced by CCG
Cost for each year of the contract is 50p/per population.
This cost recurs for three years while the project is set-up and established.
Total cost for 3years = £150,000
Cost per licence = £5.55 (£150,000/27,000)

Diagnoses
- COPD = 4000
- Diabetes = 10,000
- Asthma = 11,000
- Heart disease = 12,000

Total Number of independent diagnoses = 27,000
Number of licences available through the Unlimited contract = 27,000

NB: The Unlimited Contract aims to provide access to the procuring group to the entire my mhealth platform that includes myCOPD, myAsthma, myDiabetes and myHeart, tackling COPD, Asthma, Diabetes (types 1 and 2) and heart disease.

10.3 Value of patient and system benefits

Section 2.2 describes the patient and system benefits. Where possible, provide an estimate of the impact of these changes on NHS annual costs. Explain assumptions

and evidence sources informing your estimate. If no financial estimate is possible, describe the anticipated resource savings and related supporting evidence.

There are three key areas where myCOPD impacts on NHS for delivering care for patients diagnosed with COPD. These are the provision of a non-inferior, safe home-based pulmonary rehabilitation programme, the reduction in admissions to hospital (Topol Healthcare Review 2019 – 19%) and the reduction in readmissions to hospital (Rescue data, to be published – paper attached: -72% reduction).

To illustrate the impact; available, PHE data for the Isle of Wight will be used.

1. Pulmonary Rehabilitation

Pulmonary rehabilitation expenditure on the IOW
Number of patients with COPD = 3005
35% meet criteria for PR (MRC 3) = 1051
NB: - From PHE 2017/2018 data, National GP Profiles, 35% were MRC>=3.
IOW successfully delivered 100 completed PR episodes.

Cost to provide another 951 slots (ie 1051 – 100) at £400 - £1000 per person
This would cost £380,400 (to a maximum of £951,000) to have available.

Realistically, aim to provide 50% of demand, knowing there is a 20% completion rate
PR Provision of 50% = 951 x 50%
= 475.5 slots
Cost to provide the requisite PR = 475.5 x 400 (max cost 1000)
= £190,200 (max cost £475,500)

For each PR course provided by myCOPD, the saving would be £360 (min)
This figure equating to the current cost of PR £400-£1000 less the cost of myCOPD (£40)

Cost of delivery using myCOPD = 475.5 x 40
= £19,020
Cost saving using myCOPD = 190,200 – 19,020
= £171,180

2. Admission Avoidance

Using data from PHE 2010-2012
Cost per COPD admission = £2835
Number of hospital admissions = 230
Total Cost = £652,050

19% admission reduction (Topol) = 230 – 19% = 186
Subsequent costs = 186 x £2835
= £527,310

Savings implementing myCOPD	=	652,050 – 527310
	=	£124,740

3. Readmission Avoidance

Using the King's Fund paper reviewing hospital readmissions for COPD, 2017 (10.1038/s41533-017-0028-8), readmission rates were reported as 32% readmissions within one year, with 10% with 30 days and 18% within 90 days.

Within one year of discharge, 32% would be readmitted

Number of patients readmitted (1y)	=	230 x 32%
	=	74 people (readmitted in 1 year)

From the RESCUE study, published in BMJ Thorax 2018 (https://thorax.bmj.com/content/73/Suppl_4/A231.1), the number of patients readmitted was reduced by 72% in the group that was using myCOPD. If all 74 people had myCOPD, the readmission number would be

Readmitted numbers	=	74 -72%
	=	20

Therefore, 20 people would be readmitted rather than 74

Further savings are	=	(74 – 20) x Admission (£2835)
	=	54 x £2835
	=	£153,090

Savings across the three parameters

1. Pulmonary Rehabilitation	=	£171,180
2. Admission avoidance	=	£124,740
3. Readmission avoidance	=	£153,090
Total in year savings	=	£449,010

Therefore, **TOTAL Return on investment**, providing myCOPD to all patients diagnosed with COPD (3005) would be as follows

Cost to supply all patients	=	3005 x £40
	=	£120,200
Total in year savings	=	£449,010
Return on investment	=	449,010/120,200 x 100%
	=	373.6%

10.4 Training and pathway costs

Section 2.3 describes training requirements, section 3 describes the changes in the clinical pathway(s) and section 3.3 other system changes associated with the technology. Where possible provide an estimate of the impact of these changes on NHS annual costs. Explain assumptions and evidence sources informing this estimate. If no financial estimate is possible, describe the anticipated resource changes that will cause costs to increase. Please provide supporting evidence for any anticipated changes to resource use.

my mhealth ascribe no further costs to the delivery of the app in our current purchasing models. All training and integration requirements needed by a procuring group are part of the contract to deliver the apps to the procuring service. If the apps are provided as single units, and not part of a larger service-wide procurement, then training to use the apps comes from the in-app “How To…” videos that support the user. These resources are present through both the patient and non-patient sides to the platform.

Costs associated with the integration of the app into regional COPD programmes, be they management or simply for pulmonary rehabilitation, would depend on how and where the local leads saw the app supporting their service. Given the above (section 10.3), simply using the app in the clinical setting potentiates significant positive clinical impact and fiscal savings.

10.5 Other annual NHS costs and savings

Are there any other material costs or savings which have not been described earlier? If so, where possible, provide an estimate the impact of these changes on NHS annual costs. Explain assumptions and evidence sources informing the estimate. If no financial estimate is possible, describe the anticipated resource changes which will cause costs to change. Please provide supporting evidence for any anticipated changes to resource use.

Material savings would be made through the capture and reporting of the annual COPD check. This consists of recording the patient's lung functions test results, their MRC assessment, their CAT score, smoking status, flu inoculation, oxygen level testing and their exacerbation history over the last year.

With this information all captured in the app and reported by either the patient, clinician or both, over the course of the year, reporting this from the app would save time when coming to report this to NHSE. A formal quantification of this has not been done yet, but estimates have been made in terms of time saved. It is likely with an activated patient, this data will be present and so the review would be 10 minutes, as opposed to undertaking the testing required for completion.

10.6 Total costs and savings

Given the responses to section 10.2 to 10.5, where possible estimate the annual total costs to implement and operate the technology and the associated annual savings to the NHS. If the total costs and savings will change over time, describe the expected changes. Conclude with a sentence summarising the expected net lifetime savings (that is after all costs have been deducted) to the NHS from using this technology. If no financial estimate is possible please describe the anticipated net lifetime savings and related supporting evidence.

This response should be the consistent with that used in Section 2.2 'Cost benefits'.

Total NHS benefits for using myCOPD: -

Using the same three key parameters and assuming there to be 1.2million people diagnosed with COPD in England, the return on investment of £48,000,000 (100% licence coverage) is 370.6% in one year.

This figure does not include the time savings created through the reporting elements of the app nor does it include the uncalculated environmental benefits identified.

Given that these impacts were reported in clinical trials of short duration, the longer term implications to the management of COPD would only be enhanced as the data captured within this tool was examined and interpreted for this purpose but also as the app evolves in line with advances in the treatment of COPD.

10.7 Economic evidence

Summarise any existing economic evidence.

In February 2018, York Health Economics Consortium published an economic analysis of the impact myCOPD could have for the NHS. This was an independently produced document examining the financial implications of using myCOPD in the management of COPD in the NHS.

The conclusion read as follows: -
myCOPD is found to be cost saving compared with standard care, with a potential ROI of 846% from an NHS perspective. The web-based patient self-management tool offers the potential for improved control of COPD symptoms, and a more cost-effective means to provide access to pulmonary rehabilitation. The estimated net benefit from avoided hospital admissions in a CCG with 250,000 patients is £143,820 per year. myCOPD can also be expected to result in improved patient outcomes and associated health gain in terms of symptom management and improved quality of life.

Summarise the planned economic analysis detailing likely model structure, relevance to clinical pathway, decision problem and time horizon.

In conjunction with our NHS partners, and following a review of the current consenting and onboarding process, we plan to legitimately link patient data (with their consent), to their NHS records to enable the linking of the my mhealth data set and data sets such as HES. This would enable real-world impact assessments to be conducted to create an evidence base for the impact of the app in terms of clinical benefit but also accurately undertake a health economic and remuneration assessment.

Describe the main parameters in the planned economic analysis and the key sources of uncertainty.

To date, evidence supporting the economic analysis of myCOPD has come from small trials providing clinically and statistically significant outcomes. These benefits have been costed using retrospective data published by groups like Public Health England. Being able to combine the my mhealth data set with NHS data sets, such as HES, would expand the size and increase the accuracy of such assessments, while also providing currency to the data being used.

Parameters in this study might include

- The current three utilised metrics – PR, admission avoidance and readmission avoidance
- Antibiotics usage and outcome data
- Intervention impact on outcomes – patient reported, clinically targeted and financial
- Quality of life and QALY, investigating the COPD value pyramid

11 References

Please include all references below using NICE's standard referencing style.

Bourne S, DeVos R, North M, et al (2017). Online versus face-to-face pulmonary rehabilitation for patients with chronic obstructive pulmonary disease: randomised controlled trial. BMJ Open 2017;7:e014580. doi:10.1136/bmjopen-2016-014580. https://wessexahsn.org.uk/img/projects/MyCOPD%20RCT.pdf

Topol E (2019). The Topol Review. Preparing the Healthcare Workforce to deliver the digital future. An independent report on behalf of the Secretary of State for Health and Social Care. https://topol.hee.nhs.uk/wp-content/uploads/HEE-Topol-Review-2019.pdf

North N, Bourne S, et all (2019). A Randomised controlled trial of E-health platform Supported Care vs Usual care after Exacerbation of COPD**: The RESCUE trial; In preparation for publication Lancet Digital**

North M, Wilkinson T, Bourne S (2014). The impact of an electronic self-management system for patients with COPD. European Respiratory Journal 2014 44: 1413; vol44, suppl58. https://erj.ersjournals.com/content/44/Suppl_58/1413

Cro S (2019). Evidence GenerAtion foR the CLinical Efficacy and Cost Effectiveness of MYCOPD in patients with mild, moderate and newly diagnosed COPD; **EARLY COPD Interim Report.** Imperial clinical Trials Unit, School of Public Health, Imperial College London, 68 Wood Lane, W12 7RH.

Gates J (2019). SEE Enhanced pulmonary rehabilitation service – overview. Accompanying document. With (Confidential) data shared.

12 Appendices

Appendix A: Study identification for clinical and economic evidence

Describe the process and methods used to identify and select the studies relevant to the technology. Include searches for published studies, abstracts and ongoing studies in separate tables as appropriate. See section 2 of the user guide for full details of how to complete this section.

Date search conducted:	Enter text.
Date span of search:	Enter text.
List the complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example, MeSH) and the relationship between the search terms (for example, Boolean). List the databases that were searched.	
Enter text.	
Brief details of any additional searches, such as searches of company or professional organisation databases (include a description of each database):	
Enter text.	
Inclusion and exclusion criteria:	
Enter text.	
Data abstraction strategy:	
Enter text.	

Excluded studies

List any excluded studies below. These are studies that were initially considered for inclusion at the level of full text review, but were later excluded for specific reasons.

Excluded study	Design and intervention(s)	Rationale for exclusion	Company comments
Text	Text	Text	Text
Text	Text	Text	Text
Text	Text	Text	Text
Text	Text	Text	Text
Text	Text	Text	Text
Text	Text	Text	Text
Text	Text	Text	Text

Report the numbers of published studies included and excluded at each stage in an appropriate format (e.g. PRISMA flow diagram).

Enter text.

Structured abstracts for unpublished clinical studies

Study title and authors
Introduction
Objectives
Methods
Results
Conclusion
Article status and expected publication: Provide details of journal and anticipated publication date

Appendix B: Search strategy for adverse events

Date search conducted:	Enter text.
Date span of search:	Enter text.
List the complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example, MeSH) and the relationship between the search terms (for example, Boolean). List the databases that were searched.	
Enter text.	
Brief details of any additional searches, such as searches of company or professional organisation databases (include a description of each database):	
Enter text.	
Inclusion and exclusion criteria:	
Enter text.	
Data abstraction strategy:	
Enter text.	

Adverse events evidence

List any relevant studies below. If appropriate, further details on relevant evidence can be added to the adverse events section.

Study	Design and intervention(s)	Details of adverse events	Company comments
Text	Text	Text	Text
Text	Text	Text	Text
Text	Text	Text	Text
Text	Text	Text	Text
Text	Text	Text	Text

Text	Text	Text	Text
Text	Text	Text	Text

Report the numbers of published studies included and excluded at each stage in an appropriate format (e.g. PRISMA flow diagram).

Enter text.

Appendix C: Checklist of confidential information

Please see section 1 of the user guide for information about identifying confidential information and instructions on how to complete this section. As stated there it is the company's responsibility to highlight any commercial- or academic-in-confidence data clearly and correctly:

- information that is commercial in confidence should be underlined and highlighted in blue
- information that is academic in confidence should be underlined and highlighted in yellow.

Does your submission of evidence contain any confidential information? (please check appropriate box):

No	☐	If no, please proceed to declaration (below)
Yes	☒	If yes, please complete the table below (insert or delete rows as necessary). Ensure that all relevant sections of your submission of evidence are clearly highlighted and underlined in your submission document and match the information in the table. Please add the referenced confidential content (text, graphs, figures, illustrations, etc.) to which this applies.

Page	Nature of confidential information	Rationale for confidential status	Timeframe of confidentiality restriction
Document	☒ Commercial in confidence ☒ Academic in confidence	Data that is to be written up for publication	6months
Details	The supplementary Home Programme data file is to be written up.		
#	☐ Commercial in confidence ☐ Academic in confidence	Enter text.	Enter text.
Details	Enter text.		

Confidential information declaration

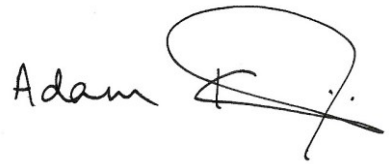
I confirm that:

- all relevant data pertinent to the development of medical technology guidance (MTG) has been disclosed to NICE
- all confidential sections in the submission have been marked correctly
- if I have attached any publication or other information in support of this notification, I have obtained the appropriate permission or paid the appropriate copyright fee to enable my organisation to share this publication or information with NICE.

Please note that NICE does not accept any responsibility for the disclosure of confidential information through publication of documentation on our website that has not been correctly marked. If a completed checklist is not included then NICE will consider all information contained in your submission of evidence as not confidential.

Signed*:

** Must be Medical Director or equivalent*



Date: 15th October 2019

Print: Adam Kirk

Role / organisation: Clinical Director

Contact email: adam.kirk@mymhealth.com

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical technologies guidance

DHT001 MyCOPD for self-management of chronic obstructive pulmonary disease (COPD)

Company evidence submission

Part 2: Economic evidence

Company name	My mHealth
Submission date	01/07/21
Contains confidential information	Yes

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1 Published and unpublished economic evidence

Identification and selection of studies

Complete the following information about the number of studies identified.

Please provide a detailed description of the search strategy used, and a detailed list of any excluded studies, in appendix A.

Number of studies identified in a systematic search.	310
Number of studies identified as being relevant to the decision problem.	1
No economic evaluations of myCOPD were identified. The literature search only identified those myCOPD clinical studies that had already been reported in the Part 1 submission. However, two of these had since been published as full peer-reviewed papers; the RESCUE study (North et al 2020) and the EARLY study (Crooks et al 2020). In addition, a further UK study on myCOPD was identified, which was submitted in June 2021 and is currently available as a preprint manuscript (Sage et al unpubl). This was identified by exploring the real world evidence (RWE) provided as part of the Part 1 submission. It is also reported in a conference abstract (Cooper et al 2021). This before-and-after study compared 1 year pre-intervention with 1 year post-myCOPD use in a broad COPD sample invited from the community. Follow-up was interrupted by the Covid lockdown and so a full year of follow-up was not available for any participants. On a per day basis there was no reduction in resource use when patients had the app, although an underpowered subgroup analysis identified a reduction in hospital bed days in those participants with the highest level of app use.	

List of relevant studies

In table 1, provide brief details of any published or unpublished economic studies or abstracts identified as being relevant to the decision problem.

For any unpublished studies, please provide a structured abstract in appendix A. If a structured abstract is not available, you must provide a statement from the authors to verify the data provided.

Any data that is submitted in confidence must be correctly highlighted. Please see section 1 of the user guide for how to highlight confidential information. Include any confidential information in appendix C.Table 1 Summary of all relevant studies (published and unpublished)

2 Details of relevant studies

Please give details of all relevant studies (all studies in table 1). Copy and paste a new table into the document for each study. Please use 1 table per study.

No relevant economic studies.

3 Economic model

This section refers to the de novo economic model that you have submitted.

Description

Patients

Describe which patient groups are included in the model.

There are two independent models, relevant to 2 subgroups of patients with COPD. The base case refers to the purchase of the Unlimited contract by a typical CCG.

1. Patients post-discharge for hospital admission for AECOPD (acute exacerbation of COPD)
2. Patients eligible for pulmonary rehabilitation (PR) within a CCG population; stable COPD with an MRC ≥3, and post-discharge for AECOPD.

   As a scenario, the PR model is also included with a PR provider as the purchaser. In this case, the population is all COPD patients referred for PR at that service.

Technology and comparator(s)

State the technology and comparators used in the model. Provide a justification if the comparator used in the model is different to that in the scope.

1. **Model 1 – post-discharge patients**

   Comparator (SOC): Patients who are discharged from hospital following AECOPD are given a discharge plan that includes a written self-management plan. There is often little or no follow-up, or scheduled review, by clinicians. (There are some supported-discharge services, in which teams including clinical nurse specialists, physiotherapists, and/or occupational therapists provide community support until the patient stabilises. However, these are not universal. Additionally, Discharge Care Bundles should ensure that patients get optimal advice and support prior to discharge, but may be poorly implemented or not at all.)

   Intervention: The myCOPD app is provided to the patient during their admission or shortly after discharge. The app provides functionality to map symptoms, report their CAT scores, access educational material, undertake medicines review, improve their inhaler technique through video content and access a PR course (following their physical assessment). Their self-management plan can be implemented using myCOPD and also provided in a written format. Clinicians may use

the dashboard to monitor patient symptoms, the patient's progress through their educational material and through the PR course.

2. **Model 2 – Patients eligible for pulmonary rehabilitation**

Comparator (SOC): All patients on the COPD register with functional breathlessness (MRC≥3) should be referred to a Pulmonary Rehabilitation (PR) course and enrolled within 90 days of referral. Additionally, all patients discharged from hospital for AECOPD should have a discharge plan that includes the offer of a referral to a PR programme, with enrolment within 30 days of referral.

PR is usually a 6-8 week course of 2 sessions per week, in which the patient engages in supervised exercise training and education on COPD management and lifestyle factors. These courses are usually run face-to-face (F2F) by physiotherapists and take place in community locations or hospital departments. An assessment is conducted before and physical exercise takes place, to ensure patient suitability and to benchmark their capacity. Another assessment is conducted on completion to determine whether there has been an improvement in the patient's performance. PR may be repeated after a year.

(See British Thoracic Society Quality Standards and National Asthma and COPD Audit Programme (NACAP) PR audits.)

Intervention: The myCOPD app is provided to the patient at assessment. Patients are instructed not to start PR until after assessment. The patient can choose between

- myCOPD-only PR: 6-week graduated exercise programme, plus education modules
- face-to-face only PR: 2 sessions per week for 6 weeks
- hybrid: myCOPD app plus 1 face-to-face session per week for 6 weeks

For all routes an assessment is required prior to the start of PR, and is recommended at completion. Sites implementing myCOPD alone have found that 3 phone calls at weeks 1,3,6 are valued by patients and assist in motivation to complete PR. These have therefore been costed as part of the model.

Model structure

Provide a diagram of the model structure you have chosen in Appendix B.

Justify the chosen structure of the model by referring to the clinical care pathway outlined in part 1, section 3 (Clinical context) of your submission.

It is impractical to try to model the whole patient pathway for COPD patients. It is a long term, progressive condition, that is highly dependent on lifestyle and environmental factors, so self-management is key to improved outcomes and delayed progression. Patients go through increasingly frequent cycles of exacerbation and hospital admission as their disease progresses. Most patients are managed in primary care, and should have annual reviews to check their condition, ensure correct medication use, and agree a self-management plan. Incentives for correct management are included in the NHS Quality Outcomes Framework (QOF, NHS Digital 2019), with several COPD-related indicators.

The myCOPD app is suitable for all COPD patients, from early, mild disease, to GOLD 4 patients who may have multiple hospital admissions per year ('revolving door' patients). myCOPD may show benefit in the whole COPD population where the app is well implemented. However, the published evidence

does not cover the whole pathway. Evidence for unselected groups of patients, or in early disease has mixed outcomes. Crooks et al (2020, EARLY study) showed no overall benefits in resource use in early disease. Sage et al, (unpubl) showed similar results in a broad unselected population of COPD patients (although there is some reduction in resource use and clinical benefit in the subgroup that engaged most with the app). However, McLaughlin and Skinner (no date) showed a reduction in GP attendances and admissions in a small group of patients in the 6 months after they were given myCOPD.

Therefore, we have based the decision modelling on two parts of the pathway where there is robust evidence of benefit – the RESCUE study (North et al, 2020) and the TROOPER study (Bourne et al, 2017). These models are run independently. For the base case the technology costs are included in the post-discharge (AECOPD) model, but excluded from the PR model. This represents a CCG purchasing the Unlimited licence contract based on their total patient population and providing it to patients being discharged for AECOPD and in addition being able to provide myCOPD to patients being referred for PR.

We have modelled a typical CCG purchasing the unlimited myCOPD licence package, which means that any number of COPD patients can receive the app for the same capital cost. However, the app may be purchased by other organisations such as hospital Trusts, PR providers, Primary/Community Care consortiums, or community respiratory services. These organisations do not cover the whole COPD patient pathway and may purchase the app for a discrete patient group. For example, a secondary care organisation may use it to manage patients post-discharge, whereas a PR provider will use it to provide PR services. By providing separate models these will be more appropriate to such healthcare organisations. Purchase of myCOPD licences by a typical PR service is also included as a scenario.

The first model includes patients admitted to hospital for an acute exacerbation of COPD (AECOPD). Such patients have a high risk of readmission. In 2017-18, 24% of such patients were readmitted at least once within 30 days and 43% at least once within 90 days (NACAP 2020c). COPD (ICD-10-CM code J44) and pneumonia (J18) accounted for around 50% of these. Harries et al (2017) estimated that for AECOPD patients admitted between 2006 and 2009 across London, 10% were readmitted for COPD within 30 days and 18% within 90 days. Freibel et al (2017) reported a rate of 17% over 30 days for 2015/16. Morton et al (2019) found readmission rates for COPD around 12-16% for 28 days and 22-25% for 90 days.

The RESCUE study (North et al, 2020) reported non-significant reductions in the number of exacerbations and hospital admissions within 90 days when patients were given myCOPD, in comparison to patients having a written self-management plan (standard of care, SOC).

The second model is based on the provision of Pulmonary Rehabilitation (PR). This is an effective and well-evidenced intervention, that improves outcomes in patients with COPD (McCarthy et al 2015; Puhan et al, 2016). It is recommended by NICE (NICE 2018), supported by QOF indicators (COPD008), and is a clinical priority in the NHS Long Term Plan (NHSE, 2019). It should be offered to all patients with stable COPD and functional breathlessness (an MRC score of ≥3), and to all patients following an admission for AECOPD. However, only 10-15% of eligible patients get a referral in any year (NACAP 2016, Moore et al 2017) and around half of stable patients and 78% of post-AECOPD patients wait longer than the recommended waiting times (NACAP 2020a). Median waiting times to enrolment from referral are substantially worse in Scotland (106 days) and Wales (154 days) than England (83 days). NHS England intend to increase the referral rates to 60% of eligible patients by 2023 (NHSE & NHSI, 2020) and digital tools such as myCOPD, are expected to be core to this expansion.

> "*By expanding pulmonary rehabilitation services over 10 years, 500,000 exacerbations can be prevented and 80,000 admissions avoided…New models of providing rehabilitation to those with mild COPD, including digital tools, will be offered to provide*

support to a wider group of patients with rehabilitation and self-management support." (NHSE 2019)

During Covid, almost all face-to face provision of PR ceased. Although services are restarting, they are constrained by social distancing requirements and may be operating at 50% capacity. Therefore, for the immediate future, face-to-face provision will be reduced whilst there is a growing backlog of patients. Some of these patients are unwilling to accept anything other than a face-to-face PR course (Apps et al, 2019), but many others will be willing and able to take up the option of home-based provision (My mHealth 2021a). Additionally, many patients who would previously have been reluctant to adopt digital healthcare solutions may be more capable and confident following Covid lockdown, due to using digital communications such as Zoom and WhatsApp.

Other barriers to face-to-face PR include:

- some PR locations may not be accessible to all patients – they are often in community centres, leisure centres, or church halls.
- offered times are usually 'working hours' only and may not be convenient for patients who work,
- some patients may not be able to travel to the location (65% of services do not offer transport provision, NACAP 2020b).

The use of myCOPD PR at this time could increase access to this service and help to reduce waiting lists. It also provides patients with continuous access to the PR exercises, to assist patients to continue PR at home after the initial 6 week period. Standard 7 of the BTS quality standards (British Thoracic Society 2014) is "People completing pulmonary rehabilitation are provided with an individualised structured, written plan for ongoing exercise maintenance" and 98.6% of PR services advise patients to do unsupervised home exercise during their PR programme (NACAP 2020b).

The TROOPER study (Bourne et al, 2017), showed non-inferiority of myCOPD PR compared to traditional F2F PR over 3 months follow-up. Therefore we assume the established benefits of PR are extended to patients using myCOPD for PR. We have modelled a multi-modality PR service exemplified by Southend University Hospital (my mHealth 2021b). Patients are offered a choice of myCOPD home-based PR, face-to-face (F2F) PR, or a combination of the two (hybrid).

Summary of models

1. The AECOPD post-discharge model is a simple decision tree comparing SOC (written self-management plan), versus myCOPD plus written self-management plan. The population is patients discharged from an emergency admission for AECOPD. The model assumes that a typical CCG purchases unlimited licences for their population but only provide them to this subgroup, at discharge from hospital. Resource use outcomes compared between the arms include hospital re-admissions for COPD, non-admitted exacerbations, and GP appointments. The model includes all patients who have an index emergency AECOPD admission during 1 year, plus 3 months of follow-up after this (duration of follow-up from the RESCUE study).

   The pulmonary rehabilitation model is also a decision tree, but more complex. It compares SOC F2F PR provision, versus the multi-modality service. In both the SOC and myCOPD arms 20.21% of eligible COPD patients are offered PR and the remainder do not get a referral. All referred patients require an initial assessment. Patients choosing myCOPD alone or the hybrid provision are registered with the app following the initial assessment, and those choosing myCOPD alone start PR straight away. Those choosing face-to-face or hybrid provision of PR must wait for the next available course. We assume that the same proportion of patients complete the PR course irrespective of method of delivery. Benefits from PR are only applied to patients who complete a PR course. Resource use outcomes compared between the arms are based on exacerbations, a proportion of which require a hospital admission. The model

includes all patients referred for PR with one year of follow up, including the waiting time if appropriate. The base case includes all patients eligible for PR in a CCG population. A scenario considers the PR service as a purchaser, in which case all patients have a referral and the number is based on the average number of referrals to a PR service in a year. The base case PR model uses the Unlimited contract to provide access for the COPD population in a given CCG. PR can also be provided as part of myCOPD used to support a PR provider service. This second model enables providers of PR services to use the platform for their much smaller cohort of patients for £10,000 pa. In this scenario, the population is all COPD patients referred to PR at that service; i.e. no patients go through the 'no PR' pathway.

Table 2 Assumptions in the model

In this table, list the main assumptions in the model and justify why each has been used.

General Assumptions	Justification	Source
A typical CCG purchases the unlimited licence package for the patients in their population. This costs £0.25 pa for every patient registered with a GP in the CCG and the contract is for 3 years.	There are different modes of purchasing licences. However, purchasing a lifetime licence for a patients at £40 per licence is no longer an option.	Company
Text	Text	Text

Model 1 (AECOPD) Assumptions	Justification	Source
All patients in the myCOPD arm are registered for a myCOPD licence. Patients choose whether to activate or use it.	In the RESCUE study, patients in the intervention group were provided with the app, but chose whether and how much to use it. Outcomes were assessed based on provision, not use.	North et al (2020)
Outcomes from the RESCUE study only apply to the 3 month period following the index admission.	We do not have data to support extrapolating the benefits for a longer period. This is a conservative assumption as the patients have perpetual access to the app content and we could reasonably expect benefits to extend into the longer term.	North et al, 2020
The maximum number of patients who have an index admission per year is estimated from PHE and QOF data (1105).	We were unable to find an estimate for the number of patients, rather than the number of admissions, per year. Patients may have more than one admission in a year, so this number includes those who have a readmission within 90 days.	IHNALE (PHE, 2021), QOF
The model is replicated each year for the 3 years of the contract. I.e. the same costs and benefits apply each year.	Text	Text

Patients discharged from an index admission do not attend a PR course during the following 3 months. Patients with myCOPD may access any of the PR content including the PR modules.	Participants in the myCOPD arm of the RESCUE study had access to the PR module but were not told to use it. Participants in the SOC arm did not receive PR.	North et al (2020)
Only patients having an index admission for AECOPD are registered for a myCOPD licence.	All the costs of the licences are divided by those patients who are able to benefit from it. Benefits are not extrapolated to patients with stable COPD. This only affects the per patient values, as total budget spend and total costs saved are independent of whether additional patients receive myCOPD.	Text
Text	Text	Text

Model 2 (PR) Assumptions	**Justification**	**Source**
Outcomes from the TROOPER study apply to the 3 month period following the index admission. We assume that non-inferiority to SOC PR in outcomes extends to resource use and for 1 year post-PR.	We do not have data to support extrapolating the benefits for a longer period. This is a conservative assumption as the patients have perpetual access to the app content and we could reasonably expect benefits to extend into the longer term.	Bourne et al (2017)
Completion rates for PR are the same for all modalities.	Completion rates are measured differently between F2F and myCOPD PR. We can tell if a patient has accessed material, but not whether they have participated in the exercises. Completion rates in Bourne et al were slightly lower in myCOPD, but the recommendation was for 5 sessions per week. The non-inferiority finding held despite the slight difference in completion.	Bourne et al (2017)
For the base case, all technology costs (unlimited contract, licence administration, training) are included in	CCGs would not purchase the Unlimited contract option solely for PR referrals. So this patient subgroup would be included in	Company

the AECOPD model, except the additional per licence registration cost	the Unlimited model only if this was purchased for a wider patient population.	
There is no increase in PR capacity at the service due to the adoption of myCOPD.	There is no published data to support an increase in capacity. Increased referrals in the myCOPD arm is included in the sensitivity analysis, but has to be interpreted with care, as face to face PR is not an intrinsically cost saving intervention within this model.	Assumption due to data availability
All patients referred for PR attend a face-to-face assessment before commencing the programme.	Guidelines indicate that patients referred for PR be assessed for suitability and for baseline measures of exercise capacity.	BTS Quality Standards (2014) and Guidelines (2013)
There is no distinction between patients referred for PR for stable COPD and those referred post-discharge.	Patients referred following an admission for AECOPD constitute about 5% of those attending PR. Also, many measures of PR activity do not distinguish between these subgroups.	NACAP PR Clinical Audit 2019 (2020a)
There are similar numbers of referrals for PR each year	NACAP reports from 2015 and 2018 report similar overall numbers of PR referrals for patients with COPD.	NACAP PR Organisational Audits (2015, 2018)
Patients who are referred to PR but do not complete the course do not receive a benefit, or a cost other than initial assessment.	We do not have data to apply outcomes to partially completed PR.	Assumption due to data availability
Patients on the waiting list for PR and those not referred having the same rate of exacerbations as patients who do not complete PR.	There is no reason to expect differences in exacerbation rates between these subgroups.	Assumption due to data availability
Patients receiving myCOPD alone do not subsequently go on to receive F2F PR (in the same year)	myCOPD alone is included as an alternative to F2F or hybrid PR modalities.	Company
Patients who are referred to F2F or hybrid PR and do not complete the course only incur the cost of the initial assessment.	We do not have data to apply costs to partially completed PR	
The published cost estimates for F2F PR include an element for the initial and final assessments	Most published cost estimates determine the cost of the whole service and then divide by the number of patients.	

The cost for the F2F part of hybrid PR is half the cost of F2F PR, plus the cost of initial and final assessments		
Patients spend a total of 1 year in the model, so that the rate of exacerbations post-PR is proportional to the time left after allowing for the waiting time for PR. (This is independent of whether they complete PR or not.)		
For the PR provider contract, referral is 100%, and uptake is governed by the patient accessing the myCOPD PR course and the patient completing it	This is a bespoke service that delivers PR only.	Company

Table 3 Clinical parameters, patient and carer outcomes and system outcomes used in the model

In this table, describe the clinical parameters, patient and carer outcomes and system outcomes used in the model.

Parameter/outcomes - general	Source	Relevant results	Range or distribution	How are these values used in the model?
Mean number of patients registered with GP in CCG, England	QOF, COPD, 2019/20	447,464	The data is not normally distributed. Therefore use IQR: 226,600 – 559,000	To determine the cost of the unlimited licence option for a typical CCG and the average number of CDOP registered patients in the modelled CCG.
Probability of patient having a diagnosis of COPD	QOF, COPD, 2019/20	1.94%	IQR: 1.64% - 2.46%	To determine the average number of patients on the COPD register for the modelled CCG
Text	Text	Text	Text	Text

Parameter/outcomes - AECOPD model	Source	Relevant results	Range or distribution	How are these values used in the model?
Average number of admissions for AECOPD per 100,000 population (2018-19)	INHALE (PHE, 2021)	247	IQR: 184 - 310	To determine the average annual number of emergency admission for AECOPD for the modelled CCG

Average number of index COPD admissions in the CCG per year	INHALE, QOF	1105	500-1105	To determine the number of patients who will be registered for a myCOPD licence.
Rate of exacerbations within 90 days of AECOPD admission for patients with SOC	North et al 2020	1.88	±1.84	To determine resource use for patients with SOC
Rate of exacerbations within 90 days of AECOPD admission for patients with myCOPD	North et al 2020	1.06	± 0.83	To determine resource use for patients with myCOPD
Rate of readmissions within 90 days of AECOPD admission for patients with SOC	North et al 2020	0.39	+ 0.50	To determine resource use for patients with SOC
Rate of readmissions within 90 days of AECOPD admission for patients with myCOPD	North et al 2020	0.24	+ 0.44	To determine resource use for patients with myCOPD
Rate of GP appointments within 90 days of AECOPD admission for patients with SOC	McLaughlin & Skinner	2.28	±20%	To determine resource use for patients with SOC
Rate of GP appointments within 90 days of AECOPD admission for patients with myCOPD	McLaughlin & Skinner	1.85	±20%	To determine resource use for patients with myCOPD
Text	Text	Text	Text	Text

Parameter/outcomes – PR model	**Source**	**Relevant results**	**Range or distribution**	**How are these values used in the model?**
Proportion of patients with COPD eligible for PR	QOF, COPD, 2019/20	29.69%	± 20%	To determine the number of patients eligible for PR. (Denominator for QOF indicator COPD08 without PCAs / QOF registered with COPD, 2019/20)
Number of referrals of COPD patients per PR service	NACAP (2020b)	495	270-718 Lower range of 135 used for threshold.	Median of 298 for England, Scotland and Wales (Section 1.1), for a 6 month period. There is some uncertainty in interpreting the duration of data collection from the publication, and a wide range of

				PR Service sizes. This has been explored in sensitivity analysis. 83% of patients are COPD (NACAP 2019)
Time to assess patients at start and end of PR	Expert opinion	1 hour		To determine resource use for patients referred for PR using myCOPD alone
SOC arm: probability of referral to PR by GP	NACAP 2015, QOF, COPD, 2019/20	20.21%	13% - 43%	This is used to calculate patients receiving PR, and the resource use for the SOC arm. Calculation detailed in text.
myCOPD arm: probability of referral to PR by GP	Calculation based on data from Southend	20.21%	13% - 43%	This is used to calculate patients receiving PR, and the resource use for the SOC arm. Assumed to be equal in both arms
SOC arm: Waiting time for PR (from referral to assessment)	NACAP PR Clinical Audit 2019 (2020a)	84 days	51-229	Calculation of exacerbations that happen while waiting for PR. Although this data has been identified, it has been excluded from the model, as it is assumed to be equal in all modalities of treatment. There is a potential cost saving if introduction of myCOPD reduced this wait time.
SOC arm: Waiting time from assessment to enrolment on PR	NACAP	13 days	6-28 days	Patients may experience exacerbations at the pre-PR rate during this time. This wait is not applied to patients who receive myCOPD as they are able to start PR via the app.
myCOPD arm: probability of having myCOPD-only PR	Company (Southend Hospital PR model)	11%	5-50%	Determines the proportion of patients referred to PR who receive this treatment method. A wide sensitivity range was used due to the variety of implementation models used.
myCOPD arm: probability of having myCOPD plus F2F PR (hybrid)	Company (Southend Hospital PR model)	11%	5-50%	Determines the proportion of patients referred to PR who receive this treatment method. A wide sensitivity range was used due to the variety of implementation models used.
probability of completing PR (of those referred)	COPD Prime	42%		59% of referral start PR; of whom 75% complete
Rate of exacerbations pa for patients not completing PR	COPD Prime (CSP, 2017)	3.31		To determine resource use

Rate of exacerbations pa for patients completing PR	COPD Prime	2.11		To determine resource use
Probability that an exacerbation requires a hospital admission	COPD Prime	15%		59% of referrals start PR; of whom 75% complete
Text	Text	Text	Text	Text

If any outcomes listed in table 4 are extrapolated beyond the study follow-up periods, explain the assumptions that underpin this extrapolation.

The TROOPER study (Bourne et al 2017) reported non-inferiority of clinical outcomes for patients using myCOPD for PR compared to patients having face-to-face PR (SOC) for 90 days follow-up. We have assumed that similar clinical outcomes will extend to similar resource use outcomes for patients completing PR courses. We have included annual rates of resource use (admissions, exacerbations) on the basis that the PR modalities are equivalent.

Table 4 Other parameters in the model

Describe any other parameters in the model. Examples are provided in the table. You can adapt the parameters as needed.

Parameter	Description	Justification	Source
Time horizon – AECOPD model	3 months	We are using the annual rate of index admissions for AECOPD, plus 3 months of resource use	North et al 2020
Time horizon – PR model	1 year, split between waiting time for PR and post-PR follow-up	We are using 1 year of PR referral data plus 1 year of resource use outcomes	Bourne et al 2017
Discount rate	Not applied	NA for 1 year time horizon	Text
Perspective (NHS/PSS)	NHS	Text	Text

Sources of unit costs	PSSRU (Curtis et al 2020), NHS Reference costs, British National Formulary (BNF)	Text	Text

Explain the transition matrix used in the model and the transformation of clinical outcomes, health states or other details.

All models submitted are decision trees.

Resource identification, measurement and valuation

Technology costs

Provide the list price for the technology (excluding VAT).

For the unlimited licence plan, an unlimited number of myCOPD licences is available for £0.25 pa per patient registered with a GP in the CCG population, as an annual cost, with a 3 year contract. The mean number of GP registered patients per CCG is obtained from QOF data. The AECOPD model includes the full annual cost for the CCG and divides this by the patients in the model for the per patient cost. The base case PR model is an additional subgroup of patients in the CCG who can be included for the same contract, administration and training costs. Only the time required to register additional myCOPD licences for PR patients are included as a technology cost. Access to pulmonary rehabilitation using myCOPD can be through the so-called Unlimited Model, or it can be through a PR package. In this a PR service provider buys access for the patients in their service at £10,000 pa. We have included this contracting provision as a scenario for the PR model. Once activated, patients have perpetual use of the app, however clinicians only get access to their data for the duration of the contract.

If the list price is not used in the model, provide the price used and a justification for the difference.

NA

NHS and unit costs

Describe how the clinical management of the condition is currently costed in the NHS in terms of reference costs, the national tariff and unit costs (from PSSRU and HSCIC). Please provide

relevant codes and values (e.g. OPCS codes and ICD codes) for the operations, procedures and interventions included in the model.

Costs	Source	Relevant results	Range or distribution	How are these values used in the model?
Exacerbation self-managed or managed in primary care (i.e. no admission)	Adapted from Jordan et al (2015)	£53.59	£37.55 - £123.00	To cost the resource use for the intervention and SOC arms
Emergency hospital admission for AECOPD	COPD PRIME (updated)	£1,583.31	£1,583 - £3,726	To cost the resource use for the intervention and SOC arms
Practice nurse per hour (band 5)	PSSRU (Curtis and Burns 2020), NHS Jobs	39	Not used	To cost the resource use for the intervention and SOC arms
GP appointment (9.2 mins)	PSSRU 2020	£39	Not used	To cost the resource use for the intervention and SOC arms
F2F PR programme	COPD Prime (updated using PSSRU 2020 staff costs)	£695.26	£418 - £837	To cost the resource use for the intervention and SOC arms
Assessment for PR	PSSUR 2020, Expert opinion	79	Not used	1 hour of band 6 and band 4
Telephone support for remote PR - time	Expert opinion	10	5-15	To calculate cost of telephone support
Telephone support for remote PR - cost	PSSRU 2020 for staff costs	18.17	Not used	3 calls at 10 min. 1st with physiotherapist (band 6) subsequent with admin staff (band 4)

COPD Reference Cost HRG codes = DZ65A-K

HES 3 character diagnosis codes ICD-10-CM = J44 for COPD

General

Primary care costs for non-hospitalised exacerbations:

We considered three alternative sources for the cost of exacerbations that are treated in primary care: NG115 (NICE 2018), Jordan et al (2015) and COPD Prime (CSP 2017). All of these include a cost and frequency for GP visits, corticosteroids and antibiotics. NG115 and Jordan also include costs of non-admitted A&E visits (these are included in hospital exacerbations in COPD Prime). NG115 also includes 10% of patients receiving visits from a respiratory team, Jordan (2015) includes prescription costs. The largest difference is due to the inclusion of LAMA therapy for two years at a cost of £395 per year for 15% of exacerbations in COPD Prime. We have not included this cost, due to the risk of double counting patients moving to additional therapies, as there is more than one exacerbation per patient during the model time horizon. The model does not include other step-up long term treatments, and as such takes a conservative approach to estimating cost savings.

Primary care costs are based on Jordan et al (2015) updated to current prices, but excluding prescription costs as the antibiotic and corticosteroid costs are explicitly included. There is an assumption that 2/3 patients will visit a GP, and 1/3 patients will be treated in A&E.

Item		Unit cost	Source
A&E no admission	33%	£74.82	2018/19 Reference Costs, weighted average for all
GP visit	66%	£39	PSSRU (Curtis and Burns 2020),
Oral Corticosteroids	2 x 28 tablets x 5mg	£1.54	Prednisolone £0.77; BNF 2020
Antibiotics	15 x 500mg	£1.11	Amoxicillin; BNF 2020
Total cost per exacerbation		£53.59	

This updated cost from Jordan (2015) is lower than several other estimates, and is therefore a very conservative approach. The lower sensitivity analysis assumes all patients are treated by the GP **(£37.55)**, and the higher uses the cost estimated by Jordan (2015), inflated to 2019/20 prices, of **£123**. This higher price encompasses costs outlined in NG115 (£78) and is in line with McLean (2016) (£118).

Exacerbations resulting in hospital admissions:

Costs resulting in hospital admissions are taken from COPD Prime, which uses the weighted average of all non-elective short and long stay costs, plus cost of ambulance and emergency medicine for 90% of patients. The cost updated to 2018/19 reference costs is **£1,583.31.** Punekar et al (2015) estimated a cost for severe exacerbation (resulting in hospital admission) of £1,487 (2013-14 prices) also using a method that included all COPD HRG codes.

By comparison costs from NG115 were £2111; Jordan et al (2015) were £2,022 and McLean et al (2016) **£3,726**. These costs were also based on non-elective stay data for COPD patients, but used only long stay admissions, and excluded HRGs for any stays of one day or less. This results in a higher cost, and no justification for this is provided. The costs used in the model are therefore conservative compared to other published COPD models.

GP appointment rate (McLaughlin & Skinner, no date) is reported as number of events in 23 patients in the 6 months before and after obtaining myCOPD. These were 105 before (105/23/2 = 2.28 per patient for 3 months) and 85 after (85/23/2 = 1.85 per patient for 3 months). The before rates are used for patients in the SOC arm of the AECOPD model.

PR Model

There are two approaches to estimate the number of patient who are eligible, and who are offered PR.

1. QOF data for 2019/20 includes a measure COPD08 which is the percentage of patients with COPD and Medical Research Council (MRC) dyspnoea scale ≥3 at any time in the preceding 12 months, with a subsequent record of an offer of referral to a pulmonary rehabilitation programme (excluding those who have previously attended a pulmonary rehabilitation programme). There are two possible denominators for this figure, one which includes exceptions and personalised care adjustments, and one that only includes exceptions. We have used the denominator using only exceptions, as some of the personalised care adjustments include reasons such as the patient not wanting to be referred, or PR services not being available locally. These may no longer apply if alternative methods of delivery are available. This results in 29.69% of patients registered with COPD being eligible for PR. From these patients, 42.65% were offered a referral to PR by their GP in 2019/20 (equivalent to 13% of all patients registered with COPD). This is not the number that accept the referral, or that start or complete PR. Clinical experts from the company advise that the introduction of a QOF code for PR has led to an increase in referrals, but that not all of these are appropriate, therefore the true number of appropriate referrals will be lower.

2. Several sources quote between 12 and 15% as the proportion of eligible COPD patients who are typically referred to PR, and this figure is widely used e.g. in the NHS Long Term Plan. NACAP (2015) "Time to Breathe better" states that in the 2013/14 audit there were approximately 68,000 referrals to PR programmes for patients with COPD in England and Wales, and a prevalence of 446,000 eligible patients (MRC grades 3 to 5). This equates to 15%.

In the model, for the SOC arm, we have taken the mean number of patients in a CCG from QOF, and applied 29.69% from QOF data to give the number of patients eligible for PR. The total number being referred nationally is taken from the NACAP data, and combined with the QOF eligibility as a denominator, **results in a referral rate of 20.21%.** The values of 13% and 42.65% are used in the sensitivity analysis.

When myCOPD has been introduced, services such as Southend were able to increase capacity (Kane 2019, my mHealth 2021b). They report a very large capacity increase (around 112%), however we have not included this change, as there may have been additional changes in the service at the same time. We have assumed that the overall number of patients referred to PR is the same in both arms of the model. The impact of this assumption is included in the sensitivity analysis.

The PR costs are based on the staff making up a PR service as reported by COPD Prime (from NACAP audit data), with staff costs recalculated using the full PSSRU cost (Curtis and Burns 2020).

A number of alternative reported costs were considered. Griffiths et al (2001) reported costs of £713 per patient, which have subsequently been inflated to £788 per patient for use by NICE in NG115 (NIC 2018) and in other models such as Yakutcan et al (2021, £837 per patient). If the original costs in the paper are inflated using the PSSRU pay and prices index to 2019/20, the costs would be £1103 per patient. However, the hospital based PR service described in the original paper appears unlike current NHS services, e.g. it includes 5 hrs of consultant time and 3 patient sessions per week.

Lower costs were reported by Healthcare Improvement Scotland (2011), who used a range of £199 to £249 per patient, with the higher costs being the total cost per patient completing the course. Inflated to 2019/20 these would be £230 to £285 respectively.

There are likely to have been significant changes to the model of delivery of PR pulmonary since 2001 (i.e. the Griffiths values), and therefore the final cost has been based on COPD Prime, which uses a breakdown of staff time as collected by the national audit (NACAP). In addition to the staff time there is an allowance for staff travel time and for rental of a location. These costs have been updated and staff costs amended to use the full PSSRU cost. Patient transport has been added for the 34% of patients who were able to claim it (based on the NACAP audit data used for COPD Prime), with an estimation of 10 miles per rehabilitation session for those patients. This results in a cost of **£695.26** per patient. An alternative approach was to inflate the staff pay costs and add a 20% overhead in line with the methodology used by Griffiths (2001). This gave a cost of £418 which was used in the sensitivity analysis.

The base case takes **£695.26 per patient**, with a lower and upper values of **£418 and £837** respectively.

Additional PR costs

For face to face and hybrid PR, the calculated costs are based on the provision of the entire PR service, and are therefore assumed to include initial and final assessments.

For patients who do not complete PR, in all branches of the model, a cost for an initial assessment is included.

For patients in the myCOPD only branch of the model, who complete PR, a cost of an initial and final assessment is included in the overall cost.

Both initial and final assessments are based on 1 hour per patient, for a band 6 and band 4 member of staff. This results in a cost of **£79 per assessment** per patient.

Exacerbation rates are determined differently for the two models. In the AECOPD model, the rates for re-admissions and exacerbations are those reported separately in North et al (2020). For the PR model, exacerbation rates are taken from COPD Prime, of which **15%** result in a hospital admission.

Outcomes following PR

There are two Cochrane reviews considering outcomes following PR (Puhan et al 2016, McCarthy et al 2015), in addition to a systematic review focusing on hospital admissions (Moore 2016).

Puhan et al (2016) reviewed evidence on outcomes for PR following an acute exacerbation of COPD, including 20 studies. They reported that from 8 studies that reported hospital readmissions (810 participants), there was moderate quality evidence that PR reduced readmissions (pooled odds ratio (OR) 0.44, 95% CI 0.21 to 0.91). They also reported high quality evidence of an improvement in health related quality of life and 6 minute walk distance (6MWD).

McCarthy et al (2015) reviewed evidence on outcomes for PR for patients with stable COPD, including 65 RCTs with 3,822 participants. They found significant improvements in quality of life, incremental shuttle walk test, 6MWD, and exercise capacity. They did not report evidence for other outcomes with direct health care resource implications such as exacerbations, hospital admissions, or GP visits.

Moore et al (2016) reviewed studies that included rates of hospitalisation and emergency department visits with and without PR. They included 10 RCTs (264 patients), 3 cohort studies (1,214 patients) and 5 before and after studies (327 patients). The majority of the studies found that the PR group had a lower rate of hospitalisations than the comparator group (8/10 RCTs, 2/3 cohort studies, 5/5 before and after studies). One large cohort study found a higher rate of hospitalisation for the PR group (despite a larger reduction from baseline than the comparator), and due to the high numbers, this has a large impact on the pooled results. The per patient, per year rates for the control and PR groups respectively were 0.97 vs 0.62 for the RCTs alone and 0.47 and 0.39 for all included studies.

Jácome et al (2014) considered the impact of PR on patients with mild COPD, and found that there was a significant positive effect on exercise capacity and health related quality of life (HRQoL), but that effects on health-care resource were inconclusive. These patients would not be offered PR within the NHS as standard of care.

In addition to these systematic reviews, a retrospective review of health care records (Moore et al 2017) linked GP and hospital records to compare rates of hospital admission and GP visits for the year before and after referral for PR. They also compared exacerbations for patients eligible and referred, with those not eligible. They report that from 69,089 patients identified as eligible, only 6,436 (9.3%) were recorded as being referred. They found that total exacerbations (GP and hospital) were not significantly different, with 2.83 per patient-year for those eligible and referred, and 2.17 for those eligible and not referred. Limitations on this study include the use of retrospective data where not all occurrences or eligibilities will be correctly identified, and of the recording of patients referred to PR, rather than those who actually receive it, which is likely to be a much smaller number.

COPD Prime (CSP 2017) is an economic model for PR for COPD, made available by the Chartered Society of Physiotherapy, and prepared by Imperial College, London. This model takes information from the systematic review by Moore et al (2016) and additional information from routine data, although the exact method is not reported. The overall exacerbations rates per patient year are **3.11 with no PR, and 2.106 following PR**. A **15% likelihood** of the exacerbation resulting in admission is applied, giving hospitalisation rates of 0.497 and 0.316 respectively.

For this model, we have taken the COPD Prime exacerbation rates as they are presented for both hospitalisation and primary care events, however a scenario analysis is also included where no impact on healthcare resource is seen. This reflects the strength of evidence for clinical outcomes following PR, and the additional capacity and flexibility offered with the addition of myCOPD.

Resource use

Describe any relevant resource data for the NHS in England reported in published and unpublished studies. Provide sources and rationale if relevant. If a literature search was done to identify evidence for resource use then please provide details in appendix A.

Parameter/outcomes – PR model	Source	Relevant results	Range or distribution	How are these values used in the model?
Time for patient assessment, before & after PR	Expert opinion, company	60 min	30-90 min	To determine resource use for the patients referred for PR, where this is not included in overall cost
Staff required for assessment	Expert opinion, company	1 x band 4 1 x band 6	Not used	To determine resource use for the patients referred for PR, where this is not included in overall cost

Enter text.

Describe the resources needed to implement the technology in the NHS. Please provide sources and rationale.

At a basic level, only time to learn how to use the licence system, and manage and allocate the staff and patient licences is required. Patients can have licences allocated by email or during an existing consultation, such as the annual review, a clinic or GP appointment, on discharge from hospital, or a PR assessment or class.

There is a hierarchy of licences. A Top-Level Account (TLA) is provided for the procuring group, they can create manager's accounts, from which clinicians' accounts are created. Patients' licences come from the clinicians signing them up. Depending on the organisation that is purchasing the app, the top accounts may be managed by a GP practice manager, CCG digital/IT services, manager of a community respiratory service, or manager/IT within a Hospital Trust. Training videos and other material are available within the app and My mHealth will provide some staff training as part of the purchase and commissioning of the licence package.

Basic use of the app and registration of patients by clinicians can be learnt in about 20 mins. Full training including use of the dashboards (varied content depending on the level of user) can be achieved in less than an hour of staff time.

Based on discussions with the Company we have estimated staff time overheads for training and setting up licences. Staff bands were estimated from role descriptions and NHS job adverts.

- 1 day (7.5 hours) of a practice manager (Band 6) to administer the top level and manager licences
- 1 hour of training for 1 practice nurse (Band 5) in each GP practice in the CCG
- 15 mins of a practice nurse per patient registered to explain the app and register the licence.

Case studies and published evidence show that patients get more benefit the more they are engaged with the app. Support and encouragement from clinical staff are needed to achieve this. Ideally the app would be ingrained into clinical management of patients with COPD, with data reviewed at annual reviews and clinic appointments. Patients may well be more accepting of digital technologies following the pandemic, especially where access to healthcare has been lacking. Technologies such as myCOPD are more likely to be seen as helpful by clinicians, patients and families/carers.

Implementation resources - general	Source	Relevant results	Range or distribution	How are these values used in the model?
Annual cost of administering the staff licences	PSSRU, NHS Jobs website, Company	£48.00 x 7.5	£360 - £720 (2 days pa)	Band 6 manager (£48 per hour) is assumed to be the appropriate level for the staff member who will administer the staff licences. We assume 1 day (7.5hrs) per year for this.
Cost to train 1 practice nurse at each practice in the CCG	PSSRU, NHS Jobs website, Company, PHE	£39 x 50	£39 x 100	Band 5 practice nurse at each practice, average of 50 GP practices per CCG
Practice nurse per hour (Band 5)	PSSRU, NHS Jobs website, Company	£39.00	Not used	Practice nurses are likely to be the staff member seeing the patient for their annual review and registering the patient for a myCOPD licence. This is used to determine costs for training on myCOPD and registering each patient licence.
Base cost of unlimited myCOPD licences per patient registered in a CCG	Company	£0.25	Not used	To determine the annual cost of unlimited licences for the typical CCG
Overall cost of myCOPD licences purchased by a PR-only service.	Company	£10,000	NA	Annual cost of licences for all patients passing through the PR service.
Time for a clinician (Band 5 nurse) to explain the app and register a patient for a myCOPD licence	Company	15 mins	10 mins – 30 mins	Practice nurses are likely to be the staff member seeing the patient for their annual review and registering the patient for a myCOPD licence. This is used to determine costs for registering each patient licence.

Implementation resources - PR	Source	Relevant results	Range or distribution	How are these values used in the model?
Support phone calls to patients on myCOPD-alone PR	Company	3 x 10 mins	5-15 min calls	To determine resource use for patients using myCOPD PR 1st phone call is by a physiotherapist (band 6) subsequent are by administrative staff (band 4)
Cost of phone calls	Company	Text	Not used	1st phone call is by a physiotherapist (band 6) subsequent are by administrative staff (band 4)

Describe the resources needed to manage the change in patient outcomes after implementing the technology. Please provide sources and rationale.

There are no additional resources requirements, as the patient outcomes involve fewer exacerbations, admissions and GP appointments.

Describe the resources needed to manage the change in system outcomes after implementing the technology. Please provide sources and rationale.

There are no additional resources requirements, as the patient outcomes involve fewer exacerbations, admissions and GP appointments.

Table 5 Resource use costs

In this table, summarise how the model calculates the results of these changes in resource use. Please adapt the table as necessary.

AECOPD model	**Technology costs**	**Comparator 1 costs**	**Difference in resource use costs (technology vs comparator 1)**
Cost of resource use to implement technology	£124,952	NA	+£124,952
Cost of resource use associated with system outcomes	£562,510	£892,102	-£329,596
Total costs	£687,462	£892,102	**-£204,641**

PR model CCG budget (no contract/admin/ training costs)	**Technology costs**	**Comparator 1 costs**	**Difference in resource use costs (technology vs comparator 1)**
Cost of additional licence registration	£1,117.28	NA	£1,117.28
Total PR costs	£154,812.21	£175,614.83	-£20,802.63
Resource use for exacerbations	£2,343,048.07	£2,343,631.21	-£583.13
Total costs	£2,498,978	£2,519,246	**-£20,268**

Adverse event costs

If costs of adverse events were included in the analysis, explain how and why the risk of each adverse event was calculated.

Adverse events are not included in the models. In the AECOPD model there are no specific risks related to the use of the myCOPD app. This is provided as supplementary to SOC. In the PR model, the myCOPD version of PR was non inferior to face-to-face PR. This includes adverse events. There were no adverse outcomes that were specifically related to the use of the app rather than the conduct of PR. There are potential additional risks for patients undertaking home-based PR, but these should be minimised by the appropriate exclusion of certain high risk patients for non-supervised PR. All patients have an initial assessment prior to the start of PR, and have phone calls at weeks 1,3 and 6. To date, there have been no clinical incidences related to the use of myCOPD reported to the company.

Miscellaneous costs

Describe any additional costs or resource considerations that have not been included elsewhere (for example, PSS costs, and patient and carer costs). If none, please state.

NA

Are there any other opportunities for resource savings or redirection of resources that have not been possible to quantify?

The peer-reviewed published and real world evidence for the use of myCOPD shows that it has patient benefits that are not captured by the resource use presented in these models.

Examples of further but unquantified benefits include:

- Improved COPD Assessment Test (CAT) scores. The CAT score is associated with patient outcomes, a higher score indicating a more severe impact of COPD on the individual. RESCUE.
- Improved inhaler technique evidence from the TROOPER study. This patient benefit comes from two contributions. Firstly, each inhaler on the market has its own video to show users the correct way to use that specific inhaler. This can be accessed at any time and can support the instigation of a new medicine. Secondly, the improved technique means greater consumption of the medication being inhaled and so increases the bioavailability of the drug, enabling it to better achieve its therapeutic goal.
- Benefits to the healthcare provider through better inhaler technique, as there is a time and inconvenience associated with bringing patients into a service building and teaching them about new medications or as part of the annual review. This is about 30-60 minutes of time for a band 6 nurse.
- The indirect impact of symptom capture and mapping and those benefits associated with recording adherence to medication. Again, likely contributing to reductions in unscheduled and scheduled care demands from this patient cohort.
- The use of the clinical dashboard as a means of triaging those patients on the platform. Anecdotal and service reviews reported this has altered the behaviour of those clinicians using the platform, altering the balance between scheduled and unscheduled demands and contributing to decisions around staffing and staff skill-mix.
- Medicines optimisation – myCOPD has the functionality to review medications entered into it and cross reference them with the current guidelines. This ensures medicines being used are correct for the setting and that there are no interactions present within the patient's medication list. This saves the clinical team time, not having to identify or recognise the conflicts that may be present in the patient's list. There is also a clear clinical safety benefit to the patient.
- Time saved for both the clinical staff and patients undertaking the annual reviews. This process occurs for each patient annually and combines CAT scores with inhaler technique assessment, medicines optimisation, symptom review, smoking cessation information and service use and exacerbation data. All this data is already present within the app, saving considerable time for both parties to complete this review process.
- Smoking cessation and support are part of the myCOPD app, supporting patients to quit and stay off smoking. This is also a QOF mandated metric.
- PR has well-evidenced clinical benefits for patients the increased activity and healthier living from education mean a reduction in alternative causes of death, such as reductions in all-cause mortality, especially cardiovascular risk factors.
- Real world evidence suggests improvements in quality of life and reductions in anxiety contributed to by the tiles in the app but also the supported environment.

The myCOPD app may be particularly relevant in the 'Covid recovery' environment. Under Covid restrictions many F2F PR services have stopped altogether. Some have adopted digital technologies, such as Zoom or apps including myCOPD. Even as F2F provision is restarting, Covid infection control measures such as social distancing mean that such services are operating at reduced capacity (My mHealth 2021a). This means that even more eligible patients have missed out on participating in PR courses since March 2020. The waiting times and referral rates can only be worse than the data reported in the published literature.

Additionally, myCOPD provides a scalable solution for providers to attain the NHS England target of 60% of eligible patients getting a PR referral, as described in the NHS Long Term Plan.

Total costs

In the following tables, summarise the total costs:

- Summarise total costs for the technology in table 7.
- Summarise total costs for the comparator in table 8. This can only be completed if the comparator is another technology.

Table 7 Total costs for the technology in the model

Description	Cost	Source
Cost per patient, per year, over 3 years of Unlimited contract	£0.25	Company (per patient registered with a GP in the CCG)
Total contract cost for the CCG Unlimited contract pa	£111,866	Company , CCG population from QOF 2019-20
Total contract cost for the PR service contract pa	£10,000	Company
Training cost over year	£1950	Company – 1 hour per staff member, 1 practice nurse per practice in the CCG. Mean of 50 practices per CCG (INHALE PHE).
High level licence administration,	£360	Company: 1 day of 1 Band 6 manager per year
Staff time to register patients	£9.75/ licence	Company: Band 5 practice nurse, 15 min per registration
Total cost per CCG over 1 year of contract – AECOPD model	£124,952	Unlimited licences + admin + training + time to register licences
Total cost per licence registered over 1 year of contract – AECOPD model	£101.23	Total cost divided amongst patients receiving a myCOPD licence (1105)
Total additional cost per CCG over 1 year of contract – Unlimited contract in PR model	£1,117	Time to register PR licences
Total cost per CCG for AECOPD and PR subgroups – Unlimited contract	£126,069	Total cost for all licence (this is an overestimate as there is overlap between the AECOPD and PR populations)

Table 8 Total costs for the comparator in the model

There is no equivalent technology in the comparator arm. Costs provided are for face to face PR, however a proportion of patients also receive PR in the intervention arm.

Description – PR model	Cost	Source

Pulmonary Rehabilitation F2F	£151,702.92	The total cost of face to face PR for all patients who complete PR in the model
1st assessments for non-completion	£23,911.91	The total cost of a single assessment for all patients referred to PR but who do not complete it
Total PR costs	£175,614.83	

Results

Table 9 Base-case results

In this table, report the results of the base-case analysis. Specify whether costs are provided per treatment or per year. Adapt the table as necessary to suit the cost model. If appropriate, describe costs by health state.

myCOPD costs	**Mean cost per CCG using the technology (£)**	**Mean cost per CCG using the comparator (£)**	**Difference in mean cost per CCG (£): technology vs comparator 1***
Contract cost – unlimited licences	£111,866	NA	£111,866
Training cost	£1,950.00	NA	£1,950.00
Administration cost	£360.00	NA	£360.00
Registration costs	£10,773.75	NA	£10,773.75
Total myCOPD costs	£124,952	NA	**£124,952**

Resource use – AECOPD model	**Mean cost per CCG using the technology (£)**	**Mean cost per CCG using the comparator (£)**	**Difference in mean cost per CCG (£): technology vs comparator 1***
Emergency re-admissions for COPD	£419,984	£682,473	-£262,490
Exacerbations – non-hospitalised	£62,783	£111,352	-£48,568
GP appointments	£79,742	£98,278	-£18,535
Total resource use	£562,510	£892,102	-£329,593
Total net costs for model arm	£687,462	£892,102	**-£204,641**

PR model CCG budget (no contract/admin/ training costs)	**Technology costs**	**Comparator 1 costs**	**Difference in resource use costs (technology vs comparator 1)**
Cost of additional licence registration	£1,117.28	NA	£1,117.28
Pulmonary Rehabilitation F2F	£126,671.94	£151,702.92	-£25,030.98

Assessments and phone support for myCOPD alone	£4,228.35	£0.00	£4,228.35
1st assessments for non-completion	£23,911.91	£23,911.91	£0.00
Total PR costs (other than myCOPD)	£154,812.21	£175,614.83	-£20,802.63
Outcomes			
Total exacerbations	£2,343,048.07	£2,343,631.21	-£583.13
Total net costs for model arm	£2,498,978	£2,519,246	**-£20,268**

For the same model, the costs per patient eligible for PR are:

PR model per patient (no contract/admin/ training costs)	**Mean cost per eligible patient using the technology (£)**	**Mean cost per eligible patient using the comparator (£)**	**Difference in mean cost per eligible patient (£): technology vs comparator**
Cost of licence registration	£0.43	£0.00	£0.43
Total myCOPD costs	£0.43	£0.00	£0.43
Pulmonary Rehabilitation F2F	£49.15	£58.86	-£9.71
Assessments and phone support for myCOPD alone	£1.64	£0.00	£1.64
1st assessments for non-completion	£9.28	£9.28	£0.00
Total PR costs (other than myCOPD)	£60.07	£68.14	-£8.07
Total exacerbations	£909.10	£909.33	-£0.23
Total net costs for model arm	£969.60	£977.46	**-£7.86**

Scenario analysis

If relevant, explain how scenario analyses were identified and done. Cross-reference your response to the decision problem in part 1, section 1 of the submission.

A. PR provider buys licences for annual patients at a set cost of £10,000. The Company provides myCOPD under 2 types of purchasing contracts.

B. Due to the uncertainty in the more recent data for PR outcomes we have included a scenario where there is no impact on resource use in the PR model.

C. Worst case scenario for the AECOPD model to explore the range of economic outcomes that might result from implementing myCOPD.

D. Best case scenario for the AECOPD model to explore the range of economic outcomes that might result from implementing myCOPD.

Describe the differences between the base case and each scenario analysis.

A. The only difference is the cost of purchasing the myCOPD licences, which were £0.25 per registered CCG patient in the base case and £10,000 fixed cost in scenario A.

B. Costs for exacerbations are removed from the PR model for scenario B to model 'no difference' in resource use outcomes for patients completing PR.

C. The best case scenario used the most beneficial input parameter values for myCOPD. We did not reduce the exacerbation or admission rates for myCOPD as the ranges given in North et al (2020) would have led to negative values, Instead, we kept these at the base values and increased those for SOC accordingly. (See table below).

D. The worst case used the least beneficial input values but removed exacerbations and admissions as resource use outcomes. There is no reason to consider that myCOPD should increase exacerbation frequency in the population and therefore we consider the worst case to be equivalence with SOC in these outcomes. There is a potential for self-management interventions to increase patient contact with primary and community services if patients become more aware of temporary deteriorations in health status or the intervention increases attention to, and anxiety about, their condition. Therefore we have retained GP appointments as an outcome, with an increase in resource use for the myCOPD arm of 20% and a reduction in SOC of 20%. (See table below.)

Input parameters for scenarios C and D	**Base**	**Best**	**Worst**
CCG population	447,464	559,000	226,600
Number of index admissions for AECOPD per 100,000	247	310	184
Number of index admissions in the CCG pa	1105	1733	417
Probability of having diagnosis of COPD	0.0194	0.0246	0.0164
Rate of GP appointments for myCOPD	1.85	1.46	2.22
Rate of GP appointments for SOC	2.28	2.74	1.85
Rate of readmissions for myCOPD	0.24	0.24	0
Rate of readmissions for SOC	0.39	0.44	0
Rate of exacerbations for myCOPD	0.83	0.83	0
Rate of exacerbations for SOC	1.84	3.72	0
Cost of an exacerbation	£53.59	£123	NA

Cost of a readmission	£1583.31	£3726	NA

Describe how the scenario analyses were included in the cost analysis.

A. Separate TreeAge model was saved for the PR service contract
B. Costs for exacerbation are removed from the total cost impact for each PR scenario
C. Separate TreeAge model was saved for the AECOPD best case scenario
D. Separate TreeAge model was saved for the AECOPD worst case scenario

Describe the evidence that justifies including any scenario analyses.

A. The Company provides myCOPD under 2 types of purchasing contracts.
B. Recent evidence reviews do not consistently show the resource use benefit following PR reported in COPD Prime and Puhan et al 2016 (McCarthy et al 2015, Moore et al 2016 and 2017). There is wide agreement for a substantial clinical benefit.
C. NA
D. NA

Table 10 Scenario analyses results

In this table, describe the results of any scenario analyse that were done. Adapt the table as necessary.

	Cost using the technology (£)	**Cost using the comparator (£)**	**Difference in cost (£)***
Scenario A – PR service contract	£555,350	£564,109	-£8,759 (-£17.65 per patient)
Scenario B – no resource difference in PR base model	£155,929.93	£175,614.79	-£19,684.87 (-£7.63 per patient)
Scenario C – AECOPD best (total costs)	£2,033,191	£2,819,069	-£1,785,878 (-£1,031 per index admission)
Scenario D – AECOPD worst (total costs)	£99,124	£29,595	+£69,530 (+£167 per index admission)
* Negative values indicate a cost saving. Adapt this table as necessary.			

Sensitivity analysis

Describe what kinds of sensitivity analyses were done. If no sensitivity analyses have been done, please explain why.

Tornado diagrams were used to explore the impact of varying each input parameter separately. This was used to identify parameters that were key drivers for the costs and report 1-way deterministic sensitivity analyses for these in each model.

Threshold analyses were conducted to determine the level of each input parameter that moved the results from cost-saving to cost-neutral versus SOC.

Summarise the variables used in the sensitivity analyses and provide a justification for them. This may be easier to present in a table (adapt as necessary).

Sensitivity ranges are included in Table 3. These are taken from the published literature, updated from other economic sources, or use a default of ±20%.

AECOPD model - readmission rates are not reduced, as the ranges given in North et al (2020) would result in negative rates. Therefore, in this model the lower range is kept at the base case values and the standard deviation is used to determine the upper limit. The cost for a hospital admission for AECOPD was only increased as the base case estimate was towards the lower end of published values. Training costs were increased by requiring that 2 staff members per practice were trained to use myCOPD and licence administration costs were doubled to 2 days per year. Values used in the sensitivity analysis are given in the table below.

Input parameter for sensitivity analysis – AECOPD model	Low	Base	High
Readmission rate, SOC	0.39	0.39	0.89
Readmission rate, myCOPD	0.24	0.24	0.68
Cost of readmission	£1583	£1583.31	£3726
Exacerbation rate, SOC	0.04	1.88	3.72
Exacerbation rate, myCOPD	0.23	1.06	1.89
Cost of an exacerbation	£37.55	£53.59	£123
Average number of admissions for AECOPD per 100,000	184	247	310
Number of registered patients in CCG	226,600	447,464	559,000
Time to register a patient for a myCOPD licence (hours)	0.2	0.25	0.5
Cost of training clinicians to use myCOPD for each practice in the CCG (avg 50)	£1950	£1950	£3950
Cost of administering the staff licences	£360	£360	£1080
Probability of having COPD diagnosis	0.0164	0.0194	0.0246

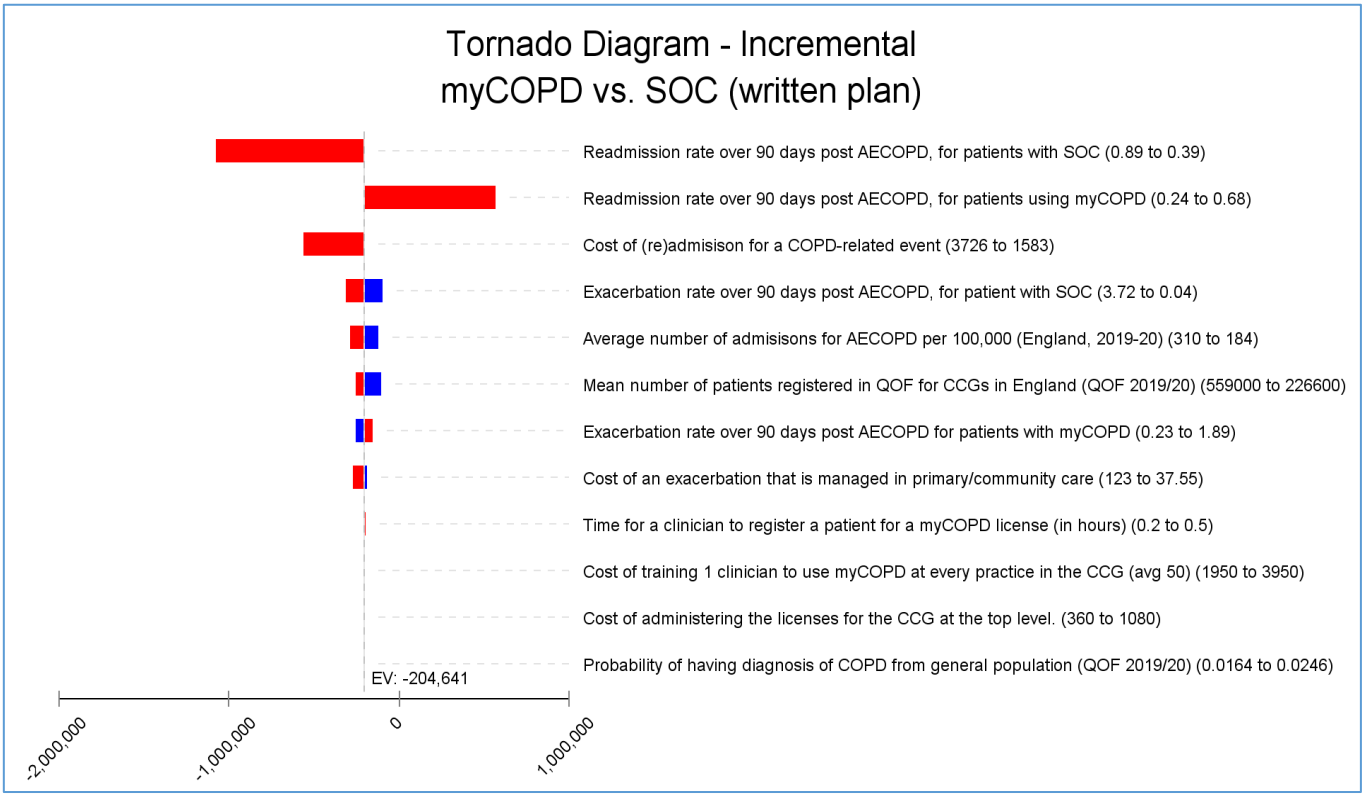
If any parameters or variables listed in table 3 were omitted from the sensitivity analysis, please explain why.

Staff hourly rates do not vary in the sensitivity analysis. We consider that the appropriate staff bands have been identified and their employment costs are well-determined. Cost for staff time are varied using to the amount of time required for each task.

Sensitivity analyses results

Present the results of any sensitivity analyses using tornado plots when appropriate.

AECOPD Model



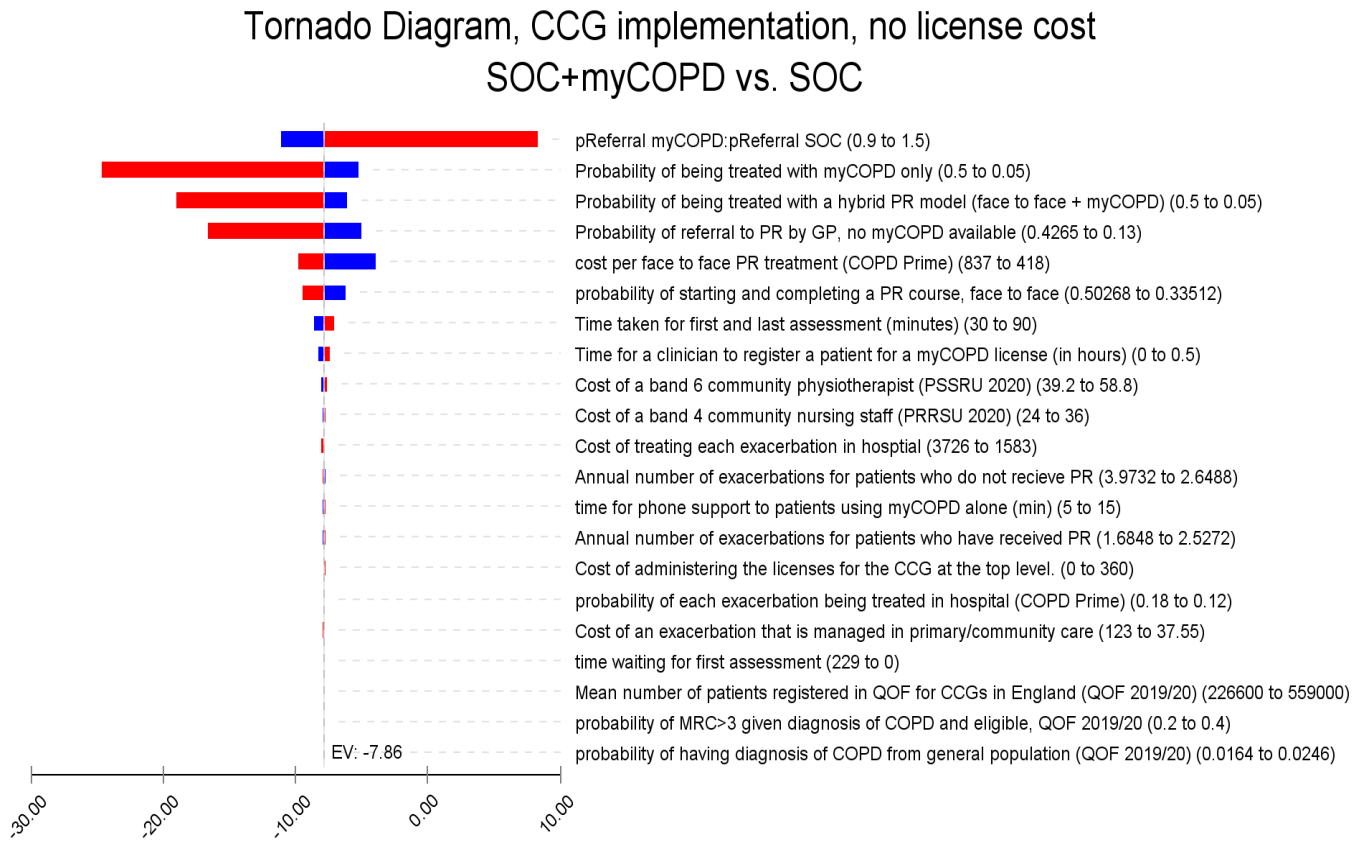
The Tornado diagram for the AECOPD model (above) shows that only the rates of readmissions for the myCOPD arms can move the model from cost-saving to cost-incurring. All other variations only reduce or increase the total-cost saving for the CCG. A threshold analysis was conducted on the rate of readmissions in the myCOPD arm.

Doubling the licence administration time (2 days per year) or doubling the number of trained staff at each practice (2 x Band 5 nurses) has almost no impact on the cost difference between the arms. Increasing the time to register each patient licence from 15 mins to 30 mins makes a small impact. The impact on staff workload and efficiency will be significant, but the cost impact is small. Staff time has therefore not been included in the best and worst case scenarios for the AECOPD model.

As the numbers of index admissions increase (CCG population and proportion of admissions), the cost-savings increase. This is as expected and indicates that areas with particularly high COPD populations and COPD-related admissions are likely to see greater absolute savings using myCOPD. (However, note that the number of admissions in the base case is already at a maximum as a proxy for the number of *patients* with an index admission.)

Similarly, as the event costs of exacerbation and readmission increase, the total savings with myCOPD increase

PR Model per CCG, no licence cost



The sensitivity analysis shows the model's key drivers as being

- changes the number of referrals in one arm, compared to the other
- the proportion of patients who are treated by myCOPD (either alone or as a hybrid)
- the proportion of patients referred to PR

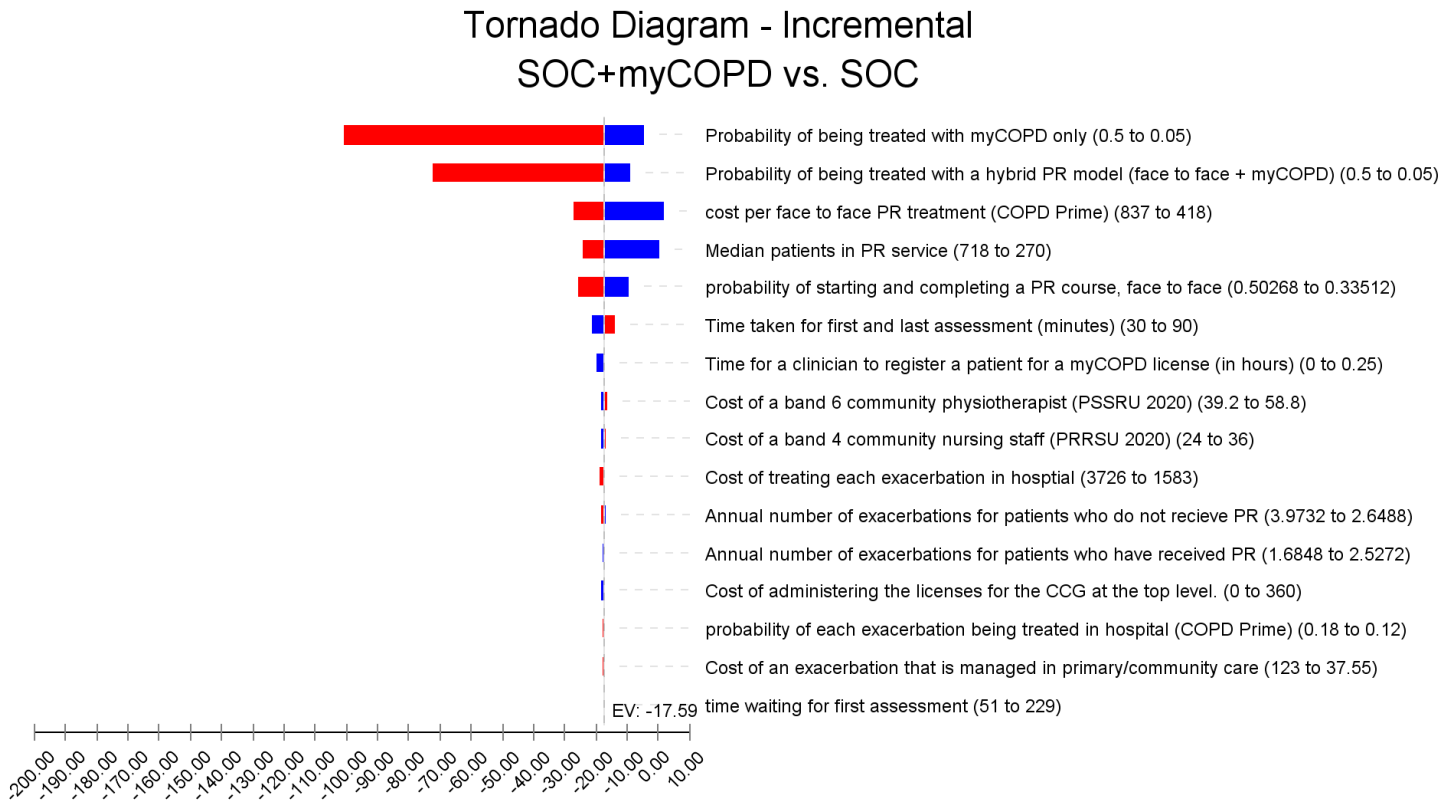
The Tornado diagram for the PR model, for a CCG, no licence cost (above) shows that only having increased numbers of patients being referred to the intervention arm compared to the comparator arm can move the model from cost-saving to cost-incurring. This is because the increased referrals increase the number of patients in all branches of the intervention arm, reducing the number of patients not receiving PR. Although this is widely recognised as having a clinical benefit, the total costs of no PR in this model are less than the total costs of face to face or hybrid PR. As fewer people receive PR in the intervention arm, it becomes less cost saving. For this reason, we have chosen to keep the numbers of referrals constant in the base case, as the purpose of the evaluation is to investigate the cost savings in myCOPD delivered PR compared to face to face PR, rather than the cost implications of PR compared to no PR.

The following table the mean cost (including exacerbations) per patient that travels through each of the arms (these do not represent total costs in the model, as they are the cost of the selected service and outcomes for a single patient, and do not reflect the proportion that are routed through each branch of the model).

	SOC Arm	myCOPD_PR (excluding licence)
No PR referral	£937.17	£937.17
Face to Face, completed	£1,303.51	£1,303.51
Face to Face, not completed	£1,016.17	£1,016.17
Face to Face, mean	£1,136.54	£1,136.54
Hybrid, completed	-	£986.86
Hybrid, not completed	-	£1,059.30
Hybrid, mean	-	£1,028.95
myCOPD completed	-	£782.02
myCOPD, not completed	-	£1,025.92
myCOPD, mean	-	£923.75

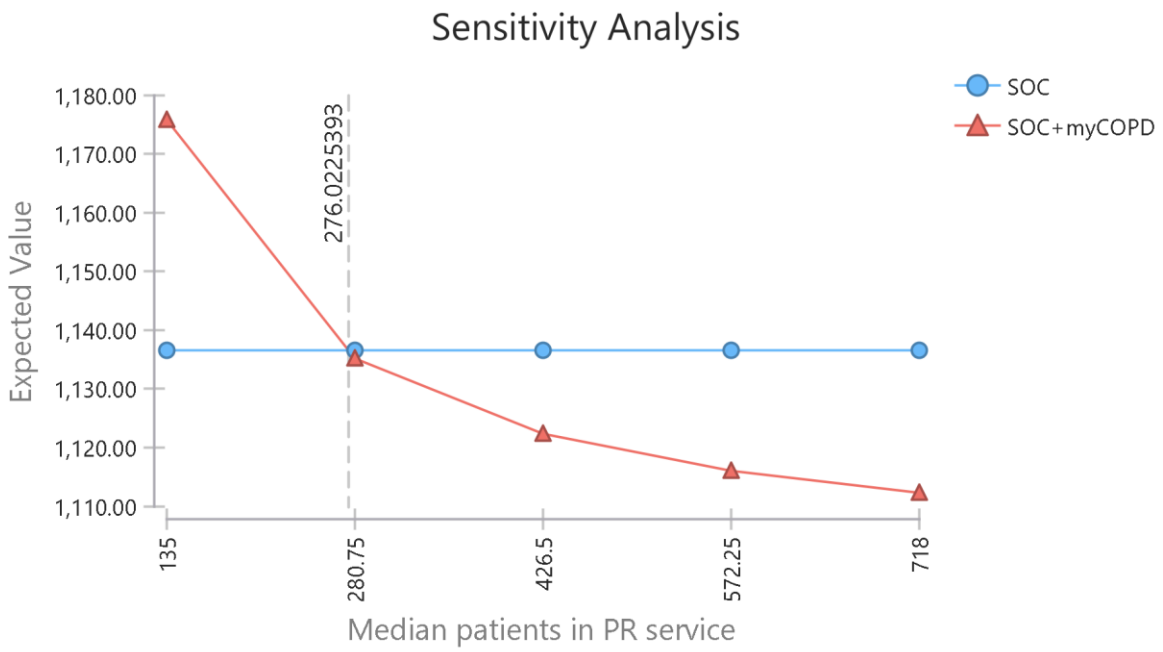
For an individual patient, the total costs including exacerbations for myCOPD and Hybrid are both cheaper than Face to Face PR provision. However only myCOPD alone is cheaper than no PR for any single patient route through the model.

PR Model, licensed for PR Service only



One way sensitivity analysis, PR model, licensed for PR Service only
Variation in both arms as size of PR service varies

Tornado diagram, PR model, licensed for PR Service only



The key drivers of this mode are

- The cost of face to face PR services
- The size of the PR service (number of referrals per year)
- The proportion of patients going to myCOPD or hybrid routes
- The proportion of patients completing either of these services.

The threshold analysis shows that PR services would require 276 referrals for COPD a year for this model to become cost saving.

What were the main findings of each of the sensitivity analyses?

AECOPD model – The 90 day rate of readmissions in the myCOPD arm at which the base case model changes from cost saving to cost-neutral/cost-incurring is 0.357. This means that, if all other parameters remain fixed, the use of myCOPD must reduce the 90 day rate of readmissions from 0.39 to around 0.36. For 1105 index admissions, this is the equivalent of myCOPD reducing the 90 day readmission incidence from 431 to 398.

PR Model, for CCG – This remains robust to all variables in one way sensitivity analysis other than the proportion of patients being referred to PR being greater in the intervention than the comparator arm. This is discussed in sections above, and is because this variable also increases the number of patients being treated by more costly methods contained within the intervention arm model.

PR Model, PR Service only – this is robust to most sensitivity analysis, becoming cost incurring only when the number of referrals a year is lower than 276, or the cost of the face to face PR service is lower than £441

What are the main sources of uncertainty about the model's conclusions?

The largest uncertainty in the AECOPD model is the rate of readmissions. This is exemplified by the large standard deviations in the result of the RESCUE study (North et al 2020). This is partly a result of the small sample size. The study was not primarily intended to test resource use, but clinical improvement following an admission for AECOPD.

For the PR model there is significant uncertainty about the proportion of patients choosing each PR modality. We were not able to obtain updated results from sites that had implemented the hybrid PR service system prior to Covid. Also, the situation is currently very fluid as PR services restart F2F provision with social distancing measures in place and therefore reduced capacity (in comparison to pre-Covid services). Many services are trialling new models of provision that include remote or home-based courses. Therefore, we have only early pilot data in which relatively small numbers of patients have used myCOPD alone. Two services (Kent and Southend) have claimed increased capacity, but we were unable to determine how this has been achieved using myCOPD.

Additionally, although the PR-related improvements in patients' clinical condition and exercise capacity are well-reported, the effect on resource use is more equivocal. Much of the base case data has been taken from COPD Prime, which is an Excel spreadsheet for providers to determine PR costs and savings. This was created by the Chartered Society of Physiotherapists, however the underlying data and assumptions in this model are not always clear.

Miscellaneous results

Include any other relevant results here.

Enter text.

Validation

Describe the methods used to validate, cross-validate (for example with external evidence sources) and quality assure the model. Provide sources and cross-reference to evidence when appropriate.

We have discussed the model structure and input parameters with the Company. This included a respiratory medicine consultant and a respiratory physiotherapist who worked in pulmonary rehabilitation.

Give details of any clinical experts who were involved in validating the model, including names and contact details. Highlight any personal information as confidential.

1. Mrs Jane Stokes PgDip MSc BSc (Hons) MCSP
   Senior Respiratory Specialist Physiotherapist, Advanced Critical Care Practitioner
   Rehabilitation and Engagement Lead at my mhealth Limited

2. Adam Kirk MBBS PhD FRCP
   Medical Director at my mhealth Limited
   Consultant NHS Physician

3. Tom Wilkinson MA Cantab MBBS PhD FRCP FERS
   Professor of Respiratory Medicine and Honorary NHS Consultant Physician

4 Summary and interpretation of economic evidence

Describe the main findings from the economic evidence and cost model. Explain any potential cost savings and the reasons for them.

The AECOPD model demonstrates cost savings when a typical CCG purchases the Unlimited licence contract and provides it to patients who have been admitted for an AECOPD. The overall budget impact in the base case is a saving of around £204k per year for the 3 year contract. Cost savings are accrued from small reductions in COPD-related readmissions, non-admitted exacerbations, and GP appointments. Staff costs to implement the technology are small in relation to the contract cost and potential resource savings.

Dividing this total budget saving between the 1105 index admissions in the model equates to a saving of £185 per licence per year. However, the per licence/per patient costs and savings are largely theoretical due to the nature of the Unlimited contract. Once a CCG has determined to purchase this, they may increase access to the app beyond this subpopulation of COPD patients. Any additional benefits from this will be accrued without incurring substantial additional implementation costs, other than the staff time to register patients.

The Tornado analysis shows that the cost savings are largely robust to reasonable changes in the input parameters, with the exception of the rate of COPD-related readmissions. NACAP data shows that only about 47% of readmissions in the 90 days following an index admission for AECOPD are COPD-related (NACAP 2020c). Others reasons include renal and cardiac function and sepsis. The RESCUE study only included COPD-related readmissions, but it seems unlikely that an app aimed at COPD self-management might have much impact on these other co-morbidities.

The PR model for the whole CCG, without technology costs, has some uncertainty around the inputs, but is cost-saving. They key drivers are the number of referrals in one arm compared to the other (largely due to the other treatment modalities in the model), the proportion of patients who are treated using myCOPD and the overall proportion of patients referred to PR. The cost savings are from face to face PR services being partially replaced by less costly myCOPD or hybrid PR.

Due to insufficient evidence, there is no reduction in time to initial assessment modelled. If the introduction of myCOPD lead to shorter waits across the whole myCOPD arm, there would be a reduction in exacerbations modelled during that period, which would lead to increased cost saving.

PR is widely considered to have a strong evidence base for improved clinical outcomes, however fewer patients receive it than are eligible. If the introduction of myCOPD were able to increase capacity to deliver PR, or increase acceptability to some patients, this should be compared against the cost of an equivalent increase in face to face PR in the comparator arm. It is important to remember

that the model does not attempt to demonstrate an overall cost saving from patients having PR vs not having PR, but a cost saving when delivering it with myCOPD included in the offering, compared to the normal standard of care.

The PR model for a PR Service – this model is cost saving, with only two parameters in one way sensitivity analysis that result in the model becoming cost incurring. These are the size of the PR service (number of patients with COPD referred every year, cost saving if more than 276) and the cost of face to face PR provision (cost saving if more than £441). This model reflects the uptake of myCOPD by a smaller group than across a whole CCG.

Briefly discuss the relevance of the evidence base to the scope.

The evidence base for myCOPD is wholly consistent with the scope/decision problem, although it does not cover the whole COPD pathway.

All the myCOPD data is taken from studies and RWE in the UK, which increases its relevance to the decision problem.

Briefly discuss if the results are consistent with the published literature. If they are not, explain why and justify why the results in the submission be favoured over those in the published literature.

There are no published economic analyses for myCOPD.

Describe if the cost analysis is relevant to all patient groups and NHS settings in England that could potentially use the technology as identified in the scope.

Only COPD patients discharged from an AECOPD event and those referred for PR have been modelled here, based on evidence from two randomised controlled trials (RCTs). These represent a small proportion of the COPD population and these modelled sub-populations overlap, given that all patients discharged from an AECOPD should be referred for PR within 30 days. myCOPD is suitable for all COPD patients and under the Unlimited licence contract could be provided to the entire COPD population in a catchment with only a very small additional financial cost. The EARLY study (Crooks et al 2020) and other evidence (Sage et al, unpubl) has failed to demonstrate resource use reductions in other COPD subgroups. However, McLaughlin and Skinner (undated) showed a reduction in GP appointments and admissions in a 'general' COPD population.

The myCOPD app should be considered as a 'complex intervention' (Craig et al 2008) as it includes multiple components and behavioural modification. As such, the type and level of benefit achieved will be strongly dependent on the way it is implemented locally. Support from clinicians and peers (e.g. in

Breathe Easy groups) and integrating the technology into the pathway (so that it becomes an expectation rather than an add-on) are likely to increase uptake and use of the app. Evidence suggests that patients who use the app more, are more likely to benefit from it (Sage et al unpubl), however both patients and clinicians report social and knowledge-based barriers to uptake of PR and adoption of digital healthcare interventions.

Briefly summarise the strengths and limitations of the cost analysis, and how these might affect the results.

The cost analysis only models the impact of the myCOPD app on 2 subgroups in the COPD population. These models are based on data from 2 small RCTs (one of which was a feasibility study) that were not powered to detect resource use changes. This leads to large uncertainties in the cost savings, particularly around high-cost COPD-related hospital admissions.

The cost analysis is based on RCT evidence and COPD resources that are produced by UK experts (CSP and RCP) and easily available. There is a substantial amount of data available relating to COPD healthcare, however it is variably reported and time-consuming to sift. There are multiple case studies, reports, and policy documents that make statements and claims that are not referenced or explained. NACAP provides a wealth of COPD-related UK data, but the large number of reports over time and with different subsets of data, and variable metrics makes it difficult to locate the right data with assurance. Published parameter values can var widely (e.g. F2F PR costs and hospital admissions) and some of the data is somewhat outdated (e.g. Griffits et al 2001). It is likely that we have missed several alternative options for parameter values. However, the key drivers in the models are not those parameters that have been widely estimated, but are specific to the implementation of the myCOPD app; resource use impact and patient uptake.

The two subgroups modelled have been treated as independent in the base case, which does not reflect likely implementation at a CCG level nor the realities of the patient population. There will be substantial overlap of the two model populations, leading to double-counting the number of patients registrations. This would lead to a slight overestimate of registration costs when combined, but this can be balanced by the lack of staff training time allocated in the PR Unlimited model. Staff time however, has very little impact on the model results.

Detail any further analyses that could be done to improve the reliability of the results.

We were unable to obtain input from independent clinicians who have implemented the app within the time constraints of this report. More up-to-date real world evidence might be obtained relatively easily, particularly relating to the implementation within PR services. In particular, better estimates of the proportions of PR referrals that take up myCOPD as an option and the effect this has on service capacity.

Additionally, more extensive structured searches for additional estimates of some of the parameters might improve the reliability. However, care must be taken to ensure that the populations match those modelled. For example, relating disease severity (GOLD status) with admission rates or PR eligibility. We did not identify estimates of the number of *patients* with an index admission and therefore used the incidence of admissions as a proxy for this parameter.

Multiway probabilistic sensitivity analysis might also be applied, and other economic analyses of the COPD pathway have reported parameter distributions for this purpose. This would help to compare the large uncertainty in one or two parameters in each model with the much smaller impact of the other parameters.

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Please include all references below using NICE's standard referencing style.

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5 Appendices

Appendix A: Search strategy for economic evidence

Describe the process and methods used to identify and select the studies relevant to the technology being evaluated. See section 2 of the user guide for full details of how to complete this section.

Date search conducted:	25/05/21
Date span of search:	2012-2021

List the complete search strategies used, including all the search terms: textwords (free text), subject index headings (for example, MeSH) and the relationship between the search terms (for example, Boolean). List the databases that were searched.

Database: Ovid MEDLINE(R) ALL <1946 to May 24, 2021>

1 Pulmonary Disease, Chronic Obstructive/ (42222)
2 copd.tw. (48806)
3 coad.tw. (517)
4 1 or 2 or 3 (61077)
5 self management.mp. or Self-Management/ (22025)
6 pulmonary rehabilitation.mp. (4052)
7 5 or 6 (25835)
8 (online or app or application).tw. (1009868)
9 (e-health or ehealth or m-health or mhealth).tw. (9050)
10 8 or 9 (1015811)
11 4 and 7 and 10 (173)
12 limit 11 to (english language and yr="2012 -Current") (141)

Database: Embase <1996 to 2021 May 24>

1 Pulmonary Disease, Chronic Obstructive/ (49921)
2 copd.tw. (90228)
3 coad.tw. (541)
4 1 or 2 or 3 (112650)
5 self management.mp. or Self-Management/ (60926)
6 pulmonary rehabilitation.mp. (9413)
7 5 or 6 (69698)
8 (online or app or application).tw. (1108005)
9 (e-health or ehealth or m-health or mhealth).tw. (10480)
10 8 or 9 (1114873)
11 4 and 7 and 10 (364)
12 limit 11 to (english language and yr="2012 -Current") (303)

Brief details of any additional searches, such as searches of company or professional organisation databases (include a description of each database):

Several documents were provided by the manufacture that had been part of the clinical submission, including real world evidence and implementation/evaluation pilots.

A Google Scholar search was conducted on 17 and 18/6/2021, using the search terms ‘myCOPD’ or “my COPD”.

Inclusion and exclusion criteria:

Economic reviews of myCOPD:

- Economic analysis of myCOPD for self-management of COPD or delivery of pulmonary rehabilitation

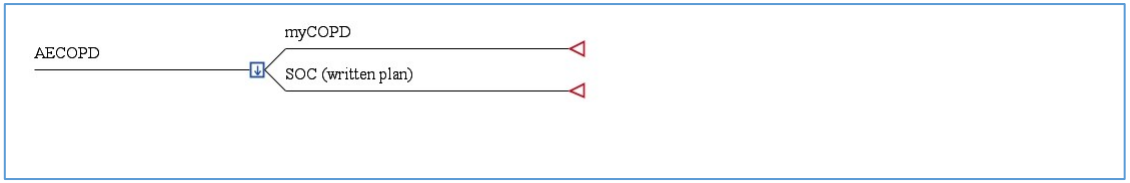
- Comparative clinical study including myCOPD
-

Data abstraction strategy:

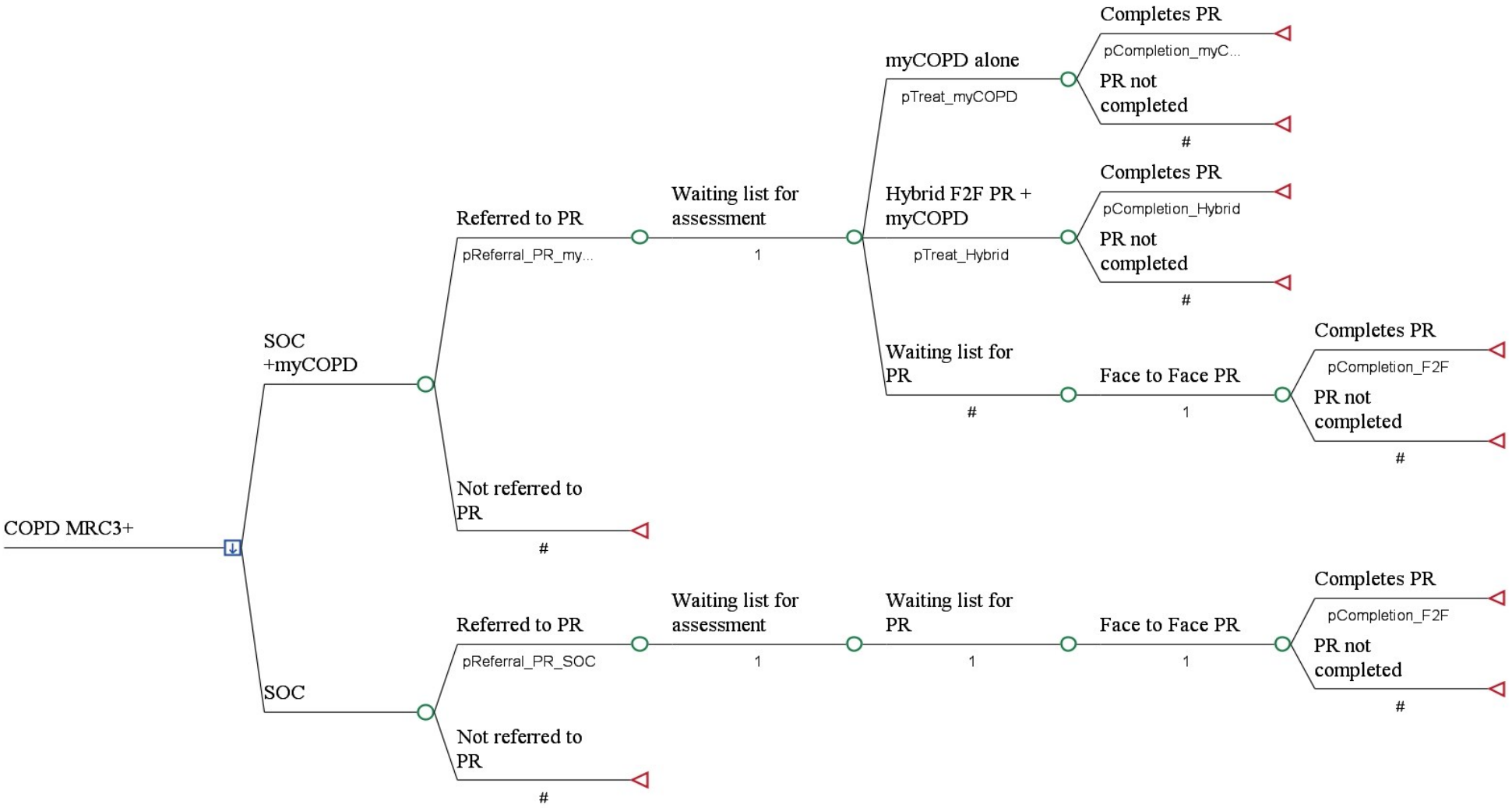
NA – no papers selected

Appendix B: Model structure

AECOPD Model



PR Model



Appendix C: Checklist of confidential information

Please see section 1 of the user guide for instructions on how to complete this section.

Does your submission of evidence contain any confidential information? (please check appropriate box):

No ☒ If no, please proceed to declaration (below)

Yes ☐ If yes, please complete the table below (insert or delete rows as necessary). Ensure that all relevant sections of your submission of evidence are clearly highlighted and underlined in your submission document, and match the information provided in the table. Please add the referenced confidential content (text, graphs, figures, illustrations, etc.) to which this applies.

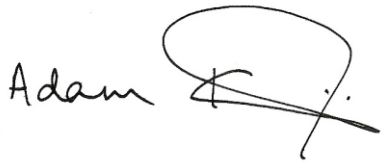
Page	Nature of confidential information	Rationale for confidential status	Timeframe of confidentiality restriction
#	☐ Commercial in confidence ☐ Academic in confidence	Enter text.	Enter text.
Details	Enter text.		
#	☐ Commercial in confidence ☐ Academic in confidence	Enter text.	Enter text.
Details	Enter text.		

Confidential information declaration

I confirm that:

- all relevant data pertinent to the development of medical technology guidance (MTG) has been disclosed to NICE
- all confidential sections in the submission have been marked correctly
- if I have attached any publication or other information in support of this notification, I have obtained the appropriate permission or paid the appropriate copyright fee to enable my organisation to share this publication or information with NICE.

Please note that NICE does not accept any responsibility for the disclosure of confidential information through publication of documentation on our website that has not been correctly marked. If a completed checklist is not included then NICE will consider all information contained in your submission of evidence as not confidential.

Signed*: ** Must be Medical Director or equivalent*		**Date:**	1st July 2021
Print:	Adam Kirk	**Role / organisation:**	Medical Director

Contact email: Click or tap here to enter text.

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Information request from the company for Medical Technologies guidance development

DHT001: myCOPD for self-management of chronic obstructive pulmonary disease

The scope was published in September 2019.
The company submitted a clinical evidence submission in October 2019.
A rapid MedTech briefing (MIB 214) was published in April 2020.
We are starting guidance development again following a pause in early 2020. The company are asked to provide any additional useful information for the guidance development.

Update to clinical submission

1. Decision problem

Please describe any proposed variation from the scope and the rationale for it.

	Scope issued by NICE	Variation from scope (if applicable)	Rationale for variation
Population	People with a diagnosis of COPD	Enter text.	Enter text.
Intervention	myCOPD as an add-on intervention to standard care	Enter text.	Enter text.
Comparator(s)	Standard care without myCOPD as an add-on intervention	Enter text.	Enter text.
Outcomes	-COPD symptoms assessment (COPD assessment test [CAT] score) -Rates of acute exacerbation -Rates of hospital admissions, readmissions or	Enter text.	Enter text.

	emergency admissions -Number of consultations with healthcare professionals in primary and secondary care -Rates of inhaler error -Compliance (adherence) to use of myCOPD including pulmonary rehabilitation (rate of course completion), education, inhaler techniques improvement and exercise. -Health-related quality of life -Patient activation measurement -Self-efficacy for appropriate medication use -Walking test (a 6-minute walking test) -Device-related adverse events		
Cost analysis	Costs will be considered from an NHS and personal social services perspective The time horizon for the cost analysis will be sufficiently long to reflect any differences in costs and consequences between the	Enter text.	Enter text.

	technologies being compared. Sensitivity analysis will be undertaken to address uncertainties in the model parameters, which will include scenarios in which different numbers and combinations of devices are needed.		
Subgroups to be considered	- Severity of COPD (Mild, moderate or severe COPD) - Time since COPD diagnosis	Enter text.	Enter text.
Functional classification and risk category	Self-Manage	Enter text.	Enter text.
Special considerations, including issues related to equality	No special considerations were submitted in the NICE scoping document	Enter text.	Enter text.

2. Technology

a. Has the technology changed since v1.7.12 (September 2019). If so please describe the changes:

b. Does the new model perform the same function and use the same mode of action as the technology in MIB 214?

c. Does the new model have a new CE mark?

d. Has the cost of the technology changed since the publication of MedTech Briefing? If so please give details

e. Is there any other information relevant to the questions in section 2 of the clinical submission which you would like to update or submit:

a. No changes in technology since September 2019

b. The platform retains the same intended purpose, function and mode of action as in the previous submission

c. Yes - With the change in regulatory requirements for medical devices switching from Medical Device Directives (MDD) to Medical Device Regulation (MDR), March 2020 (ext to Mar 21), my mhealth submitted documentation to classify as a CE marked, Class 1 medical device.

NB: Documentation is attached.

d. The cost of a myCOPD application license has not changed at £39.99

e. There is no other information relevant to question 2 being submitted regarding the technology (a) and its function (b), its classification (c) or its cost (d). There is a supplementary document evidencing use being provided.

3. Clinical context

Is there any additional or new information you want to add to section 3 of the submission?

We are providing richer data supporting the use of myCOPD

- Nationally, supporting the NHS acceptance, adoption and use of myCOPD
- Regionally, providing a greater insight into the local use of myCOPD and its outcomes
- Longitudinally, highlighting sustained use over 12 months and the detail of app content and functions accessed.

  Please see the evidence provided in this document, the attached supplementary document and the documents and poster provided as requested.

4. Evidence

Is the company aware of any new clinical evidence on the use of myCOPD, which has not been described in the clinical submission?

If new evidence is available, please give brief details, a reference for published evidence or a title and one line description for unpublished evidence – please

complete a form in appendix 1 for each piece of published or unpublished evidence**.**

List any additional evidence here:

1. The original data submitted as prepublication data from EARLY and RESCUE are now both published and are being submitted as peer-reviewed publicly available manuscripts.

EARLY - https://doi.org/10.1183/23120541.00460-2020

RESCUE - https://doi.org/10.1038/s41746-020-00347-7

2. Preprint Papers – **BigMedilytics Grant – Horizon 2020 (780495)**

Title - Retrospective development and evaluation of prognostic models for exacerbation event prediction in patients with Chronic Obstructive Pulmonary Disease using data self-reported to a digital health application

https://doi.org/10.1101/2020.11.30.20237727

3. Additional real-world evidence has been provided in the write up from Grampian and the poster both provided by Dr Kris Mclaughlin, GP at Stonehaven Medical Group.

Is the company aware of any adoption or usage data (such as audit) from the NHS or elsewhere? Please give details where possible.

Yes.

Reports have been submitted for

- Ipswich and East Suffolk - an example of the information and support provided by my mhealth to users
  (patients and HCPs)
  Document attached

- Southend - Report documenting the successful use of myCOPD to support a new hybrid model for PR delivery. CAT score improved most in the home-based interventions, more so when combined with myCOPD.
  Document attached

- Leeds – a digital article reporting the evaluation of the experience of using myCOPD in Leeds. Very positive impact on patients managing their condition. Further work being undertaken to assess the impact on the demand for healthcare services by patients with COPD using and not using myCOPD.
  Document attached

- Coventry – an evaluation of the app use during COVID-19 across several metrics. This produced mixed results with patients reporting positive outcomes but the teams feeling there was insufficient evidence
  to proceed with further investment.
  Document attached

- Grampian – Prospective evaluation of the use of myCOPD over 5 months. Positive results across CAT improvement, inhaler error reduction, reduced healthcare utilisation and patient feedback was reported – PLEASE see data below which applies to both Grampian write up and Stonehaven poster.
  Document attached

- Stonehaven (Poster) – A more in-depth review of the Grampian data.
  Poster Attached

Plus, national app usage data.

4. Ongoing use and data collection

Briefly describe any ongoing or planned data collection which is aimed at demonstrating the effectiveness of the technology. Provide details of the setting, the planned duration and the patients included. Provide details of any NHS partners involved in the data collection.

Ongoing work will take place with the Horizon 2020 BigMedilytics Grant (780495) looking at the type of contribution to big data myCOPD can make.

The project implements twelve pilot experiences that cover three themes with the greatest impact on the sector. Population Health & Chronic Disease Management and Oncology comprise the 78% of deaths within non-communicable diseases. The third theme represents operations and equipment cost, covering the 33% of the expenditure in the sector.

https://www.bigmedilytics.eu/

The company has developed a real time database and user interface which enables prospective review of aggregated, anonymised data on app registration, app access and clinical outcomes. A number of regional projects are working on integrating these data at a CCG or ICS level into eHRS to enable services and commissioners to access and use the data for clinical service delivery.

One such example is Dorset CCG. Crystal Dennis leads that project (details provided as an external, NHS expert.

5. Adverse events

Describe any adverse events and outcomes associated with the technology in recorded in national regulatory databases or clinical and data usage evidence.

There continue to be NO reported adverse events.

6. Evidence synthesis and meta-analysis

Describe any new or revised qualitative or quantitative evidence synthesis in addition to the information presented in section 8 of the clinical submission.

No new synthesis submitted.

7. Summary and interpretation of clinical evidence

Add any further information to that provided in section 9 of the submission concerning the clinical benefits, any risks relating to adverse events from the technology and the relevance of the evidence base to the decision problem.

The additional material provided further reinforces the benefit of the provision of a digital resource to support a traditionally face-to-face intervention plan for the effective management and self-management of COPD. The new data extends the value case for established disease to patients across the entire COPD pathway from diagnosis right through to severe disease and hospitalisation.

Our real-world usage evidence demonstrate that not only is digitally delivered PR now widely accepted and adopted but education, self-management and symptom tracking is now also undertaken widely across the NHS, providing healthcare professionals with a rich additional dataset to more comprehensively understand the needs of their patients.

8. Outline of economic evidence

Provide an update to any of the information in section 10 of the clinical submission.

There is currently no additional economic evidence.

9. Additional information

Expert Adviser suggestions: NICE may contact relevant experts and ask them to complete a questionnaire on the technology. Experts should work in publicly-funded UK health and social care services (for example, the NHS), and ideally have experience of using the technology in this setting. Experts working outside of publicly-funded UK health and social care services are not usually eligible. You may suggest up to 3 experts for NICE to contact.

Crystal.Dennis[redacted] – Design and Transformation Lead

k.mclaughlin[redacted] – Kris Mclaughlin, Dr; GP Stonehaven Medical Practice

Any other relevant information supporting the use of the technology.

The mymhealth platform is now being implemented internationally based on the strength of evidence and real-world use data largely driven by myCOPD in the UK.

Thank you for providing this additional information

Appendix 1 new evidence

Study details	Design	Intervention	Population	Follow-up	Outcomes (including primary and secondary)	Results
Published studies						
Evidence GenerAtion for the Clinical Efficacy and Cost Effectiveness of myCOPD in patients with mild, moderate and newly diagnosed COPD **The EARLY COPD Study** REC No 18/SS/0112 IRAS ID 24921 NCT03620630 https://doi.org/10.1183/23120541.00460-2020 ERJ Open Res 2020; 6: 00460-2020	Randomised Controlled Evidence generation study	myCOPD	Newly diagnosed COPD patients, Patients with mild and moderate COPD	EARLY was a 12-week RCT	Co-primary outcomes looking at improvements in CAT scores and critical inhaler errors. Key secondary outcomes were PAMs and app usage.	Results showed statistically significant benefit in the myCOPD group to fewer critical inhaler technique errors, but there was no significant adjusted mean difference in CAT score at study completion, −1.27 (95% CI −4.47–1.92, p=0.44) lower in myCOPD. However, an increase in app use was associated with greater CAT score improvement. For PAMs, the adjusted odds ratio for being in a higher PAM level at 90 days was 1.65 (95% CI 0.46–5.85) in favour of myCOPD.

A Randomised controlled trial of E-health platform Supported Care vs Usual care after Exacerbation of COPD: **The RESCUE trial** Authors: Mal North, Simon Bourne, Ben Green, Anoop Chauhan, Tom Brown Jonathan Winter Matt Johnson, David Culliford, Jack Elkes, Victoria Cornelius Tom Wilkinson NCT02706600 npj Digital Medicine (2020) 3:145 ; https://doi.org/10.1038/s41746-020-00347-7	RCT Feasibility study	myCOPD	Patient with a COPD diagnosis admitted with an exacerbation of COPD into secondary care.	RESCUE was a 90-day RCT	Primary outcome measurement COPD Assessment Test Secondary outcome Inhaler technique Patient Activation Measurement (PAM) St Georges Respiratory Questionnaire (SGRQ) Hospital Anxiety and depression Score (HAD) Vetrans Specific Activity Questionnaire (VSAQ) Work and Productivity Activity Impairment (WPAI) Safety – Incident of adverse events Average app usage	Results Improvement in CAT score -4.8 in favour of digitally enhanced care. Exacerbations were less frequent as were re admissions rates in the digital arm. Inhaler technique improved in the digital arm from 101 to 20 compared to the usual care arm of 100 to 72. P.0.021. There were no significant improvements in HAD, PAM, SGRQ, WPAI,VSAQ between arms. Average app usage 5 times per week over 3-month period.
Unpublished studies						
Retrospective development and evaluation of prognostic models for exacerbation event prediction in patients with Chronic Obstructive Pulmonary	Retrospective study evaluating entered symptoms to understand to what degree different variable are predictive of whether the patient will go on to report an	Heuristic and machine-learnt models were applied to entered symptom data.	2,374 patients with COPD entered 68,139 self-reported symptoms	Further studies would support greater accuracy of these models through more granular data being entered or including variables not considered in this study – vital signs, environmental	Data self-reported by patients through myCOPD can be used to predict acute exacerbations with moderate performance. Potential to triage and intervene earlier, thereby	Baseline model - AUROC 0.655(95% CI: 0.689-0.676). Machine learnt model – AUROC 0.727 (95% CI: 0.720-0.735).

Disease using data self-reported to a digital health application https://doi.org/10.1101/2020.11.30.20237727	exacerbation in the next three days.			data, activity or lifestyle information.	reducing patient ill-health and reducing the healthcare demand of these patients.	Baseline sensitivity 0.551 (95% CI: 0.508-0.596) and specificity 0.759 (95% CI: 0.752-0.767) and were fixed. Machine learnt can be tuned by dichotomising the continuous predictions it provides with different thresholds.

REAL-WORLD EVIDENCE

Supplementary Data taken from the Grampian write-up and the Stonehaven Poster provided by Dr Kris Mclaughlin.

Patients followed for 5 months and pre- and post-intervention assessments were made. Data provided below.

Improvement Measure	**Preliminary findings/results**
Improvement in symptom scores FEV1, MRC, CAT	FEV1 –net improvement of 1% MRC –net fall of 0.3 = improvement CAT –net fall of 2.1 = improvement
Reduction in number of prescribed reliever inhalers	Net reduction from 3.17 to 2.13
Improvement in inhaler technique	Good technique rose from 48% to 91% of patients

ClinicalParameter	Pre-myCOPDaverage(range)	Post-myCOPDaverage(range)	MaximumNegative	MaximumBenefit
COPDAssessmentTest(CATscore)	12.8 (1–28)	10.7 (2-23)	+8(increasefrom4to12) 8 patients saw worsening by 2 or more	-17 (fall from 24 to 7) 9 patients saw improvement of 2 or more
ShortActingBetaAgonistprescriptions	3.17 (0–11)	2.13 (0–9)	+3(increasefrom1-4)	6 less inhalers ordered post myCOPD (from 7 to 1)
FEV1	61% (32-92%)	62% (36-100%)	-20% (fall from 68% to 48%) 11 improved 8 improved >100ml 7 improved >5%	16% improvement (78% to 94%) 12worsened 7decreased>100ml 4decreased>5%
MRCscore	2.4	2.1	Decline from Grade 2 to 3 Only 1 patient recorded a decline	Improvement from Grade 5 to 3 6 patients improved their grade

Improvement Measure	Pre and post myCOPD
How well do you think you think you cope with or manage an exacerbation or flare up of your COPD	Increase from 29% to 55% those reporting Very well
How confident are you in using your inhaler correctly	Increase from 76% to 90% those reporting Extremely or Very confident
Overall, how confident do you feel about looking after your COPD	Increase from 55% to 67% those feeling Extremely or very confident
To what extent do you feel your COPD affects your ability to work, volunteer or engaged in activities you want to do	Reduction from 21% to 0% those feeling it has a Major impact

As an assessment of healthcare demand changes influenced by myCOPD, pre- and post-intervention interactions with GPs and unscheduled care were reported (data as follows).

GP practice appointments	**Count of 105 pre myCOPD, 85 post myCOPD**
Acute unscheduled admissions	**Count of 8 pre myCOPD, 0 post myCOPD**

Updated checklist of confidential information

As stated there it is the company's responsibility to highlight any commercial- or academic-in-confidence data clearly and correctly:

information that is commercial in confidence should be underlined and highlighted in blue

information that is academic in confidence should be underlined and highlighted in yellow.

- Does any additional information contain any confidential information? (please check appropriate box):
  - **No** ☐
  - **Yes** ☒

Additional information	Confidentiality	Comments
'NICE Adoption Process - Supplementary Supporting Document 20210117	unpublished	CONFIDENTIAL (commercial in confidence)
Coventry Community PR Service - Project report - Report on the use of the mHealth myCOPD platform	unpublished	CONFIDENTIAL (commercial in confidence)
Ipswich and East Suffolk Staff survey evaluation	unpublished	CONFIDENTIAL (commercial in confidence)
Kent CHFT evaluation	unpublished	CONFIDENTIAL (commercial in confidence)
NHS West Lothian project evaluation	unpublished	CONFIDENTIAL (commercial in confidence)

NICE National Institute for Health and Care Excellence

Digital health technology (DHT): Collated expert questionnaires

Technology name & indication: myCOPD for self-management of chronic obstructive pulmonary disease (COPD)

Experts & declarations of interest (DOI)

Expert #1	Beth Sage, Consultant Respiratory Physician, NHS Highland, [redacted]
	DOI: NONE
Expert #2	Nawar Bakerly, Visiting Professor, Manchester Metropolitan University and Consultant Respiratory Physician and CCIO Salford Integrated Care Organisation, Salford Royal NHS Foundation Trust, [redacted]
	DOI: NONE
Expert #3	Lisa ward, Lead Respiratory Nurse, Southend Hospital, [redacted]
	DOI: NONE
Expert #4	Professor Tom Wilkinson, Professor of Respiratory Medicine, University of Southampton, CSO mymhealth, [redacted]
	DOI: *YES - Co-Founder, Director and shareholder of mymhealth Ltd- Financial (developer and Supplier of mymhealth apps including myCOPD) (November 2011 – active); COPD Specialist Advisory Group to British Thoracic Society (December 2017 – Current)*
Expert #5	Jenny Gates, Clinical Manager Inpatient Rehabilitation, Southend University Hospital NHS Foundation Trust. [redacted]
	DOI: NONE
Expert #6	Crystal Dennis, Digital Health Lead, Dorset clinical commissioning group
	DOI: Consultancy fee received from the company producing the product as part of implementation within Dorset.
	The expert provided a written commentary (see appendix 1)

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1. **Please describe your level of experience with the technology, for example: Are you familiar with the technology? Have you used it? Have you used it? If so please give details, for example describe setting, length of time and version if applicable, Are you currently using it? Have you been involved in any research or development on this technology?**

Expert #1	We have tested the use of my COPD in a remote and rural COPD population to see if there is evidence of significant benefit within our patient population to justify NHS Highland offering it as a routine intervention for our COPD patients.
Expert #2	I am aware of MYCOPD app, and have previously evaluated this for local use within Salford through user testing. I do not currently use MyCOPD considering that we have made a decision not to proceed with using it. I have not been involved in research or an evaluation of this technology
Expert #3	YES I HAVE USED IT FOR A COUPLE OF YEARS WITHIN MY copd TEAM OF CNS's and physios and in chest OPD clinics am not involved directly in research with this tech
Expert #4	I am very familiar with the technology as I have been involved in the development of the myCOPD app, helped generate the evidence base behind its use and have led implementation projects in the NHS to develop app supported models of care. I actively use the platform in my NHS practice with COPD patients, carers and services.
Expert #5	I am familiar with myCOPD and have been using it within our Pulmonary Rehabilitation service for around 12 months. We are currently using the technology to support patients once they have completed Pulmonary Rehabilitation and to support those who are unable to attend Pulmonary Rehabilitation to commence an exercise programme

2. **Are there any issues with the usability or practical aspects of the using technology?**

Expert #1	Not to my knowledge
Expert #2	Not to my knowledge

Expert #3	I think patients need to be assisted to register. Many patients give their e mail and are interested in it but fail t log on…this could be done I the home or community setting by a COPD specialist wo talks them through it.inpt settings are not ideal but we try also OPD is hectic so we cant always spend time
Expert #4	The app has been co-developed with patient users and is widely accessible to the great majority of patients. It is fully operable on any connected device including smart phones and TVs but would not be usable to a patient without internet access. The app operating language is currently only in English however plans to translate content in 2021 are in place. The platform is being integrated into primary care eHRs in 2021.
Expert #5	There are sometimes issues with the patients setting passwords during their initial sign on. We have been working with my mhealth to address this.

3. Are you aware of any safety concerns or regulatory issues surrounding this technology?

Expert #1	There are other self management apps available but to my knowledge is the most comprehensive one
Expert #2	Not to my knowledge
Expert #3	no
Expert #4	There are no safety concerns about its use and it has been rigorously tested in trials. It s CE marked and has MHRA and NHS approvals.
Expert #5	No

Potential benefits

4. Does this technology have the potential to improve clinical outcomes? Could it lead, for example, to better monitoring of conditions or better adherence to treatment?

Expert #1	I am not experienced in using other tools but I believe there are others available
Expert #2	The technology does not offer a monitoring function. The issue of adherence if very debatable with this technology. I suppose it does have the potential to improve self-management education; however, I am yet to see the evidence to support this
Expert #3	i believe it does inhaler techniques are clear on video for patent and families t see together updating medication is great whilst in clinic self management and autonomy are preserved for patients self awareness of how their disease is managed patents more really simple to use up to date interactive information in clear simple bright optimistic visuals assist those with cognitive impairment involves families as well as the person
Expert #4	The technology has significant potential to drive better clinical outcomes in COPD, indeed it is currently being widely used in the NHS and is a cornerstone to service delivery. Fundamentally it supports patients to self-manage more effectively- it offers training on inhaler technique, breathing control and a pulmonary rehabilitation course all of which are known to improve outcomes in the condition. . The platform can capture important clinical events such as exacerbations and help provide a rich source of data to better inform clinical decision making at reviews. During the COVID-19 pandemic the app has been more widely used again and many services are using it as the main way of supporting patients with COPD through remotely supported care. It is now one of the largest platforms for delivery of pulmonary rehabilitation in the UK
Expert #5	I feel that this technology has the potential to improve the maintenance of outcomes achieved after attending a Pulmonary Rehabilitation programme.

5. What do you consider to be the potential benefits to patients from using this technology? Are there any patient or carer benefits which are not likely to be captured in the clinical evidence?

Expert #1	Improving patient understanding of the disease and to facilitate self management
Expert #2	Supports self-management education, and the delivery of useful information.
Expert #3	AS ABOVE
Expert #4	The potential benefits are to improve patient knowledge and activation, improved use of medication and improved functional status through exercise.These outcomes are evidence based and real world experience is underlining the benefits to the patient –

	inhaler technique, adherence to medication, self-management skills, reduction in symptoms and improved disease control. In addition to patient level benefits services are reporting additional value from remote working and capacity building.
Expert #5	Having completed a pulmonary rehabilitation programme patients can continue to exercise at home using the exercise component of the app. They can review education sessions delivered during Rehab by reading the relevant information at any time. Relatives and carers will alos benefit from reading the up to date information contained in the app and, therefore, support and encourage the patient.

6. What do you consider to be the potential benefits to the health or social care system from using this technology?

Expert #1	Those who are more likely to engage with self management.
Expert #2	The improvement in self-management education could potentially lead to better independence and the reduction in reliance on healthcare
Expert #3	Reducing time spent educating patients repeatedly as cognition is poor in this groupvitual monitoring self assessment of symptoms allows staff to contact patients who flare up. Patterns can be detected in flare up behaviour
Expert #4	Better self-management will reduce the burden of care on the NHS for patients with COPD. A reduction in exacerbation frequency and severity as evidenced in recent studies will particularly impact on the provision of unscheduled care including hospitalisation. The system can help clinical services work more effectively and to expand capacity by prioritising care to those patients identified by the app as poorly controlled or exacerbating or by offering digital support to pulmonary rehab services
Expert #5	This technology has the potential to support patients with the self-management of their COPD. If self-management can be improved, potentially patients will remain well and be less dependent on health or social care services

7. Do you consider there to be any benefits from using the technology to support the creation of an environmentally sustainable health and care service?

Expert #1	Not in my experience

Expert #2	No
Expert #3	This is a superb adjunct to face to face interventions particularly around pul rehab and self management and recognising flare ups
Expert #4	Definitely - patients using the platform can receive help and support in their own home and not need to travel to service centres. Improved adherence to medication through better technique and adherence reduces medication wastage.
Expert #5	No

Training for use of the technology

8. Is there any training needed to use the technology, for example, Are healthcare professionals trained in its use? what does this involve? Are patients trained in its use? what does this involve?

Expert #1	It has the potential to reduce hospital admissions in patients who use it regularly
Expert #2	Yes, although this is expected to be simple and brief
Expert #3	This is simple for patients to navigate it could be improved if it was an app rather than logging in? Staff need initial training and then very easy
Expert #4	The platform is intuitive to use for patients and clinicians. Training required for both parties is minimal and the platform contains training videos to inform users. A 2-minute introduction to the platform and how to register by email is all that is needed. Recent improvements in this on boarding process even further have streamlined this following user feedback. The training on digital is less about the use of technology but more about how digital tools per se can augment services and improve clinical care. Some practitioners run with this from day one and have delivered very impressive outcomes- doubling service capacity for example, others are less certain and so outcomes can vary depending on the clinicians using the system.
Expert #5	Healthcare professional require brief training to introduce them to the components of the app and how to sign a patient up. There is no specific need for a patient to be trained, only introduced and signed up

9. Do you think there is a learning curve associated with the use of the technology? If so please describe it for example from whose perspective and typical duration

Expert #1	Less than a hospital stay
Expert #2	Probably, although I expect this to be fairly steep and quick
Expert #3	2 hours to
Expert #4	Yes – use of the system is straightforward but for some patients and clinicians to become confident in using all facets of the system can take a few weeks. He company has created a range on online training materials to support services to optimise use and value.
Expert #5	No

10. Does training cover patient selection?

Expert #1	It could enable patients to self manage within the community and shift care from secondary to primary.
Expert #2	I am not sure
Expert #3	Not at present specifically enough
Expert #4	myCOPD is suitable for all patients with a clinical diagnosis of COPD. Simple questions around internet availability can help but no formal training on selection is needed.
Expert #5	Clinicians are guided on patient selection but no training is required

Incorporating the technology into current NHS management

11. How innovative is this technology, compared to the current standard of care? Is it a minor variation or a novel concept/design?

Expert #1	no
Expert #2	Minor variation. There are many apps in the market that deliver similar functionality. The main issue with most is retention and repeated users, and if this is translated into clinically relevant outcomes
Expert #3	It is an enormous innovation and has made a huge impact from a professional's point of view…
Expert #4	The pathways of care for the management of COPD have varied little in recent years, the outcomes for the condition eg hospitalisation rates and readmission rates are deteriorating in most regions in the NHS. This technology offers a step change in managing the condition – firstly it supports patients to self-manage much more effectively than the current model of spoken or written advice by providing accessible, video driven content that is specific to the patient themselves. It provides access to services and information for all patients everywhere who can use the platform thus standardising access to interventions such as pulmonary rehab which currently <10% of patients can access. Finally it provides a rich ecosystem of patient generated data that can help patients themselves, clinicians and services make more informed decisions around treatment. The use of these data to step up or down treatment, target limited resources at patients in active need and to move from reactive to proactive care models will be transformational. In 2020 with COVID-19 the platform has become the mainstay of care for many NHS patients and services. Face to face appointments to train in inhaler technique or deliver PR are no longer safe or feasible and hence the platform has been adopted as a key strategy to maintain clinical standards.
Expert #5	Currently patient information is often given in paper form with advice to review the BLF website. This technology provides all necessary education related to COPD in one easily accessible place. As this information is digital it can be updated as required and does not become out of date as paper leaflets can

12. What patient group is the technology suited to? Are there any specific patient selection criteria or should all patients be offered the technology? Approximately how many patients each year would be expected to use the technology, either as an estimated number, or a proportion of the target population?

Expert #1	no

Expert #2	The technology has been targeting severe patients. Until robust evidence is generated, I think there should be a targeted approach (ie. severe patients), as the cost of offering this to wide selection of patients may prove very expensive!
Expert #3	It can be used for anyone with access to IPAD/COMPUTER/SMART PHONE OR LAPTOP It can used by families so is not limited to the patients only. We offer it to anyone who can find access to a device or if family/friend has access and is willing to share the email to support them foresee this being use for all COPD patients as early as possible particularly GOLD B+C and for these needing breathless ness management and in support of P Rehab
Expert #4	All COPD patients with COPD who have a working knowledge of English and can use an internet connected device. I would estimate this to be 85% of COPD patients. Looking at current uptake of myCOPD across 100 CCGs in the UK- 43% of patients with COPD who are given access to the app- go on to use the platform. Nationally around 1.2 million people have a COPD diagnosis suggesting 1m potential beneficiaries of the technology with 430,000 likely active users. The median age of active users is 67 year with a significant population of user in their 70, and 80s.
Expert #5	Patients with COPD who have access to the internet and a suitable device.

13. What is the position of the technology in the care pathway? Would this technology replace or be an addition to the current standard of care?

Expert #1	In our experience there are a small subgroup of users who engage well and in this population it could be beneficial however this does not apply on a whole population basis and I suspect reflects the willingness of a patient to engage with self management rather than being specific to the app.
Expert #2	Currently it is not positioned in the care pathway
Expert #3	We have it as mandatory as part of COPD bundle to offer patients this to aid self management
Expert #4	The myCOPD platform can be used by patients at any stage in their disease trajectory from diagnosis through to very severe disease. All patients who are on inhled medication should have inhaler technique training and support that the platform can provide. All patients suitable for pulmonary rehab could benefit also. In primary and secondary care and can replace written paper self-management plans.

Expert #5	This is an addition to a current standard of care. It enhances the information delivered on Pulmonary Rehabilitation programmes and supports patients to maintain any improvements gain if they are motivated to use it.

14. Does this technology have the potential to change the current pathway? Would care take place in a different setting or with different healthcare professionals?

Expert #1	Difficult to know
Expert #2	Not really; and certainly not without evidence (clinical outcomes, and/or health economy outcomes)
Expert #3	Less contact with professionals and also support patient before and after P Rehab, perhaps less face to face PDs which are focussed on education of COPD
Expert #4	Yes – the technology can support the patient to self-manage and may remove the need for emergency or unscheduled care visits. In the context of pulmonary rehabilitation it can support the patient to rehab at home or in a blended model with some home and some class based sessions. Use of the clinician dashboard can enable service to prioritise care to those patients who require support at the time rather than offering routine follow up to stable patients and therefore creates a new patient centric pathway of care.
Expert #5	The current pathway for Pulmonary Rehab would remain unchanged, however, the technology has the potential to enhance the outcomes of PR and support maintenance of improvements.

15. Would changes be needed to facilities or infrastructure in order to use the technology? Are there significant capital costs associated with introducing the technology?

Expert #1	Addition to standard of care
Expert #2	No major changes required. There are significant costs associated with the price of the technology
Expert #3	The costs I believe are with the licences. The savings would be with reducing the patient contacts with staff which could be more efficient way of working No significant capital costs

Expert #4	The technology will work on any internet enabled device and as a cloud based system requires no special set up beyond NHS systems current spec. No capital costs are incurred. To reduce accessibility issues – certain regions have provided technology access for hardware see Leeds Digital projects as exemplars
Expert #5	No. The only cost would be that of the licenses.

16. Considering the care pathway as a whole, including costs and possible future costs avoided, is the technology likely to cost more or less than current standard care, or about the same?

Expert #1	Many patients found it difficult to activate and had issues with technical aspects of the app. It relies on patients having a smart phone or good access to internet
Expert #2	This is currently unknown due to lack of evidence on health care utilisation and cost efficiency.
Expert #3	No more and perhaps less
Expert #4	The costs of apps on a per patient basis are very low compared to the current costs of care including provision of medication, routine and unscheduled care plus hospital admission and pulmonary rehab services. Clinical trials data and real world evidence from app usage both demonstrate significant cost savings from myCOPD use through improved clinical outcomes and capacity build to extend PR services. The platform access of £40 compares to conventional PR delivery costs of over £6000 per patient sand could therefore deliver cost savings and capcity building. Inhaled therapies cost over £40 per month and with current technique and adherence issues over 50% of these costs are wasted the app addresses these issues.The Topol review highlighted the potential for the platform to generate considerable savings by reducing hospitalisations.
Expert #5	The only cost incurred is for the licences per patient. There is possible potential cost saving if healthcare utilisation care be shown to decrease as a direct result of the technology.

17. Is the technology likely to be able to reduce health inequalities in the NHS or improve access to care among hard-to-reach populations?

Expert #1	High speed internet access
Expert #2	Possibly, considering that it may improve self-management education in hard to reach groups. However, to use the technology, patients should have access to the internet!
Expert #3	I believe it will as I find most pts have access to the internet and it is easy for all to understand. It would probably reduce inequalities and improve access to information for patients
Expert #4	The technology can help standardise the level of support and care patients receive independent of geography. Currently many patient have little or no access to pulmonary rehab, no access to training in inhaler technique and often have to wait weeks to see their GP or practice nurse for advice and support. The myCOPD app can improve this situation for patients who can use the internet and the app.
Expert #5	No. The technology can only be accessed by those with COPD who have access to the internet and an appropriate devise.

Current use of the technology

18. Do you know how widely used this technology is in the NHS?

Expert #1	no
Expert #2	No
Expert #3	Not widely at present but across our STP
Expert #4	Currently around 20 000 myCOPD licenses have been distributed across the NHS with around 1500 new ones being distributed each month with a rapidly increasing pattern of distribution and use as CCGs and services develop awareness of the app and understand how to use it with patients. Over 50 % of CCGs in England have signed up to use the app and potentially over 50% of the COPD population could access depending on funding. The platform has delivered over 50 000 PR sessions in 2020
Expert #5	Progressively being rolled out across the country over the last 2 years.

19. Are you aware of any issues which may prevent (or have prevented) this technology being adopted in your organisation or across the wider NHS?

Expert #1	We are in the process of writing a manuscript for publication on our local experience.
Expert #2	Lack of evidence.
Expert #3	This is early and has been a pilot. The main resistance probably would be educating staff on how to engage patients and arrange the setting up for patients
Expert #4	Uptake was initially slow due to a lack of expertise in CCGs in dealing with the new GDPR regulations, compounded by a slow contracting process for funding under the ITT. These issues are now resolved, assisted by improvements in log in , addition of on line training modules and the move to digitally enhanced care in 2020.
Expert #5	No

20. Are you aware of evidence and/or any national registers collecting data on this technology? Are you aware of any ongoing research or locally collected data (e.g. audit) on this technology?

Expert #1	There is not sufficient evidence to recommend its widescale use. There needs to be further data particularly on long term engagement with the tool and the psychology around self management. I suspect those that engage with this tool would do so with other self management tools too so not clear it is specific to this app.
Expert #2	None
Expert #3	Now we are going to evaluate this locally soon
Expert #4	Most CCGs are capturing data and feedback on myCOPD use and patient experience. The ones I am aware of have been positive with over 80% of patients expressing good usability and value form the app. My mhealth has an active programme of real world evidence generation monitoring patterns of use, outcomes and patient behaviours- these will be published regularly

Expert #5	No

General advice

21. Please add any further comments on your particular experiences or knowledge of the technology, or experiences within your organisation.

Expert #1	N/A
Expert #2	No
Expert #3	I believe the NHS should incorporate this as standard in the cost of managing pts …It should be part of the mandatory treatment for patients and be given early on in disease management from the community and perhaps in GP practice to ensure patients manage their disease effectively It is current, easy to use, patients improve their medication management and it promotes self management. It also notifies staff when patients are not so well or having flare ups.. It should be an APP rather than log in…much like banking??
Expert #4	The myCOPD app evolved from 20 years of award winning research and clinical innovation working to develop new and improved models of care for patients with a life–shortening and often disabling condition. The app has been developed by and with patients and addresses their expressed needs for high quality information and guidance to support them to manage their disease effectively. There have been very few new treatments for COPD in recent decades with those recently endorsed by NICE – e.g. lung volume reduction coils cost thousands of pounds per patient and are available to few, so this context is very important as hospitalisations and outcomes for COPD continue to deteriorate across the NHS. The app roll out nationally has generated an array of personal stories of transformation of health and hope and beyond this clear and reproducible signals of clinical impact across the NHS. The proven health economic case for myCOPD in favour of its widespread use is apparent and consequently many countries outside the UK are now exploring access and routes to internationalisation based on this. I would be happy to provide any additional evidence or experience to the NICE committee if that would be useful in the appraisal. 2020 has seen a transformation of clinical pathways due to COVID-19 – NICE endorsement of this widely used platform will enable services to scale nationally and encourage access to key skills and services for COPD patients which are not uniformly available without the technology
Expert #5	I am aware of the other uses of the technology in terms of caseload management and monitoring but I am not familiar with these aspects as a part of our service.

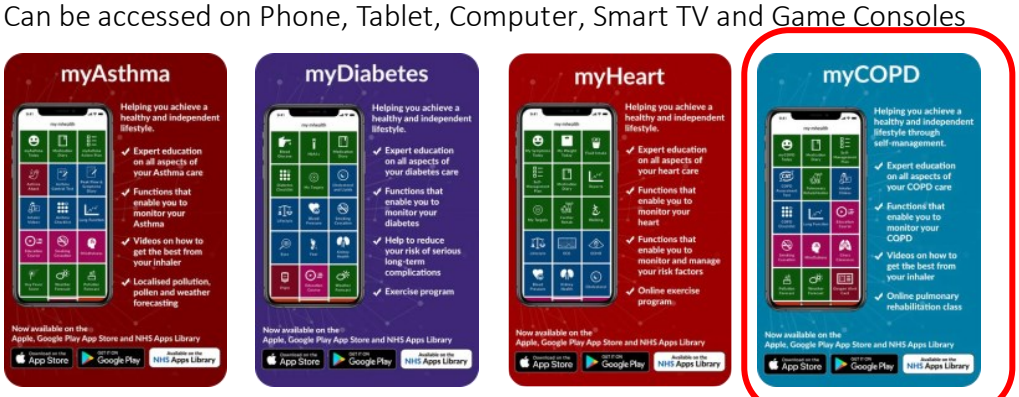
Appendix 1

myCOPD for self-management of chronic obstructive pulmonary disease (COPD)

myCOPD for self-management of chronic obstructive pulmonary disease (COPD) – Dorset CCG feedback (Crystal Dennis, Digital Health Lead, Dorset clinical commission group)

Functions and features...

Can be accessed on Phone, Tablet, Computer, Smart TV and Game Consoles



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Awareness – Accessibility – Trust - Coordination

Section One focus: Summary of impact

1 Summary

1. The NHS Dorset clinical commission group (CCG) commissioned a successful project making myCOPD available to people with COPD in specific groups from December 2020.

2. Data has proven 65% of people offered myCOPD activated their account. Therefore, this is a tool that patients see the value to using as part of their long-term condition management when prescribed by a clinical team.

3. The CCG has received good feedback from clinicians, patients and the respiratory teams who manage people with COPD in the community. (See 3.6 page 9)

4. The initial value proposition has data evidence to confirm this sits highly within:

   - A digital first approach to pulmonary rehab

- Education and advice/guidance e.g., lung function and inhaler technique
- COPD symptom scores
- Medication notifications

5. myCOPD supported improved access to services in areas of deprivation.

6. Through the Dorset Intelligence and Insight Service (DiiS) clinical dashboard, patients received personalised care and a support plan.

7. Using the DiiS clinical dashboard, capturing patient contributed data, supported decision making at the point of care as part of virtual case load management.

8. Clinical and data insight shows that 30% of those using the tool, alongside endorsement of their clinical teams, with 30% of the activated patients have registered their CAT score (at least twice) with 39.27% showing improvements (-5 or above) – a value that is clinically significant and represents a huge improvement for the patient (in terms of symptoms and quality of life admissions, readmissions and use of prescriptions).

Section two focus: Change management and adoption insights

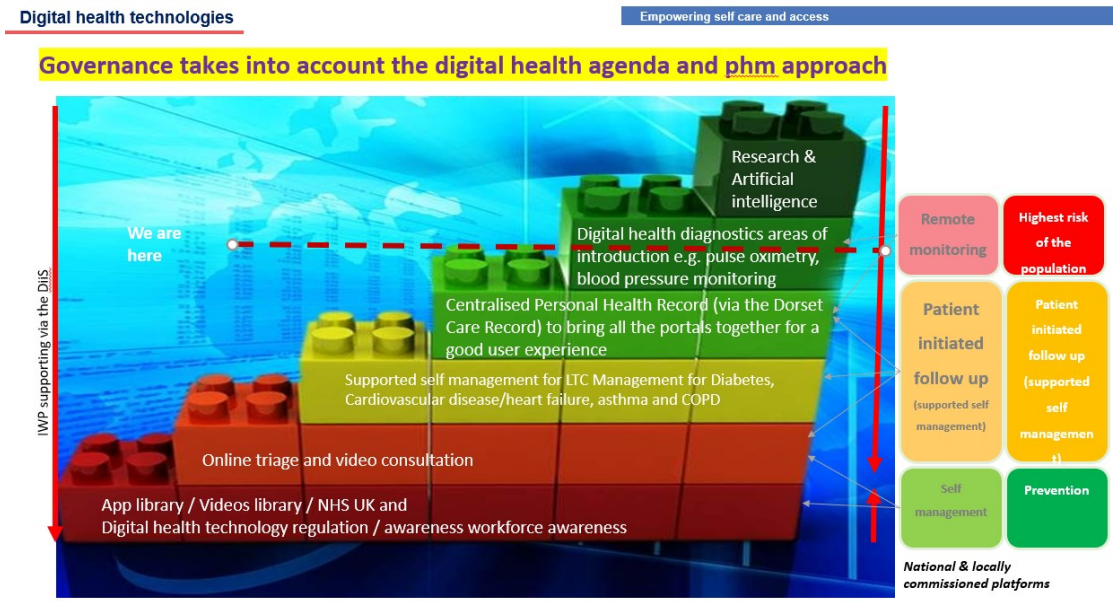
2. Deployment insights

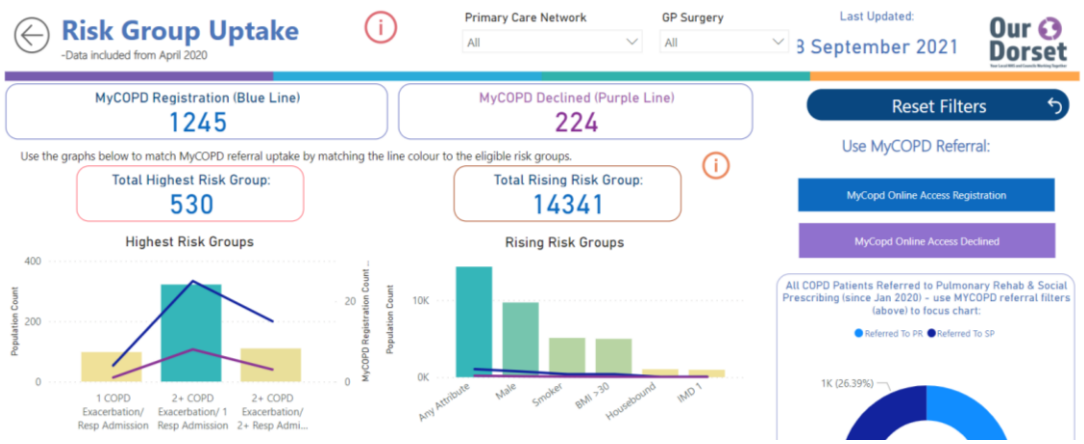
1. <u>Population segmentation in the offer of myCOPD to meet clinical need first</u>

The CCG carried out a population-based Health insight study across the region and based on that decided to use a risk stratification approach to offer myCOPD to 2 population groups:

- High-risk group: people who have a confirmed diagnosis of COPD and have had either
  - 1 hospital admission and 1 acute exacerbation in the last 12 months or
  - 2 hospital admissions and 2 acute exacerbations in the past

- Rising-risk group: people who have a confirmed diagnosis of COPD and have at least 1 other risk factor (male gender, smoker, BMI (30+), housebound) that trigger worsening symptoms or acute exacerbations of COPD.





People in the Rising risk group engaged better with the app compared with those in the high-risk group. This is partly because of the number of people in this risk group is larger (over 13,000 vs 530) in the CCG.

3. Uptake and implementation

1. the offer process is shown below:

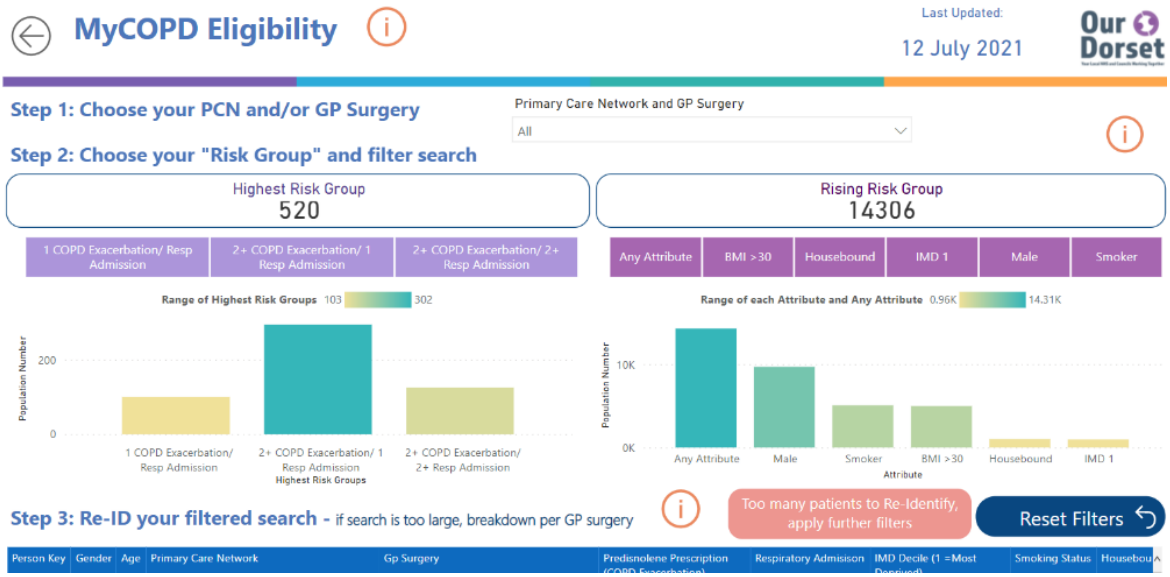
- Patients are identified as clinically in need using a population health approach
- They are offered self-registration or acceptance to offer through an SMS campaign.
- On acceptance there is an initial conversation with individuals and a digital health adviser or care-co-ordinator to provide support in registering and activation of the technology as well as how it will be used by the clinical teams.
- The initial conversation leaves the patient with some activities to get them started e.g., review of inhaler technique, medication completion and symptom tracking.
- Follow-up support is provided at different time points to improve patients' engagement. This can be done via a nudge, text messaging or face-to-face appointments, or over the phone.

We have initiated a new role of digital care coordinator within Primary Care Networks to help implementation and adoption of digital health technologies in general and improve trust and digital literacy in the CCG population.

The technology is available to all practices across the CCG. However, the update rates across different practices varies. The more "mature" GP practices (with staff capacity) tend to have higher uptake rates.

2. How many of our 17000 COPD patients were offered MyCOPD?

- We took the population targeted approach to the offer starting with the highest risk of the population.
- During the months of Dec – Jan we offered to the (as then) highest risk of the population
- And have since been focusing on the rising risk of the population, leaving the cohort choice to the primary care nurse PCN e.g. COPD and BMI30+ or COPD and Housebound etc.



3. How many accepted a licence?

- Since 2017 2074 licences have been Issued in total for myCOPD
- Since Dec 2020-present of the reidentified phm lists and SMS campaigns 1436 response have been received and responded to the offer

  of those were under the relaunch with a population heath targeted approach

- 1436 have accepted the offer
  - Of those that accepted the last recording of their BMI in primary care record = 27.3% obese and 32.5% overweight with 4.38% being morbidly overweight.
  - Of those that accepted 31.46% were smokers
  - Profile on demographics is shown below with a higher uptake in the male population to the female and within the 65-74yrs age range.
- 219 have declined the offer
  - Of those decline responses this was equally split between patients not being able to, have difficulty in performing digital technology activities, AND those who chose not to perform digital technology activities

We have been working on the registration and activation process of this with patients in order to start developing the habits straight away as opposed to offer and no follow up. The use of this with pulmonary rehab has been clearly a good driver for adoption. Data quality from secondary care continues to be a struggle for us to join the dots.

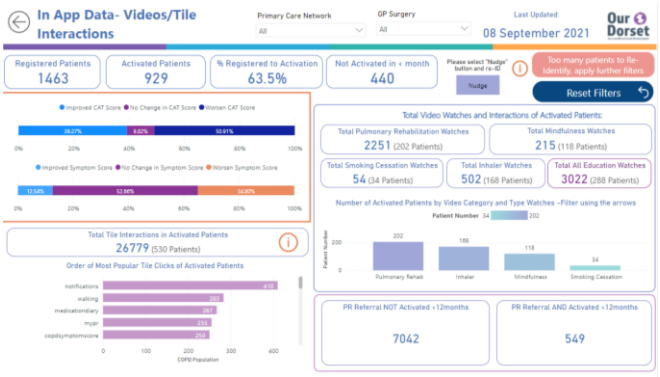
This has led to new roles in PCN's for digital care coordinators and digital health advisors. We have 3 PCN's with a DCC now and 3 more looking to adopt the same approach.

4. How many logged on?

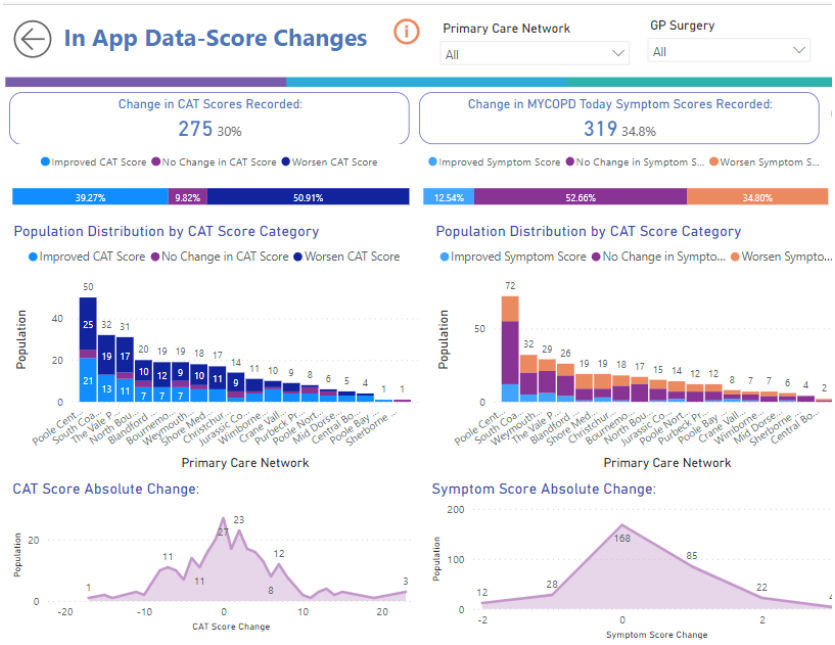
- Out of the 1469 offered in the targeted approach 929 patients went onto to activate = 63.5% activation. This was previously prior to the relaunch and phm approach approx. 43%
- The Digital care coordinators, and nurses have access to see who has not been active and as you can see in the past 4 weeks, we can see 440 patients have not been active on the mycopd platform – in expectation of the season.
- There is functionality within the Dorset Intelligence and Insight Service (DiiS) to re-id those patients that have not been active and could be nudged.

5. What the subsequent usage was of those registered?

- From the 929 activated patients over 56% of them have go onto use the platform to track their condition frequently and consistently.
- 202 patients watched the pulmonary rehabilitation videos a total of 2251 times (clearly engaged and watching this multiple times)
- 215 patients watched the total mindfulness videos a total of 198 times
- 34 patients watched the smoking cessation videos a total of 49 times
- 168 patients watched the inhaler videos a total of 502 times
- The tile interactions and behaviours:
- Notifications are the biggest interaction for the platform. The digital care coordinators are using this to keep people motivated in sharing facts about COPD or seasonal effects on COPD.
- Tracking of walking is next
- Medication tracking is next as the cause for use in the platform



- From those that are using the platform and tracking CAT scores you can see :
- 275 people or 30% of the activated patients have registered their CAT score (at least twice) and we have 39.27% showing improvements (-5 or above) & 50.91% showing worsening CAT scores (20+) with correlate to the symptoms scores on the RHS.
- PCN's are able to reidentify these patients for anticipatory care / proactive management



6. Any feedback from the patients:

- From the data we can see there must be a good user experience and value due to the data evidence we have access to. Below are some of the feedback our nursing teams

have captured.

4. Monitoring of Usage

1. Each practice can monitor technology usage by its patient and contact them if they have not used it for a while. The features within the most used are listed below from the highest frequency to the lowest as:

    - Notification
    - Walk-test
    - Medication
    - myPR
    - symptoms scores
    - education
    - inhaler video
    - smoking cession

The app has mainly used to manage people's clinical risk and encourage life- style change in people with COPD, and it is not intended to be used for remote monitoring in the CCG.

Section Three focus: Conclusion and lessons learnt

5. Lessons learnt – implementation and mobilisation

1. Clinical Safety and procurement assurance

The nature of digital health technology means that there are constant developer updates of the technology itself. To help clinical assurance / trust as a means of mitigating chains of indemnity and chains of implied liability the commissioner needs to ensure:

i) The technology meets the relevant standards such as medical device regulation and DTAC standards so the DHTs can be implemented successfully in a real-world setting (see 5.4)
ii) That the DHTs are part of the Organisation for the Review of Care and Health Applications (ORCHA) library for regular evaluation and assessments for developer updates to technology – like a batch number sign off.

2. When introduced as part of a care model the adoption rate is higher.

3. The evaluation of digital health technologies is complex, and considerations should not only focus on the activity, but the clinical benefits of the technology evidenced by data of which Dorset has done.

4. Processes are in place to aid the horizon scanning and procurement process through the Digital Technology Assessment Criteria (DTAC) process as below:

   - User experience, the usability of the technology as a tool kit – DTAC preliminary considerations / ORCHA review
   - Data protection– DTAC preliminary considerations / ORCHA review
   - Application of it within the care model– DTAC preliminary considerations / ORCHA review

5. Change management is required to aid implementation and adoption across a pathway and this in principle is the same for any digital health technology implementation regardless if a screening / diagnostic tool, pathway integration of personal health record.

6. Conclusion

1. Preliminary results suggested that people had improvement in their symptoms which was clinically important and should be considered an effective digital first approach to COPD management and prescribed as part of a model of care
2. The clinical dashboard for patient contributed data enables clinical teams to identify patients who are deteriorating for decisions at point of care or as part of a patient-initiated contact driving better efficiencies in the care model.

NICE National Institute for Health and Care Excellence

External Assessment Centre correspondence log

DHT001 - myCOPD

The purpose of this log is to show where the External Assessment Centre relied in their assessment of the topic on information or evidence not included in the company's original submission. This is normally where the External Assessment Centre:

a) become aware of additional relevant evidence not submitted by the company;
b) needs to check "real world" assumptions with NICE's expert advisers, or;
c) needs to ask the company for additional information or data not included in the original submission, or;
d) needs to correspond with an organisation or individual outside of NICE

These events are recorded in the table to ensure that all information relevant to the assessment of the topic is captured. The table is shared with the NICE medical technologies advisory committee (MTAC) as part of the committee documentation, and is published on the NICE website at public consultation.

#	Date	Who / Purpose	Question/request	Response received
1.	24/10/19	A list of 9 questions were asked of the company by the EAC.		Responses given by Adam Kirk (AK) of myCOPD over TC with NICE present. A follow up email on the 5/11/2019 provided additional information (all attached documents were shared in confidence with the EAC and NICE and are therefore not reattached here).
2.			Please can the instructions for use (if applicable) and CE mark certificate for MyCOPD be provided?	AK noted that instructions for use for digital differ from those of normal devices so it will be looked into whether the EAC can be granted access to the app as 'how-to' videos are available. CE mark certificate will be provided, but the certification could change under new legislation. This would mean that myCOPD would no

				longer be classed as a 'Medical device', since the application does not influence diagnosis or treatment. / AK has forwarded the CE declaration document (CE mark certificate)
3.			Please could you advise on the launch date of MyCOPD? Section 2.1 of the submission suggests that this was May 2018. However, other sources suggest that this was earlier, i.e. 2015 in here and the Innovation and Technology Tariff award in 2017.	• The table in the submission refers to the release date of the current version. This is not the release date of the technology – AK to feedback on actual release date. • NICE questioned the sort of changes involved with updates of the app and AK clarified that it could be functionality or performance related. • Commercial release was December 2015, with the first sale being to North Lincolnshire, March 2016
4.			We note that in Section 10.3 you refer to a 19% reduction in admissions to hospital based on the Topol Healthcare Review 2019. This document references the NHS Innovation Accelerator, Implementation Toolkit – myCOPD. We cannot see where in this document or which clinical study this value is based on. Are you aware of the primary source of the value?	AK not aware of the original source for this and will follow up I have emailed HEE (Topol.Fellowship@hee.nhs.uk) to chase the source. Ying-ying was CC'd into this. They are trying to identify the source currently. [redacted] is the contact there. **Response from Sue Lacey of the NHS Library:** • We can see that a presentation to the Digital Medicine which included MyCOPD gave figure of 20% reduction in numbers of hospital admissions. I note that this corresponds with the economic assessment you have mentioned in our correspondence Adam - York Health Economics

				Consortium piece looking at a health-economic and reimbursement piece • I find that Innovation Accelerator to which the Topol report refers is now available here. This reports that "In an independent Department of Health Economic Analysis, myCOPD has been estimated to reduce admissions and exacerbations by 25-35%". The reference is cited as a 'Department of Health Economic Analysis of myCOPD (on file)'. We do not have this. • A Health Foundation paper, 'Reducing emergency admissions: unlocking the potential of people to better manage their long-term conditions, published in August 2018, mentions myCOPD as part of a wider commentary on evaluations of e-health interventions in which the figure of 19% appears. • From what we can see the economists used the lower figure of 19% in preparing the hypothetical scenario which appears in the Topol Review and perhaps did not correctly reference this.
5.			Are you able to share any preliminary results from the EARLY trial? These can be shared confidentially	• AK stated that there is difficulty with releasing the results, but that the results look good so far. He will follow up to see if they can be shared confidentially. • Yes I will attach and create a new confidentiality table which I will attach to this email. (This has been received).

6.			In Table 2 you refer to pragmatic real world data analysis of data generated by the app myCOPD. Are you able to share any results from this analysis?	• This should be able to be shared confidentially • Attached are the examples from West Lothian, Highlands and Islands, Ipswich and East Suffolk and Southend (Confidentially – as this is to be published)
7.			In Section 8.2 you refer to patient feedback being provided in an appendix. We can't see this information within the submission. Has it been provided?	• This will be shared • This has been attached to the email. (This has been received).
8.			An excel file "Home Programme Report" has been provided. Are these data from the Southend study (PR overview report)? If not, what do these data relate to?	• AK clarified that this does relate to the Southend study. • Yes these initial data are from that program, illustrating the benefits observed through digital platform
9.			Is myCOPDonline a different company from myCOPD?	• AK confirmed that the only names they have are 'myCOPD', 'my mhealth ltd' & 'Health Quest'. myCOPDonline is therefore not affiliated with myCOPD.
10.			We have identified an abstract - North 2015, which we think is the same study as the ERS 2014 abstract? What trial does this relate to? Is it relevant to the submission?	• Unconfirmed - AP to send North 2015 abstract to myCOPD to assess. • AK confirmed the ERS abstract is relevant to the submission.
11.	29.10.2019	A list of 8 questions was sent by the EAC to 4 Expert Advisors		• Responses received by EAC were collated below. Responses were received from 3 of the 4 experts.

		named by NICE in order to inform the full EAC report:		
12.	29/10/2019	Matthew Turner	**COPD pathway** MyCOPD is being considered for use in people with COPD. Without the availability of MyCOPD, does standard care typically follow that which is described in the NICE guideline on COPD in over 16s: diagnosis and management (NG115)	• I would say yes, but we have been trialling rollout of the COPD GOLD framework recently and there has been discourse between local clinicians on how this may / may not contradict what is stipulated in NICE guidance.
13.			A randomised control study compared MyCOPD with face-to-face pulmonary rehabilitation (PR) in people with a modified Medical Research Council dyspnoea of grade 2 or greater. Face-to-face PR comprised 2 supervised sessions for 6 weeks and exercises at home 3 times per week. Is this programme of face-to-face PR typically offered within the NHS for those with COPD of grade 2 or greater?	• Only the clinician can answer this. Option 1 for F2F pathway is 1 class per week for 12 weeks; option 2 is 2 classes per week for 6 weeks. I am not aware of the home exercise component.
14.			Please could you provide any information (or peer-reviewed papers) around changes in the COPD Assessment Test (CAT) that might be considered clinically meaningful?	• Our specialist provider is keen for primary care to adopt CAT as part of annual review process but as I understand it, it is not commonplace for this to be done by practices as is not standard QOF expectation. CAT has been promoted as part of rolling out GOLD as is deemed by specialist team to offer a more nuanced assessment of patient symptoms. No discussion I'm aware of regarding changes to the CAT.
15.	31/10/2019	Dr Nawar D Barkerly	**COPD pathway** MyCOPD is being considered for use in people with COPD. Without the availability of MyCOPD, does standard care typically follow that which is described in the NICE guideline on COPD in over 16s: diagnosis and management (NG115).	• Generally yes. Uptake of some therapies, however, is variable. Pulmonary rehabilitation and smoking cessation are examples. However, the implementation of myCOPD in the pathway does not equate to improved uptake for these interventions if no evidence is generated through clinical trials to support this hypothesis.

16.			A randomised control study compared MyCOPD with face-to-face pulmonary rehabilitation (PR) in people with a modified Medical Research Council dyspnoea of grade 2 or greater. Face-to-face PR comprised 2 supervised sessions for 6 weeks and exercises at home 3 times per week. Is this programme of face-to-face PR typically offered within the NHS for those with COPD of grade 2 or greater?	• Yes. However, the F2F programme described in this intervention is NOT the standard within the NHS. The standard is 2 weekly supervised exercise sessions for 6 weeks. There is an alternative Home PR programme for those with reduced ability to attend PR venues. This is similar to what is described above in your question (WHICH IS NOT THE STANDARD FOR F2F PROGRAMMES)
			Please could you provide any information (or peer-reviewed papers) around changes in the COPD Assessment Test (CAT) that might be considered clinically meaningful?	• CAT is a "GSK-funded" test and offers a measure of symptom severity in patients with COPD. This was developed by the same clinician who developed SGRQ, Prof Paul Jones from St George's Medical School. All references can be found on the test's online web portal. Please follow this link: https://www.catestonline.org/hcp-homepage/references.html
17.	01/11/2019	John Hurst	**COPD pathway** MyCOPD is being considered for use in people with COPD. Without the availability of MyCOPD, does standard care typically follow that which is described in the NICE guideline on COPD in over 16s: diagnosis and management (NG115).	• This document is the gold standard. However there is strong evidence that care doesn't reflect this. There is poor access to diagnosis. The newer recommendation have not yet been fully implemented yet, but older recommendations and those relating to pharmaceuticals are followed.

18.			A randomised control study compared MyCOPD with face-to-face pulmonary rehabilitation (PR) in people with a modified Medical Research Council dyspnoea of grade 2 or greater. Face-to-face PR comprised 2 supervised sessions for 6 weeks and exercises at home 3 times per week. Is this programme of face-to-face PR typically offered within the NHS for those with COPD of grade 2 or greater?	• Most PR classes are 2 hours, 2 times a week for 6 weeks, with supervised group exercise.
19.			Please could you provide any information (or peer-reviewed papers) around changes in the COPD Assessment Test (CAT) that might be considered clinically meaningful?	• A 2 unit change is considered clinically meaningful. The CAT has only 8 items and is multilingual, so can be used in clinical easily. The 6 minute walking test is a more important measure of clinical outcomes though.
20.			Since John Hurst had not had experience with using myCOPD personally, he could not answer the remaining questions about myCOPD usage, but did report about what other experts have said about it	• People do use it clinically, but patients don't always want to use it, and they therefore don't use it. This is particularly the case in primary care. Older patients are most likely to have COPD and often aren't particularly tech savvy. There is also a lack of robust evidence (vs. clinically proven techniques) and there are concerns about myCOPD being rolled out. Clinicians and patients would rather do a trial and practise run of how to do exercises/treatments (e.g. how to use an inhaler) in person & face to face rather than being shown a video such that they can receive individual feedback. Overall, myCOPD is not delivering what it is trying to.

21.	07/11/2019	Email questions & answers Originally question was asked of Mal North, then Adam Kirk when that wasn't possible, and then answered by Tom Wilkinson, professor associated with my mhealth.	1) In the myCOPD arm of care, do patients receive "usual care" alongside myCOPD, and if yes, is this the same as "usual care" in the comparator arm? 2) What is "usual care" in this trial (aside from the self-written management plan)?	• The RESCUE patients were recruited from an NHS site – a large acute hospital as inpatients, • The randomisation into therapeutic arms resulted in patients either receiving the app or a paper self-management guide- the latter is standard practice and offered widely in the UK • All others aspects of care were the same for all subjects in that they went through the usual discharge and follow up processes offered by the local NHS services in primary and secondary care- ie discharge medication and advice, specialist review in hospital, primary care follow up and access to outpatient services, onward referral to additional services etc • I am happy to discuss if uncertainty remains- I think it's important to recognise in this appraisal what the standard of care is and that support for COPD patients post discharge is vary variable- recent publications have demonstrated wide variability and uniformly p[oor outcomes: the UK fares very poorly with upto 45% of COPD patients readmitted in the RCP national audit within 3 months- the use of an app which offers standardised advice and support to all is one approach to address what is a genuine crisis in the NHS and drives the winter bed pressures we hear about every year.
22.	02/02/2021	Expert engagement meeting minutes	1) Please describe the clinical pathway for patients with COPD? Is the condition usually managed in primary care? • Issues which may be covered: Proportion of patients with o self-management plan	• COPD is a long-term chronic condition. Most people are managed in primary care. GPs may involve in the diagnosis of the condition. After a diagnosis, patients are managed in primary care with most routine follow ups at 6 months or 1 year conducted by practice nurse practitioners,

			○ training on inhaler techniques and breathing control? ○ training on pulmonary rehabilitation? ○ education on the disease, treatments and progression? Who delivers these interventions? How effective are these treatments?	escalating patients to the GP when required. Practice nurses provide follow-up care and monitoring. • If the condition progresses, people may be referred to secondary care. Hospital admissions for COPD tend to depend on: severity of the condition and/or severity of the exacerbation, with about 15% to 20% of people with exacerbations admitted. • Exacerbations are complex and their management of exacerbations is crucial – increases rates or severity are associated with disease progression, higher resource use and decline in quality of life Not every patient with an exacerbation requires admission to hospital • Other reasons being referred to secondary care include: people are referred for defining diagnosis, and some people are referred due to the condition progression to manage symptoms but not necessarily related to exacerbation. These are a minority however. • In secondary care: patients may be seen by a specialist nurse, or physiotherapist for pulmonary rehab, oxygen therapy, inhaler technique and education on eg smoking cessation. Respiratory consultants are also involved in patient management, arranging for necessary tests, changing treatments, convening DMTs. Both consultants and nurses may undertake the 5 actions required within the discharge bundle, with the aim of reducing readmissions. • Over the last 15 to 20 years there has been an increase in early supportive discharge and increased management at home, reducing admission rates but hospitalisation is still a

				significant proportion of the healthcare cost of COPD. • As with any long-term condition, self-management and education are essential. There are interventions support self-management such as monitoring medications, and evidence show the benefits of these interventions. In recent years, digital solutions for self-management become available; for instance, use of smart phone apps and telemonitoring have increased. The apps often have components for behavioural change (eg smoking cessation and inhaler technique) to support self-management and provide education on the course of the disease. • Self-management plan can be made and amended throughout patient's care journey at different points. Plan is made at the early stage of a diagnosis made, and can be amended in primary care and secondary care settings. • In current practice, self-management plan is often prescribed with little education for patient. For instance, there is deficient education for inhaler techniques. Patients are given description of the inhaler with little education to its technique. The amount and quality of education provided is highly variable and often too late to prevent disease progression. Over 85% to 90% of patients are not able to access pulmonary rehab- yet this is when education on the disease tends to be provided. Understanding the disease is key to effective self-management. • Timely access to the care pathway is important. Currently there are variations in how soon people can access the services including making a diagnosis, getting a GP appointment and referrals

				to secondary care. Moreover, pulmonary rehabilitation is available to less than 15% of eligible patients. • Causes for the access problems include the limited finite resources available; sometimes these patients are poor at advocating for their own needs; and exacerbations are most frequent in winter when the NHS is managing peak demands. • All experts agreed patients would benefit from easy access to discrete and early interventions and this does not happen now. • COVID has required radical changes in pathways and tools e.g clinicians are not able to use placebo inhalers and single use inhalers are expensive. • All experts agreed the current provision of education and self-management in respiratory care is variable, often delivered to people who are at the severe end of the spectrum rather than with mild or moderate disease and overall is poor. This needs to change. Other changes required include earlier diagnosis, earlier referral to secondary care and more evidence-based interventions. Their absence leads to patients not being educated and having a poor knowledge
23.			2) Are patients generally also referred to secondary care? What are the main factors that trigger a deterioration in a person's condition which may cause hospitalisation? e.g is the main trigger related to viral or bacterial infections?	• People are generally referred to secondary care for further interventions managing their symptoms or managing their co-morbidities. Their referrals can be trigged as the following: 1. People are referred by their GPs because of clinical deterioration which sometimes is not picked up until the annual review. 2. People are presented in crisis as emergencies.

				3. People are identified by searches of patient records to identify the frequent presenters. • In general, there are significant delays in referring from primary to secondary care.

24.			3) Please describe the position of myCOPD in clinical pathway for a person with COPD? Is it intended to be used alongside or instead of other interventions?	• myCOPD provides self-management, support for medication and symptom management, patient education and pulmonary rehabilitation. It should be used with patients across the disease spectrum to provide timely access to each component. Patient information captured should help decision-making in managing the condition.
				• Discrete interventions can be blended with the current pathway.
				• The app can record events in real time enabling reviews to be informed by evidence rather than relying on poor recall. Also, patients have access to their own data, encouraging learning.
				  • Use of the pulmonary rehabilitation digital platform has enabled services to extend their reach
				  • In secondary care, the interoperability of the apps means more bespoke interactions are possible e.g. an increasing number of clinical settings are using the information from the app to monitor their patients, in the absence of face-to face appointments.
				  • One expert suggested the biggest advantage was access to education but that needs to be introduced early in their management in primary care.
				  • COVID has caused many settings to re-design their clinical pathways, by adopting a range of

				digital applications. The changes have enabled local services to deliver interventions e.g. to provide pulmonary rehabilitation, when face to face was not possible. • One expert advised the app is not used enough for follow-up – using it to deliver follow-up at 72 hours would increase compliance with that indicator in the COPD discharge bundle. • Another expert noted the app has lots of potential in the treatment pathway, but it is a complex intervention. As such its evaluation and implementation should be managed in line with the Medical Research Council's guidance. A key aspect of the guidance is developing the evidence base and evaluation prior to implementation and embedding in clinical pathways. • This may require each component / function of the app to be considered separately but it is also vital to consider the whole, together with its interoperability into other systems. Currently evidence on the app largely focused pulmonary rehabilitation, and evidence on other functions are limited. Additional information on factors such as activation, engagement and retentions rates are required, together with impact of its use on changing behaviours and outcomes. To overcome the Hawthorne effect (observation of behavioural change does in itself change behaviour) requires well-designed clinical studies or robust real world evidence.

25.			4) Do patients generally use the app as recommended or complete the programme being prescribed?	• During the pandemic, most people manage the condition themselves at home (without instruction). Working closely with patients, the app collects patient information, which may be informed the decision making for care management. • There is an increase in patient engagement during the pandemic, more people activate the app. For healthcare professionals, one expert noted that the use of the app enables clinicians to improve patient contacts and see more patients remotely. • One expert suggested that there is an increase in the use of the internet during the pandemic, and this should be considered separately from the use of digital health technology in the current care pathway. More evidence is needed to support the latter one.
26.			5) How reliable do you find patient recall without the app in respect of events such as exacerbations? Do you think use of the app helps in the understanding and management of exacerbations?	• Currently recall is poor and mainly used at the annual review. • The app can collect this information and share it with a GP who can use it: 1. With individual patients. 2. To manage a patient cohort. • Enables early intervention which helps decrease hospitalisation. • Patients show engagement, need to use this to then drive the effectiveness of interventions. • Clinical use of the app for monitoring purposes has increased 10-fold recently and is ever increasing. This is consistent with increased use of the internet e.g. clinicians now use

				zoom frequently to instruct patients on say inhaler techniques. • Also, if a patient downloads the app but does not engage with it initially then they may still start one day. • Engagement over a relatively short period may improve behaviour, with long term benefits even if the patient ceases engagement. • App records every time someone logs on – these data are available. • The app has ongoing updates and generic advice.
27.			6) What change observed in CAT score will consider to be clinically meaningful? What is a clinically significant level of reduction in exacerbations?	• Current evidence suggested that 2 points change in CAT is considered to be clinically significant. • Exacerbations are a coarse measure of effect and can be impacted by many factors. • Rather than looking at change in exacerbation rate we should consider number needed to treat. • Results from previous myCOPD trials, noting their limitations on size and short follow-up, no longer generalise to current settings because pathways have changed so much in response to COVID. • There is no standardised evidence of outcomes with the current pathway and indeed there is considerable variation across settings.

28.			7) How is inhaler technique assessed?	• Currently patients are reminded of the correct technique at their first visit, but by the next visit approximately 50% need a second reminder. This is assessed by watching them – no test can inform this. • Trials report inhaler errors and this is the outcome to adopt.
29.			8) What are the most widely recognised outcome measures used in self-management of COPD?	• The experts advised errors in inhaler technique is a good measure but warned that inhalers differ in terms of the information provided on their use so it is not an ideal outcome for a clinical trial.
30.	05/02/2021	Expert engagement meeting notes – Beth Sage (BS, Consultant Respiratory Physician. NHS Highland)	YW updated the key issues discussed at the expert engagement meeting: • Lack of training for patients when self-management is prescribed. Variation in accessing to services such as diagnosing, rehabilitation in people with COPD,	• BS agreed that most people with COPD are managed in primary care including GP and other communicate services. People are referred to secondary care largely for confirming a diagnosis and managing symptoms of COPD when the condition deteriorates.
31.			Follow-up questions from the EAC: 1) What percentage of patients receive education and inhaler training whilst in the mild and moderate stage of the disease; and in future, post vaccination, will these be delivered face to face in primary care?	• BS suggested that very few people received education and inhaler training while managing their conditions at home. The percentage could be variable depending on who are in contact with the patient. For instance, people may get an inhaler at the pharmacy, at the time the pharmacist may provide instruction for people how to use an inhaler. Respiratory nurse may check people's inhaler techniques while reviewing patients.
32.			2) Many services have undertaken major redesigns to meet COVID restrictions whilst still delivering the interventions required to by the NICE guideline. How do you see service delivery in primary and secondary care in a post vaccination future?	• BS thought service delivery is unlikely to change after the pandemic because most patients prefer to have interactions with healthcare professionals. People's health seek behaviour may have an

				impact as people are used to see or in contact with healthcare professionals on the face-to-face basis. Especially for people living with long-term chronic condition and elderly people, they like to the opportunities to able to travel to surgery or hospitals to talk to healthcare professionals. During the pandemic, NHS highlight provides online rehabilitation, but face-to-face service will resume after the pandemic. There is a possible to provide service in a blended way offering both face to face and on-line access depending on patients' preference. • The use of myCOPD may have its place in the care pathway if people engage well with the technology (using frequently). BS thought myCOPD could be an add-on intervention to be used with other interventions for managing COPD. Some preliminary results from the local evaluation, a small percentage of patient engaged very well ("high frequency users"), and data suggested that a trend of a reduction in hospital admission in this group of people. But data are not able to capture the characteristics of this group of patients. Perhaps further data will be useful to able to predict people who would engage well with the technology. The initial figure suggested that 80% of people activated the app within a week signed up. Of these people, only 15% use multiple modules in the app, 30% use only one module. 15% never use the app. The reason for not using the app may be difficult to use (technical issues), uncertainties about the benefits and people don't feel a need for use the app. • The cost of the technology is £40 per license. Because COPD is a common condition especially

				those in old age group, and it would be quite expensive for healthcare service to provide the app to each person with COPD. Therefore the app is only provided to a selection of patients during the local evaluation; for instance those use the app frequently. • There is no evidence on the long term effect of the app. • Outcomes used in the local evaluation include hospital admission rate; rate of using community service; rate of using GP out-of-service; the number of ambulance calls. The local evaluation also considered to use community prescribing data (use of emergency prescribing) as an outcome measure. • The app's clinician interface features are limited, and clinicians are not able to monitor patient remotely. Little information is available for clinician to review patient data. For instance, if clinicians could assess patient data, doctors/nurses would be able to pinpoint these data to engage with patients to manage their conditions. • BS also thought patients may lack an understanding of the importance of their data in managing their conditions; for instance how their data can be utilised by the clinicians to help monitor or manage their condition.

33.	18/02/21	The company was contacted through a Zoom call to discuss questions relating to their submission	1) Attrition data	• Adam Kirk explained they presented a KM curve graph but he numbers under the graph do not relate to it and hence the confusion. • The graph is a live data set and every drop in the graph is someone stopping using the app, the graph shows the failure of a proportion of users during a specific period of time to use the app. • People do not use the app every day for 6 weeks – like with any chronic disease they use help sporadically as and when they need it. e.g. at 30 days the number of users is still approximately 50% but they may not be using it every day, • The numbers are the number of 'active' users at that period of time • People use the app episodically – it may look like a failure but it isn't as they then use the app again later as part of their management plan.
34.			2) Funding and assistance – RWE evaluation sites	• Sites receive no funding, but they can access their own dashboard for data. • Some request specific reports but there is a cost for that. Also they can get advice from the company's research team. The platform was free under the Innovation and Technology Tariff 2017/18.
35.			3) Quantify use of myCOPD as link between patients and healthcare professionals	• The company explained the platform is used differently in different clinical settings. • E.g in primary care the interactions with the clinical team may be limited, whilst they are intensive when a person is using the app for supervised PR.

36.			4) Average activation rate nationally	• 47.9% currently
37.			5) Trend over time of activation rate	• Increasing all the time as sites and co-learn together where the app sits in the pathways and refine implementation process. • Main factor influencing use is how the clinicians build it into their communities and 'sell it' to their patients. • The company sctively discourages clinicians selecting people to avoid bias. • The platform offers connection between patients and HCPs which is so important particularly just now during the pandemic. Patients must give permission to enable HCPs to see their data.
38.			6) Any evidence missed	• Company to send the one more evaluation plus the draft Dorset report. • Others are in the pipeline.
39.			Real world evidence – summary of evidence so far	• There are 18 documents, plus the user information downloaded from the platforming early January 2021. • The main methods are surveys which are subject to biases. • User engagement is on a spectrum – evidence suggests highly engaged users benefitted most from the app. • User information – the attrition and engagement rates are most useful and do reflect how users use it in the real world. These data are dynamic.

				• The totality of evidence is pretty consistent from the user perspective, despite notable variation between sites on e.g activation rates. Whilst each individual evaluation is low quality, together they provide a decent evidence base for decisions, particularly when combined with the data from the platform.
40.			Clinical evidence – summary of evidence so far	• YHEC summarised the comparative clinical evidence and how it matched the scope. It noted in 2 RCTs there were differences between the care that patients received beyond MyCOPD which is potentially, a source of bias that may impact on any treatment effect with MyCOPD. The methodological quality of RCTs was acceptable but low for the observational study. All RCTs were judged to have acceptable internal and external validity. The observational study had low internal validity but acceptable external validity. The EAC concluded that, due to the differences between the RCTs, meta-analysis was not appropriate. • All 4 studies had quite small sample sizes (<100), and this also led to imbalance in some baseline characteristics between the treatment groups. This combined with the short follow-ups (3 months being the longest) limited the power of the studies to detect statistical differences. • The company noted many studies in the Cochrane review of PR included fewer patients than theirs did.

41.	09/07/2021	Email correspondence with Susan Peirce (Cardiff and Vale UHB – Cedar)	Susan Peirce emailed NICE to inform them of a mistake in one of the citations in the Part 2 submission	• In 'Model Structure', top of p21 (as submitted) the citation for Apps et al (2019) should actually be: Morton-Holtham L, Wells E, Sharma B, et al (2021) P82 Comparison of virtual pulmonary rehabilitation platforms use in a regional network Thorax 2021;76:A132 Available from: https://thorax.bmj.com/content/76/Suppl_1/A132.1 • I have just received 2 PDF posters from the same authors, who I contacted a couple of weeks ago. I can forward these to the EAC if I get permission to share them. They relate to the use of remote PR (various types) across Kent during the Covid lockdown – only a bit more information than the Thorax abstract.
42.	13/07/2021	Clinical experts initially contacted to help answer questions for submission	Alexander Hicks Nawar Bakerly Lisa Ward Beth Sage Thomas Brown Christopher Jones Jenny Gates	Alexander Hicks: no response Nawar Bakerly: call on 04/08/21 (details of questions and answers further down in correspondence log). Lisa Ward: responded with written answers (details questions and answers further down in correspondence log). Beth Sage: Not working with patient groups specific to model populations – EAC responded with shorter list of questions – no response. Thomas Brown: Unable to respond to questions. Suggested Dr B Green and Mr J Robson could help. No response from Dr Green. Ms Robson responded with answers to questions (details further down in correspondence log). Christopher Jones: Unable to respond to questions. Suggested Matt Turner may be able to help. Matt

				Turner was unable to respond to questions. Suggested Paris Moakes may be able to help. Paris Moakes unable to help as no clinical experience with myCOPD. Suggested Ruth Barlow and Mark Bramley. Ruth Barlow: Out of the office until 9th August. No response to questions. Mark Bramley: Unable to help with responding to the questions but suggested contact with Jenny Gates (the EAC previously contacted Jenny Gates) Jenny Gates: No response to questions.
43.	16/07/21	The company was contacted through a zoom call to discuss questions relating to their submission. Written responses to the questions were provided after the meeting and have been included in the responses here.	1) Please could you describe the pricing structure for myCOPD in more detail, both for the CCG model and the PR service model.	• There is the PR service for a whole CCG and the PR service only - these are different models. The PR CCG is applied where the CCGs have already purchased the app and it is rolled out to PR, but the PR service only is when a PR service purchases the app themselves (the PR service is specific to PR providers and there is a fixed price of £10,000 per year). The PR service could be for the whole CCG but there could also be multiple PR service providers for a CCG. • The CCG can give the app to the PR services if they have purchased it. Anyone who has access to myCOPD can prescribe it to patients with COPD. The PR provider service is not incorporated in another costing way.
44.			a) How would this change with the move from CCG to ICS?	• The costing format will remain the same. This will be 25p/capita population.

			b) Is it possible to estimate a cost per person using myCOPD rather than on a CCG level (recognising this may involve making assumptions)?	• The PR models have determined a saving per patient, using the number of patients eligible for PR (CCG unlimited model) and the median number of referrals per year (PR-service only model, scenario A). The same can easily be done for the AECOPD model by dividing the total cost saving by the number of index admissions. However, this assumes that only these patient subgroups would receive the app. The cost per patient varies depending on who and how many receive the app. The cost per patient goes down if everyone with COPD gets the app, but we only have robust evidence for patients in these subgroups. Therefore it is a conservative assumption (i.e. higher per patient cost) to only divide the contract cost between these specific patients. It is rather arbitrary in this case to try and use strict per-patient modelling. The overall impact on the purchaser is the same, and considering the whole budget impact is much simpler to grasp.
45.			c) Is it correct that the licensing fee is a 3-year contract for CCGs but that this could be used on unlimited new patients?	• The contract is called Unlimited. It is a three-year term. The cost is calculated at 25p/capita population QOF-registered in the CCG. The CCG can then provide an unlimited number of licences over that term for prevalent and incident cases of COPD. Additional patients can come into the AECOPD model during the three-year licensing period but the model is based on the average number of people in a typical CCG.

46.			2) Was there a reason for excluding the economic study you referred to in your first economic submission from October 2019?	• The YHEC paper is based on a hypothetical saving: if there was a 20% reduction in admissions due to 24hr earlier diagnosis, then the saving would be. This is not based on any published data. It appears to be based on a DOH economic analysis that is not available. • Following the meeting with NICE and the EAC (8th July 2021), this document has now been included as a demonstration of what is possible through the application being used widely and effectively. These figures are not unreasonable, and this was an independent assessment conducted by the YHEC.
47.			3) In the submission it states that the patients in the PR model are a subgroup of the AECOPD model and therefore when looking at the unlimited license option, only the costs of registering these patients are included (with license, training costs etc excluded). Therefore, these results cannot be viewed as standalone, please can you confirm this is correct?	• The text in the submission text could have been a bit clearer. PR patients are not a subgroup of AECOPD patients. The Unlimited contract model would only be used for the PR subgroup of COPD patients if the contract already existed. I.e. a CCG would not purchase the unlimited contract and only register PR patients on the app, as the numbers of referrals are too low. Therefore, it makes no sense to apply the full costs of purchasing the technology to both the AECOPD and the PR (CCG) models. Consider that a CCG purchases the Unlimited licence and registers either only AECOPD patients, or AECOPD and PR patients. The models are structurally 'independent', in that they are not combined in a single pathway, consider discrete (if overlapping) populations, and exist as separate files. NACAP data (National Asthma and COPD Audit Programme: pulmonary rehabilitation clinical and organisational audit report 2019) states that

				5.2% of patients receiving PR were referred after admission to hospital for AECOPD. • Note: myCOPD licences include all the interventions, possible benefits and indications that are contained within the app – AECOPD benefit, PR, education, inhaler technique, mindfulness, time savings on service delivery, medication review and adherence etc. Whilst the costing models were separate for AECOPD and PR, in the Unlimited contract, they are provided for through distributing the licence to patients diagnosed with COPD. Including the licence costs for Unlimited for both indications would incorrectly represent the initial capital outlay which procures access to the application.
48.			a) Please can you comment on whether there is likely any crossover between the two models in terms of the patients included and whether any of the benefits of reduced exacerbations could be double counted?	• This was covered in the Summary and Interpretation section. There will be some overlap. Patients who are admitted for AECOPD should receive a PR referral to enrol within 30 days. Therefore, technically the AECOPD subgroup could be considered to be included in the PR model. However, post-AECOPD enrolments are only around 5% of total PR patients (see assumptions), PR outcomes are not generally distinguished between these two eligible subgroups, and large proportions of both eligible subgroups do not start PR. Many patients discharged from AECOPD will not receive PR and most starting PR will not be there because of an admission. It is very difficult to determine what an appropriate overlap would be. Also, the trials on which the models' outcomes are based did not include any overlap – in the RESCUE trial the intervention was self-management (although

				patients in the myCOPD arm had access to the PR module), in the TROOPER trial the intervention was PR (it is unclear if patients had access to the rest of the myCOPD modules). So additionally, there is no data on which to determine whether patients in an 'overlap' population would receive greater benefits.
49.			4) The probability of having a diagnosis of COPD from the general population is 1.94%. This figure does not appear to be used in the model. What is the purpose of this figure?	• Left over from an earlier iteration of the model.
50.			5) The AECOPD model includes a cost for exacerbation without admission, which includes a proportion of people having GP appointments (using Jordan et al.). A separate cost for GP appointments related to COPD symptoms/exacerbation is also included (using McLaughlin et al.). This appears to be double-counting – please provide justification for why the proportion of patients having a GP appointment in the Jordan paper should be included in the cost of unadmitted exacerbations.	• The McLaughlin & Skinner poster refers to unscheduled GP appointments attributable to COPD, and not to appointments specific to exacerbations. This could include non-exacerbation related appointments. There is likely to be some double-counting of exacerbation-related GP appointments by including both of these.
51.			6) The cost of non-admitted exacerbations includes an A&E visit without admission. Please clarify how you got to the value of £74.82 as we were unable to reproduce this value.	• We will provide this in an additional spreadsheet • *(information in Appendix to this document)*
52.			7) In the submission an assumption is included which states the model is replicated for each of the three years of the contract (same benefits and costs each year). This doesn't appear to have been done. Please provide your reasoning for this.	• This means that the same model, inputs, and results are assumed to apply for each of the three years of the contract. This just means that the annual cost of the contract is applied to the model (25p) rather than the total for the 3 years (75p), as we assume the same annual resource use savings and a constant number of referrals each year.

53.			8) In the submission the time horizon is stated to be three months, but the model includes some annual costs (registration and cost to set up licensing). Can you please clarify the time horizon used?	• We are using the annual number of index admissions to determine how many patients would receive the app over each year of the contract. However, the published evidence only supports the benefit that each patient receives for 3 months following discharge. It makes no difference to the outcome, whether you consider the index admissions spread throughout the year or all happening at the start of the contract year.
54.			9) The cost of training clinicians to use myCOPD is estimated by using an average of 50 GP practices per CCG. Please provide a source for this.	• QOF data for 2019-20 lists the practices in each CCG. We calculated the average from the Excel spreadsheets (either the CCG level or GP practice level) available from https://digital.nhs.uk/pubs/qof1920.
55.			10) Can you please clarify whether the nurse registering patients would be a nurse at a GP?	• Yes, Band 5 nurse in a GP practice. This is a conservative estimate as lower grade staff would also be involved (such as HCAs).
56.			11) The results reported in the submission do not appear to match those in the submitted model when using the PR service costing method. Please can you clarify which are correct.	• These are both correct, 1 is the base case, 2 is scenario A. There are separate TreeAge files for both of these. • 1 – for PR across the CCG unlimited contract (p30) • 2 – for PR-only service, scenario A

					Total net costs per patient using the technology	Total net costs per patient using the comparator	Incremental	
				Submission 1	£969.60	£977.46	-£7.86	
				TreeAge model 2	£1,118.95	£1,136.54	-£17.59	

57.			12) Please can you confirm the figures used for the calculation of the '20.2% probability of referral to PR by GP' and their sources. We were unable to reconcile these values from the information provided in the submission.	• The QOF data for COPD008 gives a referral rate of 43%, however this has only been collected for one year and clinical advice was that this may include higher than normal numbers of inappropriate referrals and did not reflect their normal experience. NACAP data and several reports such as NHS Long Term plan report percentages of around 15%. A small amount of this difference may be that NACAP data is based on MRC3 and above patients as the denominator, and QOF data uses eligible patients as the denominator (based on MRC3, but with additional conditions). Therefore, we have applied 40% (from COPD Prime) to all patients with a diagnosis of COPD (as recorded in QOF 2020), to give the number with MRC3, and applied 15% (COPD Prime, NACAP 2018) to give the number of patients referred. This new number is used to calculate 20.21% of all eligible patients recorded in QOF. We accept that there is some uncertainty around this, and that is reflected in the sensitivity analysis submitted.
58.			13) The value of 29.69% used for 'probability of being eligible for PR' is stated to be based on the denominator for QOF indicator COPD08 without PCAs/QOF registered with COPD. We can only reconcile this value by taking the denominator with PCAs – please can you confirm what values were used to calculate this and whether that is appropriate/was intended?	• This was based on the number used as eligible for PR, excluding PCAs (347,631) and the total number registered as having a diagnosis of COPD (1,170,786).
59.			14) For the service costing model, the number referred for PR is 495. The submission states that this is based on figures from Section 1.1 of the NACAP 2019 report. The median value of 298 referrals is provided in Section 1.1 of the report. However, we were unable to identify where the 83% figure was from for the	• Apologies, the citation for this value is incorrect and the reference is missing (there are a lot of NACAP reports with similar titles). The correct reference is: NACAP (2018) Pulmonary rehabilitation: An exercise in improvement (Clinical and organisational audits of pulmonary

			proportion of patients with COPD – please can you confirm where this was taken from?	rehabilitation services in England and Wales 2017). Organisational audit data analysis and results. April 2018. (It's Q4.4, p21.)
60.			15) The cost of F2F PR in the submission is stated as £695 and reported to be from the COPD Prime tool updated with PSSRU. Please can you confirm the original figure used and provide calculations or further details on how this was updated using PSSRU (i.e. if inflated, from what year, using what index, or were individual elements reported in COPD Prime updated)?	• I will forward an additional spreadsheet with the calculation. It was based on the COPD Prime staff numbers, costed at PSSRU staff rates, with the addition of a small amount of patient travel time. • *Information in the Appendix of this document*
61.			16) The training cost in the submission is stated to be £1,950 per year and this was included in the AECOPD model (1 hour for practice nurse band 5 per GP practice. Assumed 50 practices per CCG). However, the cost applied in the PR model is £195 (calculated as 5 * £4839). Please can you confirm whether this is an error in the model and should be consistent with the AECOPD model?	• The model is for a single PR service only, and the training is calculated accordingly. In the PR Service model, training the staff in the PR service on the app use is additional to this. We assumed 5 members of staff in the service at Band 5 for this. (Apologies, this may not have been explicitly included in the submission).
62.	16/07/21	Additional comments and questions from EAC and company meeting	Please can you provide further detail on where the 11% probability of being treated with myCOPD only and with a hybrid model has come from and how it was calculated?	• This is the percentage of patients who took up remote PR from the Southend study. This includes patients who used myCOPD, DVD and booklets, however the cost of activating myCOPD has been applied to all remote PR patients on the assumption that they will have been offered it. The overall completion rates are reflective of this mix. The information is from a slide on the webinar: https://vimeo.com/539559604. (at 24 minutes)
63.		•	YW asked what the care pathway is for the AECOPD patients.	• It was confirmed that the care pathways are variable. There may be some patients who have hospital at home, some with early discharge etc. However, it was decided that these wouldn't be modelled.

64.			YW highlighted that the way in which people engage with the app has an impact on potential benefits. She asked whether this been considered in the model.	• SP stated that there are multiple components so it is highly dependent on how patients use it, how it is implemented, etc. There is a paper which does discuss how the more patients use it, the more benefits they receive. Measures of self-efficacy increase but this has been accounted for in the resource use benefits.
65.			YW questioned whether mysmart COPD was relevant to the submission.	• AK confirmed that this was a research study being run using myCOPD to collect data. BD confirmed this was not relevant to the submission.
66.	20/07/21 10:00 – 11:30am	Company Engagement meeting minutes	Uptake Discussion: EAC: In the company economic model, the outcomes have been applied to every person who has been discharged from hospital with AECOPD, assuming that all those offered myCOPD would be registered to myCOPD. This would not be the case and the EAC will be adding this to the economic model. The lower the uptake the less cost-saving myCOPD will be due to the model being costed per CCG and not per person. There are options on data for this, but none are ideal. Uptake likely to be higher in this population than a broader population (as seen in RWE studies) as they have just been hospitalised and may require more support. A carer can help with using the app but only through the patient's account. RESCUE is likely to be the best source for uptake, but note uncertainty with this (people may not agree to use myCOPD in a trial environment – the majority of those who were eligible but did not begin the trial did not give a reason). Threshold analysis can be conducted around the uptake due to the uncertainty in this parameter. The average age of user of myCOPD is 70 (so will likely have had COPD for a while as average age of diagnosis is 65 years). The proportion of people over 65 with a smartphone is 65%.	• Company: The company expects the age of users to increase as digital becomes more widespread. A discussion took place around whether uptake will increase over time as awareness of MyCOPD grows. The company advised that there is a general lack of awareness on PR. Patients will likely be informed about the app by health care professional. Patients are more likely to use interventions as health care professionals become more confident in use. Activated health care professional likely to be the biggest driver to uptake. The more informed the health care professionals are the more likely they are to refer the app and uptake will increase. • The company advised that patients typically found out about the app through clinicians. Digital health advisers within local areas now exist who enable process of registering and activating. The company are also working to use notifications integrated through e.g. EMIS to let patients know about the app. MyCOPD could form part of an annual review and patients may be offered the app then. • A discussion took place around the pricing model of myCOPD. Previously a fee of £40 per

				user was in place, but the company found a subscription model is more globally accepted by commissioners as the cost if fixed and they are able to budget for it. The company provides digital health advisers if the contract is long enough.
67.			Readmissions and exacerbations in RESCUE study discussion: EAC - The EAC raised the concern of double counting with non-admitted exacerbations and readmissions.	• Company: The company advised that these are not defined as mutually exclusive, so patients could, in theory, be included in both pots through the care pathway. However, the overlap between patients is likely to be minimal so can treat them as mutually exclusive and somebody who is readmitted is likely to have used the resources associated with a non-admitted exacerbation before admission. In order to assess this fully resource use data on each individual patient in RESCUE would be required which is not available. It was agreed that they could be treated as mutually exclusive with the possibility of double counting of some resources noted in the assessment report. (Note: Follow up with an author of the RESCUE study suggested double-counting would not occur (see correspondence with Tom Wilkinson on 29/07/21))
68.			Discussion surrounding extending benefits of MyCOPD beyond 3 months: EAC - A discussion took place about the time horizon for benefits in the model. These are conservatively assumed to end after 3 months. The EAC proposed conducting a scenario with benefits extended beyond 3 months.	• Company: The company advised that a user doesn't need to maintain usage of app to maintain benefit of app (users will still have learnings from the app). Benefits likely to reduce over time, but not stop at 3 months. Some people do keep using myCOPD for a year and beyond, intensifying use around contact with clinicians or when their symptoms worsen. Users have the app for life (this

				doesn't stop when the CCG contract runs out) and therefore can continue to benefit. Benefits may also increase as people become more comfortable with using technology as part of health care pathways. There is evidence to show benefits of the app improve with increased useage. • All: agreed with using a 3-month time frame for the base case analysis with scenario analyses considering longer term benefit.
69.			Discussion around cost for those who start, but don't finish face-to-face PR. The EAC: advised that this will be included in the model and is expected to improve outcomes for myCOPD.	• Company: No comment
70.			Discussion around the decision point in the PR model. The EAC: proposed changing the starting point in the model so that it considers only those who have agreed to try myCOPD (either on its own or as part of the hybrid model). The people choosing the face-to-face PR in the intervention arm will be removed, as well as the same number of people in the comparator arm. This won't change direction of results, but will change magnitude.	Company: No comment. • NICE: The NICE committee would like to see cost-per-patient choosing myCOPD results and this approach leads to consistency in the per-patient results between the AECOPD model and the PR model and therefore will hopefully allow for clearer communication to Committee.
71.			Discussion around the comparator in the PR model: NICE: questioned whether the face-to-face PR should still be the only comparator now that COVID has potentially changed the standard of care.	• Company: advised that costing of face-to-face PR is done as per pre-pandemic service provision. During the pandemic some of this was provided virtually, but other comparators (e.g. apps) are not well established. As things return to normal, the number of people having PR in each face-to-face class will have reduced due to social distancing.

				• All: Agreed that there is no clear alternative to myCOPD apart from face-to-face PR.
72.			Further question 1. Please can you talk us through the cost included to administer the top-level licenses (£360) in terms of who these licenses need to be administered to and what is involved etc for both settings (i.e. CCG and PR service).	• There is one top-level licence. The person with this top-level license can activate managers who can then activate clinicians. Clinicians then activate patient licenses. Anyone who buys myCOPD for the population will be the top-level license holder (they could also be manager/clinician). The £360 covers this full hierarchy and managing the service. This value was estimated based on how much time it would take and cost of staff time (applied bands to these based on job adverts e.g. digital health champions). The staff member does not need to be senior. A name and email address is needed to activate a clinician and an email is sent to them to set it up. • This is a one-off cost, there may be some need to readminister licenses for staff turnover, for example, but this wouldn't need to be done every year.
73.			Further question 2. From the calculations provided last week, it still seems that the proportion of patients eligible for PR (29.69% in the model) is calculated using QOF data including PCAs (the denominator excluding them appears to be much lower at 174,784). Please can you confirm whether this is intentional and talk through the reasons for including/excluding PCAs.	• Written answer to be provided (see correspondence with Megan Dale on 23/07/21.
74.	22/07/2021	Jennifer Robson (expert) was contacted via email to answer the following questions:	1) In your experience, what proportion of COPD patients would be willing to use myCOPD following an acute exacerbation in hospital? Has this, or is this likely to, change since the coronavirus pandemic?	• Out of [redacted] patient contacts (not unique patients) we have only issued [redacted] licenses. In our first year of practice ([redacted] patient contacts, not unique patients) we would routinely tell every patient about MyCOPD and ask if they would like access. Uptake was very low. In our experience the limitation is more about who is ABLE to use the technology to access the app. There was a large proportion of patients who

				either did not have a smart phone/tablet/computer/internet access to use the platform, or were not competent in using the technology to access MyCOPD. • Of those who said that they could use the technology and who were signed up by our staff [redacted] did not access the programme at all. Only 6 out of [redacted] are currently using their MyCOPD account (accessed within the last 2 months). Only [redacted] patients have used it within the last 12 months. • Due to the poor initial uptake of COPD we have now stopped routinely asking, but will offer MyCOPD to patients who appear to be capable of using the required technology (have a smart phone or tablet with them in hospital, or report using electronic prescription ordering etc).
75.			2) Is it feasible that a patient could benefit from using myCOPD more than once? For example, if they were to start using it after a hospitalisation for acute exacerbation but their usage tailed off, would they likely get the same/some benefits from using the app again following another hospitalisation episode?	• I think this is something that needs to be studied more closely. The Rescue study was a very small study and I think there are likely to be other confounding variables, such as socioeconomic factors. Patients who do not have access to smart phone/ etc or internet are likely to be from lower socioeconomic classes who are more likely to have poor health state and greater smoking exposure. • I have no doubt that MyCOPD can be a useful tool in self-management of COPD for some, but I do not believe we are quite at the stage where the majority of people with COPD are in a situation that they can routinely use and access online tools. This is likely to change in the future, but may take more than 10 years, unless more is done to address digital poverty. The COVID lockdowns demonstrated that many households with school aged children did not

				have internet access or computers to access home learning. • In principle someone may benefit from its use a second time, but my question is why did they stop using it in the first place? Generally people continue to use things they find helpful.
76.			3) In the RESCUE study the people in the comparator arm received a written action plan that those in the myCOPD arm did not receive following a hospitalisation for acute exacerbation. Hence, myCOPD is not the only difference between the two treatment arms. Is this likely to introduce bias? Would this happen in clinical practice?	• Yes this is more likely to introduce bias. Although MyCOPD is aimed at providing a personalised management plan, and therefore you could argue should be able to replace a written management plan. In our practice if we set a patient up on MyCOPD we did not issue a written management plan as well, on this basis.
77.			4) What happens to/is provided to the average patient when they are discharged from hospital after an acute exacerbation with standard care? How would you expect this to change with the introduction of myCOPD?	• Our DC bundle consists of: • BLF leaflets as appropriate on COPD, breathlessness, smoking, eating well for lung health, activity and exercise, oxygen, planning for final stages • Information leaflets on breathlessness management strategies, inhaler use, fan therapy • A personalised printed self-management plan • Referral to pulmonary rehab if appropriate and consent given • Referral to smoking cessation services if appropriate and consent given • Inhaler use discussion and technique checked, change in inhaled therapy if indicated (either through inhaler technique errors or adjustment of treatment) • In our service follow-up depends whether they have had a previous admission to hospital in the last 3 months, or if they are known to a community respiratory team. Our hospital covers 2 main CCGS, one has a community respiratory team who offer admission

avoidance and post discharge reviews, the other does not.

- If a patient has had 1 hospital admission within 3 months due to AECOPD then they get a personalised COPD DC bundle and asked to make a GP appointment for post exacerbation review within 2 weeks of discharge. In practice I do not think many of these happen. If they are already known to the community resp team then follow up is arranged with them instead of the GP. The majority of these happen.
- If a patient has had 2 or more hospital admissions within 3 months due to AECOPD then they get a personalised COPD DC bundle and they are discussed at COPD MDT and considered for a secondary care outpatient appointment, sometimes this is not appropriate if they are already under the care of a community team or would be unable or unwilling to attend the outpatient department. In some cases we will refer to Community Matrons for support.
- Hopefully the table below helps clarify this:

All patients get a personalised COPD DC bundle	Community Resp team in CCG	No Community Resp team in CCG
1 admissio	If known to Comm team request 2/52	Request 2/52 GP fu

				n in 3/12 due to AECOPD	Comm Resp team follow up If not known to Comm team request 2/52 GP fu	
				>1 admission in 3/12 due to AECOPD	Discuss at COPD MDT Consider respiratory OP appointment If known to Comm team request 2/52 Comm Resp team follow up If not known to Comm team then offer referral and 2/52 Comm resp team fu	Discuss at COPD MDT Consider respiratory OP appointment Or Community Matron referral

- In practice we did not change any of this for patients that we started on MyCOPD. MyCOPD was very much added as an extra layer of information and resource for patients, rather than a replacement. I think knowing what we now do about the use of MyCOPD I am happy that we treated it this way as I have concern

				that self-management may not have been as good if we had relied on MyCOPD alone. • Our 'frequent flier' patients all tend to be inappropriate for MyCOPD use and therefore this tool does not aid their self-management and reduce hospitalisation or unscheduled healthcare use.
78.			5) Some clinical evidence suggests there may be a reduction in GP appointments for those with COPD using myCOPD. Would you expect the subgroup of people with COPD who have just been discharged from hospital following an acute exacerbation to also have a reduction in GP visits?	• I think all patients admitted with AECOPD should be seen at their practice still as it is helpful to review their self-management plan and ensure patients know how to follow it in the future to avoid future admissions. In our experience patients are not always in a state to absorb this information fully when they are unwell in hospital and therefore it can be helpful for this to be explained when they are more stable, even at the point of discharge. • It is more likely that good quality annual reviews and personalised self-management plans, along with access to rescue packs, delivery of the NACAP COPD care bundle and appropriate support from community respiratory services are more likely to impact on unscheduled healthcare utilisation.

79.			6) Would you expect users to have additional benefits (such as a further reduction in GP visits) if they started a PR course with myCOPD when they had already been using other elements of the app?	• PR is known to have significant benefits for patients with COPD and online PR has been shown to be non-inferior to face to face PR in the TROOPER study. However, it should be noted that the research conducted in this area was by the team behind MyCOPD. They only looked at CAT symptom scores and 6 min walk distance, not at any other outcomes. Part of the benefit of face to face sessions comes from patients seeing others with similar disease, being able to talk to specialist nurses and physios and having education and information sessions as part of the programme. Benefits derived from this will not necessarily be seen in outcomes measured in their study. • I think intervention for patients with COPD should be highly personalised, and this can only be the case if whoever is providing the support is aware of guidance, and takes time to understand the particular problems of the patient and understand interventions that can be put in place to address the patient's specific problems. • In my opinion the best opportunity to provide personalised COPD Management is at the patients' annual review but it appears that GP practices are under- resourced to provide this.
80.	27/07/21	Follow up questions with Jennifer Robson (expert) via email:	1) Do you have a sense of how PR service delivery might have changed since the pandemic for standard of care? Is it likely to return to face to face sessions being offered for the majority of patients in the future?	• Our update in May from our PR team was "As an update we are due to restart face to face groups in June/July. We are only accepting new referrals for the virtual programme while we are working through our lists, but we will accept patients for face to face from the hospital if they are discharged following an exacerbation of their COPD, or requiring Pulm Rehab prior to a lung transplant."

				• As per my comments on MyCOPD I do have concerns that this means there could be a large number of patients in digital poverty that may not be able to access Pulmonary Rehab as, unless they have been in hospital or are awaiting assessment for transplant they will not be able to access fact to face programmes.
81.			2) How long does it take, on average, to register a patient for a myCOPD licence, including time taken to explain to them how to use it? What staff member (please specify band if possible) would typically do this?	• On average I would say it takes about 30-45 minutes to explain MyCOPD and set it up. We will register them and add their medications to the self-management plan. However, we do not then sit with the patient and teach them how to use the interface in any great detail, or how to input any extra details, such as lung function results, vaccination. We also do not monitor their use or get in touch with them after discharge to see if they are using it or if they need any help. We are not resourced to be able to provide this. • We initially had a challenge talking to patients about the app because there was no patient information leaflets for us to give to the patients. We were given a test patient log in but the user name and password was so cryptic that we needed to have it written down. We also do not have tablets or laptops to actually show the patients or set it up with the patient at the bedside. Therefore, we need to go away to an office or desktop computer to set up. We did approach MyMHealth about this and did not get anywhere with them for quite some time. Eventually we got a small promotional leaflet that we could hand to the patient. Our rep also stated that we may be able to get a couple of tablets, but that never happened. This all added time to our patient setup and explanation,

				however, I suppose if you were in a clinic room and had a computer there with you it may be quicker. You would have the benefit of being able to demonstrate the interface and how to navigate around the tiles etc. • Our team only consists of Band 6 and Band 7 staff so they are the ones who have the patient contact and set-up the licence. I suspect a Band 4 or 5 member of staff would be able to do this also, if they have the training.
82.			3) How long does it take to implement staff licenses for use of myCOPD, for example to cover someone implementing licenses to all staff expected to use the app with patients for a whole CCG? Would 1 day of a band 6 practice manager seem reasonable to cover use of myCOPD for a CCG?	• I wasn't involved in setting up the teams access so can't comment. It was approx. 4 years ago that we received the training and I think it was at least an hour and then we went away and had a play with it.
83.			4) The company has assumed the following training requirements to implement myCOPD for a CCG: • Number of staff members trained per CCG: Average of 50 (1 per practice) if purchased at CCG level • Level of staff: Practice nurse (band 5) • Length of training: 1 hour • Frequency: One-off Please can you comment on whether you think this is reasonable for use of the app with patients?	• As above I think it would be at least an hour to learn how to use the app fully, including how to monitor patients etc. I would think there was then a bit of extra training on how to set up other members of staff. The clinicians would then probably want to go away and trial it themselves to make sure that they were happy in how to use it fully, both in clinician mode, and patient mode. So I suspect in reality the 'learning time' would be greater than an hour. • I also remember that we had great difficulty in the training session as the trusts security firewall prevented us from logging in initially, we had to use the reps laptop and all gather around. I'm not sure what had to be done at trust or MyMHealth ends to rectify this problem., or whether this has potential to be a problem now we are 4 years down the line. When we did get access and the firewall would allow us on the web browser was not up to date

				enough to display properly which resulted in struggles seeing all of the tiles, and inputting info etc. Again, I am not sure if this has the potential to be a problem in some practices/CCGs.
84.			5) You mentioned the TROOPER study in one of your answers and how they only look at CAT scores and the 6 min walk test. Do you think it's reasonable to expect that the non-inferiority demonstrated for those outcomes would extend to a similar reduction in acute exacerbations following f2f PR being seen with myCOPD PR?	• There is some small scale evidence to say that 6min walk distance, speed and desaturations can be used to predicted mortality and hospitalisation, therefore these measures could be a surrogate indicator of these. Similarly, the CAT score can also assist predication of COPD exacerbations, and therefore may act as a surrogate measure. However, the BODE index is probably the most sensitive measure of risk of exacerbation, hospital admission and mortality, although this has its limitations also. • With this in mind then the non-inferiority could potentially demonstrate a reduction in AECOPD. However, I think this should be evaluated further. With so many PR services now offering virtual platforms, in many different ways, now would be a great time for somebody to study this.
85.	23/07/2021	Email correspondence with Megan Dale (Cardiff and Vale UHB – CEDAR) to clarify the description of PCAs	From the calculations provided last week, it still seems that the proportion of patients eligible for PR (29.69% in the model) is calculated using QOF data including PCAs (the denominator excluding them appears to be much lower at 174,784). Please can you confirm whether this is intentional and talk through the reasons for including/excluding PCAs?	• The value of 347,631 COPD patients who are eligible for PR which has been used includes all the patients who are classified as “PCA”s. This was deliberate, however the submission wording I used may have been confusing. (It was described as excluding PCAs (personalised care adjustments), which I intended to mean that the adjustment process had been excluded and the larger number of patients used).

				• PCAs represent those people who meet the eligibility criteria for PR, but don't do it for a reason that is beyond the control of the GP (and therefore they should not be penalised for these). Around 2/3rds of the PCAs for PR are that the patient declines PR. Other reasons include no availability. The prevalence of these PCAs could be reduced by having a more accessible version of PR (such as myCOPD). Therefore, we use the population that includes these patients.
86.	27/07/21	Lisa Ward (expert) was contacted via email to answer the following questions:	1) In your experience, what proportion of COPD patients would be willing to use myCOPD following an acute exacerbation in hospital? Has this, or is this likely to, change since the coronavirus pandemic?	• 80% either the patient or a family member
87.			2) Is it feasible that a patient could benefit from using myCOPD more than once? For example, if they were to start using it after a hospitalisation for acute exacerbation but their usage tailed off, would they likely get the same/some benefits from using the app again following another hospitalisation episode?	• Yes
88.			3) In the RESCUE study the people in the comparator arm received a written action plan that those in the myCOPD arm did not receive following a hospitalisation for acute exacerbation. Hence, myCOPD is not the only difference between the two treatment arms. Is this likely to introduce bias? Would this happen in clinical practice	• I don't understand this question.
89.			4) What happens to/is provided to the average patient when they are discharged from hospital after an acute exacerbation with standard care? How would you expect this to change with the introduction of myCOPD?	• They are discharged to Community Respiratory nurse teams to follow up and visit if needed. They all are managed using the COPD Bundle and also offered my COPD app along with our local leaflet for self-management.

90.			5) Some clinical evidence suggests there may be a reduction in GP appointments for those with COPD using myCOPD. a) Would you expect the subgroup of people with COPD who have just been discharged from hospital following an acute exacerbation to also have a reduction in GP visits?	• I'm not sure but I am sure it is possible. It would depend on the engagement and quality of the interaction when signed up to the APP.
91.			b) If yes, would the magnitude of this reduction be similar to the general COPD population?	• I'm not sure.
92.			6) Would you expect users to have additional benefits (such as a further reduction in GP visits) if they started a PR course with myCOPD when they had already been using other elements of the app?	• Yes, I would.
93.			7) The company has assumed that the additional support required for people to use myCOPD for PR (as opposed to face to face PR) would comprise: i. An initial 60-minute assessment to determine suitability and take baseline measurements ii. A 60-minute assessment on completion of the programme to determine improvements in patient performance iii. Three 10-minute phone calls throughout to assist with queries etc. Please can you comment on: a) Whether the time allowed for assessments and phones calls would likely be sufficient?	• Yes
94.			b) What band of staff member would likely carry out these assessments and phone calls?	• Trained person Band 3 and above

95.			c) If there are any additional resources required?	• Video calling devices
96.			8) How long does it take, on average, to register a patient for a myCOPD licence, including time taken to explain to them how to use it? What staff member (please specify band if possible) would typically do this?	• Band 3 upwards in respiratory care. It takes between 15-30 mins to do it properly.
97.			9) How long does it take to implement staff licenses for use of myCOPD? Would 1 day of a band 6 practice manager seem reasonable to cover a CCG?	• I'm not sure.
98.			10) If myCOPD were to be implemented (or has already been implemented) what would you expect the impact to be in terms of referrals to PR i.e. would capacity to deliver PR increase and if so would referrals be likely to increase?	• An increase in referrals and more capacity would be available.
99.			11) The company has assumed the following training requirements to implement myCOPD for a CCG: • Number of staff members trained per CCG: Average of 50 (1 per practice) if purchased at CCG level • Level of staff: Practice nurse (band 5) • Length of training: 1 hour • Frequency: One-off Please can you comment on whether you think this is reasonable for use of the app with patients who have been discharged following acute exacerbation in addition to those referred for PR services?	• I think it is fine.
100.			12) The company has provided an additional scenario where myCOPD is purchased by a PR service provider for use to deliver PR programmes only. In this case only 5 members of staff are assumed to be trained (to cover around 500 referrals per year, approximately 20% of which are expected to be delivered via	• I don't know.

			myCOPD). Please can you comment on whether this seems reasonable?	
101.			13) The TROOPER study demonstrated non-inferiority between face to face PR and PR delivered via myCOPD in various outcome measures including the 6-minute walk test and CAT scores. Is it reasonable to expect that this would extend to a similar reduction in the rate of acute exacerbations being seen between the two treatment delivery methods?	• I expect it to be possible that it will result in reduction of admissions for simple exacerbations.
102.	29/07/2021	Query to the corresponding author of the RESCUE study by email (Tom Wilkinson)	'We would like to know if you managed to record the treatment for those who had an exacerbation and were also readmitted in the 90 days. For example, if people with an exacerbation had either a primary care or non-admitted secondary care visit, would their readmission follow this, or would the readmission be instead of the primary care/non-admitted secondary care visit in some cases? If this did occur and you have recordings of specific numbers for each arm (myCOPD and TAU) then that would be really helpful.'	• The route to hospitalisation was via GP referral unless it was an acute emergency. • I do not have the data as to the granular detail of reporting at the time of readmission but the assumption should be all subjects contacted their GP prior to admission as this was the self-management advice for all
103.	30/07/2021	Further query to Lisa Ward (Expert) in response to her being unable to answer the list of questions for the clinical experts	Do you have a sense of the proportion of patients that are likely to agree to use myCOPD (either alone or as part of a hybrid approach using myCOPD with reduced face to face PR sessions) rather than having face to face PR?	• Responded that Mid and South Essex NHS FT are currently using myCOPD in PR and that Jenny Gates would be the person to speak to.
104.	30/07/2021	Query to Jenny Gates (Expert) as a follow on from query to Lisa Ward	Given you are still using myCOPD for PR we were wondering if you would be able to give us an idea of what the uptake is like? Do you have a sense of the proportion of patients that are likely to agree to use myCOPD (either alone or as part of a hybrid approach using myCOPD with reduced face to face PR sessions) rather than having face to face PR.	• We use myCOPD to support delivery of our home programme in eligible patients. The home programme makes up around 10% of our service. Patients are offered myCOPD or a paper-based programme. Around 4% of patients undertaking PR chose the home programme using myCOPD.

105.	30/07/2021	Query to the company	We are currently looking for real-world evidence uptake data (rather than usage data) for myCOPD specifically in the AECOPD population (those discharged from hospital with an acute exacerbation). For example, out of those offered myCOPD who have just been discharged from hospital with an acute exacerbation, how many people agree to be registered for myCOPD? Whilst the RESCUE study does provide an indication of uptake through the flow diagram of study participants, data from a real-world setting for this particular population would be useful. Have you any information for this you could provide?	• No response from company
106.	04.08.21	Call with Nawar Barkerly (Expert) to discuss questions related to the submission	1) In your experience, what proportion of COPD patients would be willing to use myCOPD following an acute exacerbation in hospital? Has this, or is this likely to, change since the coronavirus pandemic?	• Important to remember around 70% of the cohort would have access to a smart phone. It is then difficult to determine within this population would be attracted to using the app. Someone new with acute exacerbation maybe more inclined to use to gain information. I estimate around 50/60% of those with access to smart phones would be willing to use the app.
107.			2) Is it feasible that a patient could benefit from using myCOPD more than once? For example, if they were to start using it after a hospitalisation for acute exacerbation but their usage tailed off, would they likely get the same/some benefits from using the app again following another hospitalisation episode?	• I don't think it is a very strong hypothesis as it is unlikely to see benefits. I question what the difference between someone is having the app and not using it 6 months down the line then having another acute exacerbation hospitalisation and then being reintroduced to the app. It may be difficult to motivate them to use the app. I doubt it will be useful, however it is a complex environment.

108.			3. In the RESCUE study the people in the comparator arm received a written action plan that those in the myCOPD arm did not receive following a hospitalisation for acute exacerbation. Hence, myCOPD is not the only difference between the two treatment arms. Is this likely to introduce bias? Would this happen in clinical practice?	• It is standard care for a written action plan to be given out in clinical practice. This is driven by the good practice tariff which prior to discharge a bundle is given to the patient (inhaler discussion, smoking cessation, PR referral assessment, written action plan etc.). This will include a written action plan. I believe this is likely to continue and this will be used on top of the app. However, not likely to introduce bias.
109.			1) What happens to/is provided to the average patient when they are discharged from hospital after an acute exacerbation with standard care? How would you expect this to change with the introduction of myCOPD?	• See above answer
110.			2) Some clinical evidence suggests there may be a reduction in GP appointments for those with COPD using myCOPD. **a.** Would you expect the subgroup of people with COPD who have just been discharged from hospital following an acute exacerbation to also have a reduction in GP visits?	• Unable to answer for this population
111.			• Would you expect users to have additional benefits (such as a further reduction in GP visits) if they started a PR course with myCOPD when they had already been using other elements of the app?	• Hypothetically yes, it is likely, as there is existing evidence.

112.			3) The company has assumed that the additional support required for people to use myCOPD for PR (as opposed to face-to-face PR) would comprise: i. An initial 60-minute assessment to determine suitability and take baseline measurements ii. A 60-minute assessment on completion of the programme to determine improvements in patient performance iii. Three 10-minute phone calls throughout to assist with queries etc. Please can you comment on: a) Whether the time allowed for assessments and phones calls would likely be sufficient b) What band of staff member would likely carry out these assessments and phone calls c) If there are any additional resources required	*a)* This is crucial as it tells you if the patient has benefited, if the patient does this themselves they may cheat. Depends on type of assessment but probably yes. Time for phone call sufficient *b)* Band 5/6 *c)* Only video links if this doesn't happen already - this would be better as you would pick up some clinical information.
113.			• How long does it take, on average, to register a patient for a myCOPD licence, including time taken to explain to them how to use it? What staff member (please specify band if possible) would typically do this?	• No idea as have never done it. If it takes longer than 3 minutes that is too much.
114.			• How long does it take to implement staff licenses for use of myCOPD? Would 1 day of a band 6 practice manager seem reasonable to cover a CCG?	• Cannot answer this question as no experience of it

<table>
<tr><td>115.</td><td></td><td></td><td>• If myCOPD were to be implemented (or has already been implemented) what would you expect the impact to be in terms of referrals to PR i.e. would capacity to deliver PR increase and if so would referrals be likely to increase?</td><td>• I think capacity would increase as there is a cohort of people who can’t go to from one place to the other due to external factors. Need to be careful with increasing capacity and making conclusions about consequences. Increasing capacity may impact capacity elsewhere and increased capacity would mean you would need increased staff.</td></tr>
<tr><td>116.</td><td></td><td></td><td>4) The company has assumed the following training requirements to implement myCOPD for a CCG:
<table><tr><td>Number of staff members trained per ccg</td><td>Average of 50 (1 per practice) if purchased at ccg level</td></tr><tr><td>Level of staff</td><td>Practice nurse (band 5)</td></tr><tr><td>Length of training</td><td>1 hour</td></tr><tr><td>Frequency</td><td>One-off</td></tr></table>Please can you comment on whether you think this is reasonable for use of the app with patients who have been discharged following acute exacerbation in addition to those referred for pr services?</td><td>• No time to answer</td></tr>
<tr><td>117.</td><td></td><td></td><td>5) The company has provided an additional scenario where myCOPD is purchased by a PR service provider for use to deliver PR programmes only. In this case only 5 members of staff are assumed to be trained (to cover around 500 referrals per year, approximately 20% of which are expected to be delivered via myCOPD). Please can you comment on whether this seems reasonable?</td><td>• No time to answer</td></tr>
</table>

118.			6) The TROOPER study demonstrated non-inferiority between face to face PR and PR delivered via myCOPD in various outcome measures including the 6-minute walk test and CAT scores. Is it reasonable to expect that this would extend to a similar reduction in the rate of acute exacerbations being seen between the two treatment delivery methods?	• No time to answer
119.			• Do you have a sense of how PR service delivery might have changed since the pandemic for standard of care? Is it likely to return to face-to-face sessions being offered for the majority of patients in the future?	• Likely change as there is now more appetite for being remote. People are more used to it and prefer remote services since the pandemic.
120.	05/08/2021	Email queries to the Paris Moakes - NHS Castle Point and Rochford CCG - the MSE lead for myMhealth app delivery	1) What proportion of purchases of myCOPD are made by the CCG rather than the PR service provider? 2) In the company submission it is assumed there are approximately 500 referrals per year to a PR service. This is based on a median reported by the NACAP audit. Do you agree with this figure?	• No response
121.	06/08/21	Email query to the company	Once the 3-year unlimited licence contract is over, does a new 3-year contract begin or does it become a rolling 1-year contract?	• Thank you for the query. At the end of the Unlimited contract (3 years), the group will then sign-up to a following 3-year contract, not a 1-year rolling contract.

Appendix 1.

During correspondence with the company and experts, additional information is sometimes included as file attachments, graphics and tables. Any questions that included additional information of this kind is added below in relation to the relevant question/answer:

File attachments/additional information from question 51 and 60:

1. Proportion of patients referred to GP

The QOF data for COPD008 gives a referral rate of 43%, however this has only been collected for one year and clinical advice was that this may include higher than normal numbers of inappropriate referrals and did not reflect their normal experience.

NACAP data and several reports such as NHS Long Term plan report percentages of around 15%. A small amount of this difference may be that NACAP data is based on MRC3 and above patients as the denominator, and QOF data uses eligible patients as the denominator (based on MRC3, but with additional conditions).

Therefore, we have applied 40% (from COPD Prime) to all patients with a diagnosis of COPD (as recorded in QOF 2020), to give the number with MRC3, and applied 15% (COPD Prime, NACAP 2018) to give the number of patients referred.

This new number is used to calculate 20.21% of all eligible patients recorded in QOF. We accept that there is some uncertainty around this, and that is reflected in the sensitivity analysis submitted."

Numbers in bold, black are reported in the associated reference (full references listed in report).

Other numbers are calculated from these, as shown. Results used in model are in red. Use population eligible from QOF (see tab), 29.69% of those registered with COPD (347,631 eligble for PR, excluding PCAs)

Use 20.21% referred to PR, as this is the equivalent to 15% if had taken NACAP denominator.

QOF 2020	COPD Prime	NACAP 2018	apply 40% and 15% to QOF	Used in model
60,407,685	56,817,654			
	2.94%			
	1,667,600			
1.94%	1.82%			
1,170,786	1,034,578			
	40.00%		40.00%	
	413831.2	446,000	468,314	
29.69%				
347,631				
42.65%	15.00%	15.25%	15.00%	20.21%
148,273	62,075	68,000	70,247	70,247

2. Quality Outcomes Framework Data

NHS Digital

COPY TAKEN TO ACCOMPANY myCOPD SUBMISSION (original available on NHS Digital website)

% eligible **29.69% equal to COPD08 patients eligble including PCAs / total COPD patients registered**

Table 10: Prevalence, achievement and personalised care adjustments, respiratory group, COPD, 2019-20, region and national level

**Indicators in this group have changed*

Return to Contents

			Prevalence							
			2018-19				2019-20			
Region ODS code	Region ONS code	Region name	Number of practices	List size	Register	Prevalence (%)	Number of practices	List size	Register	Prevalence (%)
ENG	E92000001	England	6,664	58,336,119	1,125,714	1.93	6,720	60,407,685	1,170,786	1.94

The percentage of patients with COPD and Medical Research Council (MRC) dyspnoea scale ≥3 at any time in the preceding 12 months, with a subsequent record of an offer of referral to a pulmonary rehabilitation programme (excluding those who have previously attended a pulmonary rehabilitation programme)

COPD008							
Achievement Score (max 2 per practice)	Numerator	Denominator	Underlying Achievement net of PCAs (%)	PCAs	PCA Rate (%)	Denominator plus PCAs	Patients receiving Intervention (%)
11,438.57	148,273	174,784	84.83	172,847	49.72	347,631	42.65

3. Cost of PR service calculations

Cost of PR service, adapted from COPD Prime

	COPD Prime		
Expense	**osts per patie**	**2020 PSSRU**	
Staffing	£295.95	£640.19	Derived below
Patient transport	£0.00	7.072	66% of programmes do not fund (National Audit)
Staff travel	£26.00	£26.00	Figure from KSS Survey
Facilities hire	£22.00	£22.00	Figure from KSS Survey
Other overheads	£0.00		Data not available. Can be input
Total Costs Per Patient	£343.95	**£695.26**	

37.5 hours per week

Staff Costs (Derived From National Audit)

From COPD Prime (not used)

Band	WTE	PSSRU 2020			Band Midpoint sa	Cost	
		Annual salary	**overhead**	**Annual cost**			**Total**
2	0.178571429	£17,609	218%	£38,303.13	£16,210.00	£2,894.64	£6,839.84
3	0.629464286	£18,283	218%	£39,769.21	£17,972.00	£11,312.73	£25,033.30
		Hourly rate	Weeks per ye	Annual cost			
4	0.252232143	£30	42.4	£47,700.00	£20,844.00	£5,257.53	£12,031.47
5	0.218191964	£39	41.9	£61,278.75	£24,555.00	£5,357.70	£13,370.53
6	0.685267857	£49	41.9	£76,991.25	£30,057.00	£20,597.10	£52,759.63
7	0.587053571	£59	41.9	£92,703.75	£35,891.00	£21,069.94	£54,422.07
8a	0.116629464	£68	41.9	£106,845.00	£43,436.50	£5,065.98	£12,461.28
8b	0.011160714	£81	41.9	£127,271.25	£51,362.50	£573.24	£1,420.44
Total	**2.678571429**					**£72,128.86**	**£178,338.56**

COPD Prime results:

Pension contribution	14%		
Total Cost with pension	£82,443.29	£178,338.56	
Referrals per 1.0 WTE	104		Source: National Audit
Referrals per total WTE	279		Referrals per 1 WTE * Total WTE
Cost per patient, staffing	**£295.95**	£640.19	Cost with pension/Referral per total WTE

4. NHS cost collection 2018/19

Back to Inde: **National Schedule of NHS Costs - Year 2018-19 - NHS trusts and NHS foundation trusts**
ACCIDENT & EMERGENCY
(Selected to only include non-admitted, no other selection)

Service Code	Service Description	Currency Code	Currency Description	Attendances	National Average Unit Cost	Total Cost	No. Data Submissions
T04NA	Type 04 non admitted	VB01Z	Emergency Medicine, Any Investigation with Category 5 Treatment	1	£11	£11	1
T04NA	Type 04 non admitted	VB08Z	Emergency Medicine, Category 2 Investigation with Category 1 Tre	670	£27	£17,794	3
T01NA	Type 01 non admitted	VB10Z	Emergency Medicine, Dental Care	2,056	£36	£74,477	7
T03NA	Type 03 non admitted	VB10Z	Emergency Medicine, Dental Care	16	£37	£593	4
T04NA	Type 04 non admitted	VB07Z	Emergency Medicine, Category 2 Investigation with Category 2 Tre	210,216	£39	£8,128,510	4
T04NA	Type 04 non admitted	VB09Z	Emergency Medicine, Category 1 Investigation with Category 1-2 T	36,798	£41	£1,525,810	4
T04NA	Type 04 non admitted	VB03Z	Emergency Medicine, Category 3 Investigation with Category 1-3 T	10,707	£44	£476,249	2
T04NA	Type 04 non admitted	VB11Z	Emergency Medicine, No Investigation with No Significant Treatmen	240,323	£45	£10,815,573	5
T04NA	Type 04 non admitted	VB06Z	Emergency Medicine, Category 1 Investigation with Category 3-4 T	89,503	£51	£4,583,004	3
T03NA	Type 03 non admitted	VB03Z	Emergency Medicine, Category 3 Investigation with Category 1-3 T	81,433	£56	£4,567,899	13
T03NA	Type 03 non admitted	VB09Z	Emergency Medicine, Category 1 Investigation with Category 1-2 T	739,421	£56	£41,590,247	32
T03NA	Type 03 non admitted	VB11Z	Emergency Medicine, No Investigation with No Significant Treatmen	541,575	£57	£30,613,741	32
T04NA	Type 04 non admitted	VB05Z	Emergency Medicine, Category 2 Investigation with Category 3 Tre	1	£66	£66	1
T03NA	Type 03 non admitted	VB06Z	Emergency Medicine, Category 1 Investigation with Category 3-4 T	26,805	£72	£1,919,617	24
T02NA	Type 02 non admitted	VB09Z	Emergency Medicine, Category 1 Investigation with Category 1-2 T	8,830	£73	£643,915	7
T03NA	Type 03 non admitted	VB99Z	Emergency Medicine, Patient Dead On Arrival	58	£79	£4,554	3
T01NA	Type 01 non admitted	VB11Z	Emergency Medicine, No Investigation with No Significant Treatmen	120,226	£80	£9,669,107	79
T02NA	Type 02 non admitted	VB08Z	Emergency Medicine, Category 2 Investigation with Category 1 Tre	777	£85	£66,372	7
T03NA	Type 03 non admitted	VB07Z	Emergency Medicine, Category 2 Investigation with Category 2 Tre	63,499	£89	£5,630,970	27
T03NA	Type 03 non admitted	VB08Z	Emergency Medicine, Category 2 Investigation with Category 1 Tre	84,599	£89	£7,530,711	26
T02NA	Type 02 non admitted	VB06Z	Emergency Medicine, Category 1 Investigation with Category 3-4 T	733	£89	£65,295	2
T03NA	Type 03 non admitted	VB01Z	Emergency Medicine, Any Investigation with Category 5 Treatment	43	£93	£4,005	7
T04NA	Type 04 non admitted	VB10Z	Emergency Medicine, Dental Care	1	£99	£99	1
T02NA	Type 02 non admitted	VB05Z	Emergency Medicine, Category 2 Investigation with Category 3 Tre	10	£106	£1,056	4
T03NA	Type 03 non admitted	VB05Z	Emergency Medicine, Category 2 Investigation with Category 3 Tre	2,476	£111	£274,334	21
T02NA	Type 02 non admitted	VB04Z	Emergency Medicine, Category 2 Investigation with Category 4 Tre	5	£119	£596	2
T01NA	Type 01 non admitted	VB09Z	Emergency Medicine, Category 1 Investigation with Category 1-2 T	173,745	£121	£21,062,676	74
T02NA	Type 02 non admitted	VB11Z	Emergency Medicine, No Investigation with No Significant Treatmen	12,431	£122	£1,517,847	7
T03NA	Type 03 non admitted	VB02Z	Emergency Medicine, Category 3 Investigation with Category 4 Tre	54	£135	£7,291	2
T02NA	Type 02 non admitted	VB07Z	Emergency Medicine, Category 2 Investigation with Category 2 Tre	91	£137	£12,476	6
T01NA	Type 01 non admitted	VB99Z	Emergency Medicine, Patient Dead On Arrival	236	£140	£33,011	20
T01NA	Type 01 non admitted	VB06Z	Emergency Medicine, Category 1 Investigation with Category 3-4 T	16,627	£140	£2,334,413	61
T02NA	Type 02 non admitted	VB03Z	Emergency Medicine, Category 3 Investigation with Category 1-3 T	167	£157	£26,192	5
T03NA	Type 03 non admitted	VB04Z	Emergency Medicine, Category 2 Investigation with Category 4 Tre	1,134	£160	£181,210	15
T01NA	Type 01 non admitted	VB08Z	Emergency Medicine, Category 2 Investigation with Category 1 Tre	135,622	£171	£23,165,407	76
T01NA	Type 01 non admitted	VB07Z	Emergency Medicine, Category 2 Investigation with Category 2 Tre	59,263	£200	£11,876,847	65
T01NA	Type 01 non admitted	VB05Z	Emergency Medicine, Category 2 Investigation with Category 3 Tre	10,209	£229	£2,333,668	53
T02NA	Type 02 non admitted	VB02Z	Emergency Medicine, Category 3 Investigation with Category 4 Tre	2	£232	£464	1
T01NA	Type 01 non admitted	VB04Z	Emergency Medicine, Category 2 Investigation with Category 4 Tre	15,234	£245	£3,732,385	64
T02NA	Type 02 non admitted	VB01Z	Emergency Medicine, Any Investigation with Category 5 Treatment	87	£253	£21,990	2
T01NA	Type 01 non admitted	VB03Z	Emergency Medicine, Category 3 Investigation with Category 1-3 T	24,745	£287	£7,098,323	63
T01NA	Type 01 non admitted	VB01Z	Emergency Medicine, Any Investigation with Category 5 Treatment	470	£342	£160,715	37
T01NA	Type 01 non admitted	VB02Z	Emergency Medicine, Category 3 Investigation with Category 4 Tre	3,613	£372	£1,343,794	53

WEIGHTED AVERAGE
£74.82

NICE National Institute for Health and Care Excellence

National Institute for Health and Care Excellence

Centre for Health Technology Evaluation

Pro-forma Response

External Assessment Centre Report factual check

DHT001 myCOPD for self-management of chronic pulmonary obstructive disease

Please find enclosed the assessment report prepared for this assessment by the External Assessment Centre (EAC).

You are asked to check the assessment report from York Health Economics Consortium External Assessment Centre to ensure there are no factual inaccuracies contained within it. If you do identify any factual inaccuracies you must inform NICE by midday (12am), **18th August 2021** using the below proforma comments table. All your comments on factual inaccuracies will receive a response from the EAC and when appropriate, will be amended in the EAC report. This table, including EAC responses will be presented to the Medical Technologies Advisory Committee and will subsequently be published on the NICE website with the Assessment report.

12 August 2021

Issue 1

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Many typos and Syntax errors – example Figure 3.1	Corrections	Reflects a large document created at pace.	Thank you we have updated those typos detailed under Issue 2. Figure 3.1 was submitted by the company and therefore cannot be updated by the EAC.

Issue 2

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
p20, para 2, sentence 2 P97, para 1, sentence 3 P101, assumption5 P113, para 1 P128, para 2, last sentence P159, last para, sentence 2 P130 and p92:	‘health records’. ‘patient’ ‘half’ ‘outcomes’ ‘inaccurate’ replace ‘cost benefits’ with ‘benefits’ There seems to be a rogue Vancouver style reference [29] and (29). I think this should be McLaughlin & Skinner (2020).	Minor typos	Thank you, these have been corrected.

Issue 3

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
P22, paragraphs 2 and 4: There is some confusion about references for the myCOPD studies	"3 documents on TROOPER (Bourne et al. 2017, Wilkinson et al. 2017, My mhealth Ltd 2015a), 3 documents on RESCUE (North et al. 2018, My mhealth Ltd 2015b, North et al. 2020), ***2 documents on EARLY*** (Crooks et al. 2020), (My mhealth Ltd 2015a) and 3…"		Thank you, this has been updated.

Issue 4

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
P44 Statement - The EAC noted that, in TROOPER and RESCUE trials, participants in the intervention arm received usual care, but that this was not fully aligned with usual care in the comparator arm. This section is incorrect – see justification	Remove the incorrect explanation.	In TROOPER, randomisation was between PR delivered by myCOPD or by face-to-face classes. The face-to-face delivery mode is usual care. The study text states that patients were randomised "to either the online arm (myPR) or to receive standard face-to-face PR". These participants had 2 face-to-face PR sessions per week for 6 weeks, as is standard. Patients attending PR are encouraged to continue the exercises at home during and after the PR course. BTS Guidelines state: "In line with	This is not factually inaccurate. The scope states the intervention should be myCOPD plus standard of care but in these two studies myCOPD was not the only difference between the two arms as stated in study description the justification for amendment. No change made.

		published pulmonary rehabilitation studies and the outcomes they demonstrate, a third session of prescribed exercise is recommended. This can be performed unsupervised. Encouragement of regular physical activity five times a week for 30 min each time is encouraged in line with standard healthy living advice." In RESCUE, randomisation was between myCOPD or a written self-management plan. This provision of a self-management plan is usual care and should be received by all patients (See NICE guidelines). Thus, there was not *additional* interventions, just different elements of usual care. Additionally, this should bring the studies fully into scope.	

Issue 5

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
P48, para 3; The EAC states that it is not clear how the 43 participants in the Grampian interim evaluation were selected.	The 43 patients were from a single centre.	The poster on this project (McLaughlin and Skinner) states that 3 practices were involved in the evaluation (n = 64) and the 43 patients invited to the interim analysis were from a single	This is not factually inaccurate. The poster does not state the reason for selecting this practice or these patients for the interim evaluation. Therefore, no change made.

		practice. This was the only practice that took part in the interim evaluation	

Issue 6

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
P51 – With regards to the co-authorship of TROOPER and RESCUE, there is failure to highlight the mitigations that were taken to avoid the reported potential bias.	Added language around the use of an independent, established, highly published, clinical trials unit (Imperial College London CTU) to review the data and perform the analysis to avoid such biases.	Whilst it is entirely agreed that these were co-founders/employees and there was a potential for bias, the company put in mitigations to remove that bias.	The following sentence has been added 'The company advises that the authors were not involved in reviewing the data or performing analysis and that this was undertaken by Imperial College London clinical trial unit in order to reduce such biases.'.

Issue 7

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
P59, bottom; The EAC state that no RWE reported evidence on the number of acute exacerbations.	Include reference to McLaughlin and Skinner data (even though it is not used in economic analysis for this parameter).	McLaughlin and Skinner reported that in the interim analysis of the Grampian evaluation "The proportion reporting exacerbations every other day reduced from 28% before using myCOPD to 22% six months after."	Thank you this has been updated. We have also updated Tables 4.2a and 7.1 to include this.

Issue 8

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
S7 P76 Table 7.1 and following summary The table lays out information reporting improvements in CAT score (RCT and RWE), reductions in hospital readmissions (RCT and RWE), improvement in the reduction of inhaler errors (RCT and RWE), adherence that has continued to increase through app activation and usage, that included PR, HRQoL that was equivalent to traditional care and improved 6MWT (RCT and RWE). The following summary suggests this evidence is “weak” despite having RCT evidence confirmed by RWE.	Consideration of a change of language – the table is very positive; the summary should reflect the table.	The power and effect change in these studies were provided to demonstrate equivalence or benefit which was successful and confirmed by RWE. The table and the following summary appear incongruent. The data supports the aims to provide a viable alternative to traditional face-to-face which is failing to deliver to its demand. The two-fold benefit in inhaler use may well underpin many of the benefits. If a clinician believes a medication should be prescribed, it should be administered correctly to have the desired effect. myCOPD delivers this for inhalers through its use as an intervention supporting this.	The word ‘weak’ has now been removed from this sentence.

Issue 9

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
S8 P76 – incorrect statement	This is a poorly written statement. In the context of COPD and its nature and the demographics	It is unclear what this statement is aiming to say; that the studies *were*	We were unable to identify this sentence in the report. The sentence on P76

'it is unlikely that these recruitment methods would not recruit hard to reach COPD patients'	of the people affected by the condition, these studies would reach "hard to reach" groups. The statement says "unlikely to not". Please can we clarify, remove the double negative or simply rewrite.	*unlikely* to recruit hard to reach people, or that they were *more than likely* to recruit hard to reach people. Not clear what justification has been used to make this statement – unlikely. RESCUE recruited patients from hospital during AECOPD. This is a cohort of patients defined by disease activity, exacerbation risk and poor clinical outcomes. This is a group that is by definition "hard to reach," frequently being admitted to hospital due to poor connection with healthcare, poor self-care and self-efficacy.	currently reads "It is likely that these recruitment methods would not recruit hard to reach COPD patients." and does not contain a double negative. Therefore, no change made.

Issue 10

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
S8 P77 para2 – This paragraph misunderstands the comparator and what constitutes "usual care"	This should be removed as it is referring to the self-management plan.	See issue 2. This time though the comparators are being reported as in scope sentence 1. Again, there is reference to the additional written support – this is the self-management plan and should be provided to all patients with COPD.	We have updated the sentence to say "including" rather than "with" so the sentence now reads "This was reflected in the studies which included face-to-face PR, usual care *including* additional written support and usual care (undefined) as comparators."

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Issue 11

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
S8 P78 – myCOPD is beneficial to only two populations eg Section 11 – PR and AECOPD. This is not true from the evidence presented. The document fails to address the magnitude of the importance of good inhaler technique and the success myCOPD has had in improving this.	Inhaler technique is an essential part of managing respiratory conditions in all settings. myCOPD provided a supportive resource in all settings, RCT and RWE, improving some centres from 48% to 91% (Grampian). This is a hugely successful and impactful finding given the ubiquitously poor inhaler technique and the cost of inhalers to the NHS. This element of myCOPD, improving inhaler technique in all environmental settings and in patients with mild to severe disease, would play an essential role in the effective delivery of inhaled medications to all patients receiving inhaled treatment, reduce costs from ill health and wastage, of drugs and medications but also devices.	This facet of myCOPD has been overlooked. Its success was common to the papers and to the RWE reports. It is also likely that is plays a pivotal role in all the downstream impacts of respiratory treatment (improving drug delivery and bioavailability), reducing wastage (of drug and devices) and reducing costs (through sustaining health and reducing prescriptions). This function of myCOPD provides another population of individuals that would benefit from its use – those people on inhaled medication. Despite there being no economic costs associated with this at this stage, there is clearly benefit to this on many levels, not least complying with NICE guidelines and the delivery of such training in the annual review and on switching medications.	Evidence on inhaler technique has been extracted and is reported throughout Section 5. As stated in the clinical conclusions (Section 10.1) using myCOPD is demonstrated to be associated with improved inhaler technique. No change made.

Issue 12

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
P80 Table 8.1 Lack of evidence supporting coordination of patient services	Language change to highlight the use of myCOPD for the delivery of PR and inhaler technique (different care elements) across different services (different services).	It is not clear from your documentation what constitutes "coordination of patients' care or services". It is clear that NHS services, trusts, CCG's and other sectors are introducing and using myCOPD as well as PR providers, that are not part of the same organisations. These two groups are not part of the acute trusts managing AECOPD. To do this there must be coordination of both patient care and the services patients receive.	'Coordination of patients' care or services was taken from the claimed benefits defined in the NICE scope. No evidence presenting outcomes on this was provided and therefore no change has been made.

Issue 13

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
P80 – Error in referencing scope, as explained above – the alignment of intervention.	This should be removed as explained above, given the use of usual care.	The comparators were utilising usual care.	See response to Issue 4. No change made.

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Issue 14

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
P80 – Weakness of lack of long-term follow up data. This is one example where this issue is referenced, but this issue has two key flaws.	Where reference to lack of long-term follow is cited as a weakness, this should be reviewed as it does not accurately or clearly reflect the intent or outcomes of usual care. This is in terms of the physical impact, but also the behavioural effects provided by digital therapeutics. See justification and literature.	1. Usual care consists of annual follow ups interspersed with intense periods of care around exacerbations. The statement regarding this deficit fails to appreciate the trial data in the context of the interventions. PR is an essential part of care and its impact is delivered in a short course traditionally. It is unclear what the long-term impact missing is. This is an effective way to deliver PR, inhaler technique and education evidenced by data, supported in all settings. 2. The lack of long-term follow up statement fails to demonstrate clear understanding of the nature of effective engagement and impact on behavioural change which is a fundamental aspect of the nature of self-management and of how digital therapeutics deliver their effect. This has been highlighted and discussed at length. Please see the provided literature. 3. Cooper et al and the Grampian data both provide evidence of benefit in bed stay at twelve months	Thank you for this further information. There is still no evidence presented on the impact of myCOPD on patient outcomes beyond 12 months. No change made.

		and inhaler technique at five months respectively.	

Issue 15

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
S8.1 P81 – The use of myCOPD has increased rapidly is correct but fails to provide context	myCOPD is the most widely used digital therapeutic in the management of COPD, being used across many healthcare sectors. During Covid, the use increased rapidly.	This context reflects the existing usage in the NHS, endorsing its usability and usage, but also highlights the flexibility services found in using to deliver different elements of care to those patients with COPD at a time when traditional services were unable to operate.	This is not a factual inaccuracy and no reference supporting the additional statement has been provided. No change made.

Issue 16

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
P87, comparator: 'Physiotherapy' per se is not generally provided as a post-discharge service.	Suggest replacing with: "(for example, early supported discharge or community respiratory services)".	Early discharge/hospital@home/ admission avoidance services often employ physiotherapists, alongside OTs and nurses, to provide home support.	Thank you, this has been updated.

Issue 17

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
P87, bottom; The EAC state that NACAP data shows that follow up is arranged for 37.8% of discharged patients, but that this is for acute and non-acute exacerbations.	Remove second half of last sentence.	We don't recognise the concept of hospital admission for a non-acute exacerbation.	This has been removed.

Issue 18

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
P90, assumption 2 – The EAC has applied a take-up rate of myCOPD of 46% based on the recruitment outcomes for the RESCUE study. This is applied as 41 + 15 +1 (patients who accepted it + patients refusing for study reasons + patient unavailable) out of 124 invited.	Remove/amend sentence "The RESCUE trial states that only 46% of people eligible for myCOPD agreed to use it". 46% is the proportion who may have been able to participate in the study, but chose not to, mainly without stating a reason. The EAC need to clarify that they are using an assumption that those who declined to take part in the RCT without giving a reason would also have declined to register for myCOPD if offered as normal practice.	Of 124 patients, 66 declined with no reason, 15 had no time for the study, 1 was abroad during the study and 1 did not have internet access. The EAC have discounted those with no time or abroad from the denominator. They have then assumed that all of the 66 who declined with no reason were patients who would not have taken up myCOPD if offered it, when not in the context of an RCT.	This is not a factual inaccuracy. This number and the assumptions made/reasons behind patients declining are further discussed on P93.

Issue 19

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
P95, para 1: The EAC state that the company did not present data on why people were offered PR.	We suggest changing this to: "The company acknowledge this in their submission but noted that NACAP reports that 5% of patients participating in the audit were referred after admission to hospital for AECOPD. The overlap between model populations is therefore small and most outcomes are not reported separately for these subgroups."	We quoted the NACAP data that only 5% of PR patients were post-AECOPD, and stated that therefore we disregarded the reasons as most outcomes are for the whole PR population and not presented separately for post-AECOPD and stable patients. This is listed in the assumptions table.	Section of the sentence stating 'but did not present data on why people were offered PR' has now been deleted.

Issue 20

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
P97, para 1, sentence 3:	Remove the sentence.	In the PR service scenario, it would likely be the PR service staff and not a GP who would register the patients for the app.	This sentence has been removed.

Issue 21

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
P95: 'patients in the RESCUE study were told not to use the PR elements',	Should be 'not told to use…'	Patients in the RESCUE study were not directed to the PR content, either to use it or not use it.	Thank you this has been updated.

Issue 22

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
P96: The company also model a hybrid approach where myCOPD would be used alongside standard care, although the EAC notes no RCT evidence has been generated for this approach so far and therefore it is assumed in the model to be non-inferior to myCOPD alone. Hybrid PR is based on RWE (Southampton) and is now suggested as the most likely implementation of myCOPD PR use.	Hybrid PR is based on RWE (Southampton) and is now suggested as the most likely implementation of myCOPD PR use. The AR should note that there was a long delay between development of scope/clinical evidence submission and economic modelling with changes to the way the app was costed and availability of data (in addition to any coronavirus changes)	Long delay in economic evidence submission.	An overarching statement has been added to the beginning of Section 9.

Issue 23

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
P103 - The addition of the cost of incomplete PR, should generate greater savings	This addition should be reviewed and language reflect the subsequent findings.	Incomplete digital PR costs have been added to the economics. It is not clear from the documentation whether these same costs were added to the face-to-face model. Given the completion rates favoured digital delivery, from the data, this logically would create increased cost savings.	The following sentence has been added 'This leads to additional estimated savings with myCOPD due to these costs being higher in the face-to-face treatment arm of the model.'

Issue 24

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
P105, para 3, sentence 4: The EAC states "It is possible that some of the benefits demonstrated from using myCOPD could stem from PR, leading to an overestimate of benefits when compared with SoC."	Suggest: "It is possible that some of the benefits demonstrated from using myCOPD in this Grampian RWE could stem from face-to-face PR, leading to an overestimate of benefits when compared with SoC."	We initially read this as applying to the RESCUE study, but now think it applies to McLaughlin and Skinner.	This applies to both studies. We have clarified this within the report.

Issue 25

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Table 9.4 – Time taken to onboard patients AND P114	The time should remain at 15 minutes	In the initial use of myCOPD, clinicians were the primary workforce onboarding patients. It was unfeasible and simply not possible to spend more than 15 minutes doing this in a busy clinic. Comments regarding 45 minutes are simply unrealistic for registration. This would make the service unfit – simply the practicalities of this do not make sense. We query whether the clinical experts are including additional tasks in this estimate that may be	This is not a factual inaccuracy and reflects what we heard from clinical experts, therefore no change has been made. We agree that there is uncertainty in this value, hence sensitivity analysis is conducted using a wide range (including 15 minutes).

		done at the same time as registration but are not actually related to getting the patient a license. Now the onboarding process has been refined (less information and entries to make) and is not done by clinicians, either nursing staff or administrative staff now undertake onboarding. These modifications have reduced the time and salary outlay associated with onboarding. This is also supported by the numbers of patients being registered per day.	

Issue 26

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
p117, para 2: The EAC state "The EAC could not match the company's unit cost of a non-admission to A&E (£74.82) with the 2018/19 NHS reference costs."	"The company provided the calculation breakdown on request."	This calculation was provided to the EAC on request.	Added 'Details of this were subsequently provided by the company on request.'.

Issue 27

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
p120, paragraph 4: The EAC states that the readmissions rate is incorrect in the report and model. This is not true.	Suggest: "The best-case scenario value for the rate of readmissions for SoC is reported incorrectly in the company submission. The standard deviation reported in RESCUE (North et al. 2020) is 0.5, and the base case value is 0.39. This leads to a best-case scenario value of 0.89. This is correct in the company model."	The EAC is correct that there are errors in the reporting of the best case scenario values. The exacerbation rates *were* adjusted using the values in North et al (2020), but the readmission rates were *not* (adjusted as described in the report). The table on p31 of the submission is incorrect and should show exacerbation rates of 1.06 (±0.83) for myCOPD and 1.88 (±1.84) for SOC. However, these values were correct in the model. We stated that we did not use the error rates from North et al (2020) for myCOPD as this would lead to a negative rate for the best-case scenario. Instead, we kept the myCOPD rate at the base value (0.24) and only increased the SOC to its maximum. This value is incorrect in the report (0.44) but correct in the model (0.89).	A value of 0.44 is used for readmission at 90 days with standard of care in the best-case model we received. Therefore, no change made.

Issue 28

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
P121, para 3: The EAC state: "There is an error in the company submission for the rate of GP appointments for SOC. This should read 0.82 (reduction in SOC by 20%)." This is not true.	Suggest: "There is a slight error in the company submission for the rate of GP appointments for SOC. This should read 1.83 (reduction in SOC by 20%) rather than 1.85. This is correct in the company model."	The GP sensitivity ranges are as intended in the model, with a slight error in the report. For SOC, this is 2.28 ± 20% or 2.28 ± 0.456, giving a best case of 2.74 and a worst case of 1.83 (in the report as 1.85).	This has been updated.

Issue 29

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
The EAC describe the model using clinical outcomes as surrogates for economic ones in the TROOPER study (eg p159)	Remove reference to surrogate outcomes.	We were not using surrogate outcomes to suggest savings in resources use, but more taking the overall conclusion that myCOPD was non-inferior to face-to-face PR. Thus, we used the generic resource use outcomes from standard PR and applied them to myCOPD PR.	This is not a factual inaccuracy. Non-inferiority in clinical outcomes such as CAT score are used as surrogates for non-inferiority in resource use outcomes such as reduction in exacerbations. No change made.

Issue 30

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
S9 – failure to reference the impact of inhaler technique	Whilst advice was provided by NICE to CEDAR that economic assessments could only be	Advice was received that without published evidence regarding the	This is not a factual inaccuracy. Economic evidence on inhaler technique

	submitted with published evidence to support the claims, the success of the inhaler technique impact would have a very beneficial impact on the health-economic assessment of myCOPD across multiple levels – health of the patients, reduced scheduled and unscheduled demand, reduced waste, improved QoL, better drug utilisation and impact and many more.	impact and costing of the facet, incorporation would not be valuable. Inhaler technique, without costings is an essential and beneficial element. Additionally, the incorporation into NHS NICE recommendations provides the opportunity to fully examine the HE&R ramifications of good inhaler technique.	improvement was not provided by the company and therefore was not critiqued within the economic section of the report.

Issue 31

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
S11 – refers to only 2 groups benefitting – PR and AECOPD, to the exclusion of individuals receiving inhaled medication.	The benefits to those patients using the app receiving inhaled medication are powerful and should be included in the benefits cited for the myCOPD use.	This has been covered above. It remains an essential element to highlight to the reader however.	This is discussed in Section 10.1. This is not a factual inaccuracy and there is limited space in Section 11, so this is not repeated here.

Issue 32

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
S11 – Long-term follow up referenced again	Needs refining in view of the points made earlier in this document and the data provided in Cooper et al and from Grampian.	Data is provided that does support some long-term outcomes which continues to evidence benefits in bed stay at twelve months and the improved inhaler technique at five months from Grampian. This is in	We have noted that RWE is available to 12 months for some outcomes.

		line with impacts from traditional care	

Issue 33

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
Lack of literature review	The language around the lack of a company conducted literature review should be softened.	When we began this process with Jae Long, this was specifically not asked for following clarification.	This is not a factual inaccuracy and it is not clear which section of the report/type of literature review this refers to.

Issue 34

Description of factual inaccuracy	Description of proposed amendment	Justification for amendment	EAC response
S11 – Economic summary statements regarding activation rates	The language should reflect the data that has been provided and contextualised by the company.	This data is captured by the company regionally and nationally and is available. Citing opinions predicting the rates is not relevant when there is data available to reference. It is not reflective of the rates available nor the availability of those data. Additionally, clinical services can review this information directly through their manager's account dashboard, providing them with real-time updates as to the success.	This is not a factual inaccuracy. Section 11 refers to uptake rates (i.e. agreement or willingness to use the app) not activation rates. Therefore, no change made.